# RI News

**Title:** [Salmonella: Outbreak in small children](https://www.ages.at/en/news/detail/salmonellen-ausbruch-bei-kleinkindern)

Summary: In recent weeks, several small children in Austria have fallen ill with salmonella. These illnesses were most likely caused by an organic cashew butter with raspberries from dm drogerie markt.

Date: 03/06/2025

**Title:** [AGES Podcast: Tracking down pathogenic germs in our food with food detectives](https://www.ages.at/ages/presse/podcast/detail/folge-006-csi-ages-mit-lebensmittel-detektiven-krankmachenden-keimen-in-unserem-essen-auf-der-spur)

Summary: Listeria in cheese, salmonella in kebabs or campylobacter on the chopping board - our food detectives are on the trail of pathogenic germs in food! Our expert and epidemiologist Sabine Maritschnik…

Date: 07/06/2025

**Title:** [Diphtheria outbreak in Western Europe: Study traces transmission routes for the first time](https://www.ages.at/en/news/detail/diphtherieausbruch-in-westeuropa-studie-zeichnet-erstmals-uebertragungswege-nach)

Summary: A diphtheria outbreak in 2022 led to the largest increase in reported infections in Western Europe in 70 years. Clinical and genomic data from the outbreak indicate a source of transmission along…

Date: 04/06/2025

**Title:** [Salmonella outbreak: 35 people fall ill](https://www.ages.at/en/news/detail/salmonellen-ausbruch-35-menschen-erkrankt)

Summary: Since December 2024, 35 people in Austria have fallen ill with a specific strain of salmonella. The Ministry of Health has commissioned AGES to investigate this food-borne outbreak.

Date: 25/06/2025

**Title:** [Heat telephone: 0800 880 800](https://www.ages.at/en/news/detail/hitzetelefon-0800-880-800)

Summary: Excessive heat can lead to illness and death. Our heat hotline is available free of charge throughout Austria on 0800 880 800 and offers practical tips on how to cope better with the heat.

Date: 26/06/2025

**Title:** [Enjoyment with vegetables: cooking according to the seasons](https://www.ages.at/en/human/nutrition-food/nutrition-recommendations/recipes-to-cook/vegetables)

Summary: Our new cookery book is here! We are delighted that we were able to realise this project together with the motivated students and teachers of HBLA Pitzelstätten. Browse and cook now!

Date: 04/07/2025

**Title:** [AGES clarifies listeria outbreak](https://www.ages.at/en/news/detail/ages-klaert-listerien-ausbruch-ab)

Summary: The Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK) has commissioned AGES to investigate an outbreak of foodborne illness caused by listeria.

Date: 10/01/2025

**Title:** [AGES Podcast Episode 002 - Food pyramid](https://www.ages.at/ages/presse/podcast/detail/folge-002-ernaehrungspyramide-gesundheit-und-planeten-retten-durch-ernaehrung)

Summary: Saving health and the planet - through nutrition? Nutrition expert Lisa Sturm introduces us to the risk of malnutrition and overeating.

Date: 01/02/2025

**Title:** [Be careful with products that contain fungal toxins](https://www.ages.at/en/news/detail/vorsicht-bei-produkten-die-pilzgifte-enthalten)

Summary: Once again, people had to be hospitalised because they had consumed products containing psychoactive mushroom poisons - a dangerous trend that can lead to serious health problems.

Date: 05/02/2025

**Title:** [Insects in food](https://www.ages.at/en/news/detail/insekten-in-lebensmitteln)

Summary: Insects are classed as novel foods in the EU. They may only be used in food after a complex authorisation procedure.

Date: 13/02/2025

**Title:** [Respiratory infections and how to protect yourself from them](https://www.ages.at/en/news/detail/atemwegsinfektionen-und-wie-man-sich-davor-schuetzen-kann)

Summary: Our video shows how respiratory infections occur and how you can protect yourself against them

Date: 19/02/2025

**Title:** [2024 tick study: 20 % carriers of Borrelia bacteria](https://www.ages.at/en/news/detail/zeckenstudie-2024-20-traeger-von-borrelien)

Summary: One in five ticks in Austria could transmit borrelia to humans. This is the first result of our tick study, which was launched a year ago.

Date: 17/03/2025

**Title:** [AGES and MedUni Vienna strengthen co-operation](https://www.ages.at/en/news/detail/ages-und-meduni-wien-verstaerken-zusammenarbeit)

Summary: Co-operation agreement signed for joint research and development work.

Date: 18/03/2025

**Title:** [PrEP-medicijn via halfjaarlijkse injectie Yeytuo krijgt positief advies](https://www.cbg-meb.nl/actueel/nieuws/2025/07/25/prep-medicijn-via-halfjaarlijkse-injectie-yeytuo-krijgt-positief-advies)

Summary: Yeytuo (lenacapavir) mag een handelsvergunning krijgen om de kans op infectie met het hivV-virus type 1 (hiv-1) te verminderen ...

Date: 25/07/2025

**Title:** [Nieuwe behandeling voor zeldzame ziekte NPC krijgt positief advies](https://www.cbg-meb.nl/actueel/nieuws/2025/07/25/nieuwe-behandeling-voor-zeldzame-ziekte-npc-krijgt-positief-advies)

Summary: Het medicijn Aqneursa (levacetylleucine) mag op de markt komen voor de behandeling van patiënten van 6 jaar en ouder met de ...

Date: 25/07/2025

**Title:** [Medicijnen met 10 meest gebruikte werkzame stoffen grotendeels in Europa geproduceerd](https://www.cbg-meb.nl/actueel/nieuws/2025/07/24/medicijnen-met-10-meest-gebruikte-werkzame-stoffen-grotendeels-in-europa-geproduceerd)

Summary: Recent onderzoek naar de productieketen van medicijnen met de 10 meest gebruikte werkzame stoffen in Nederland laat zien dat deze ...

Date: 24/07/2025

**Title:** [Bureau Diergeneesmiddelen publiceert nieuw kwartaaloverzicht van bedrijven in grondstoffenregister](https://www.cbg-meb.nl/actueel/nieuws/2025/07/14/bureau-diergeneesmiddelen-publiceert-nieuw-kwartaaloverzicht-van-bedrijven-in-grondstoffenregister)

Summary: Per 1 juli 2025 plaatst het Bureau Diergeneesmiddelen (BD) kwartaaloverzichten van fabrikanten, importeurs en/of distributeurs ...

Date: 14/07/2025

**Title:** [Moment waarop nieuwe slots beschikbaar komen in planningstool gewijzigd](https://www.cbg-meb.nl/actueel/nieuws/2025/07/08/moment-waarop-nieuwe-slots-beschikbaar-komen-in-planningstool-gewijzigd)

Summary: Het moment waarop nieuwe slots beschikbaar komen in de planningstool, waarmee firma’s een timeslot reserveren voor een ...

Date: 08/07/2025

**Title:** [Column 'Over medicijnen': Zomer, tijd van de teek](https://www.cbg-meb.nl/actueel/nieuws/2025/07/02/column-over-medicijnen-zomer-tijd-van-de-teek)

Summary: Het is zomer En wat is er fijner dan lekker de natuur in te trekken Struinen door het lange gras, wandelen door de bossen...

Date: 02/07/2025

**Title:** [Proef met simultaan nationaal wetenschappelijk advies voortgezet](https://www.cbg-meb.nl/actueel/nieuws/2025/07/01/proef-met-simultaan-nationaal-wetenschappelijk-advies-voortgezet)

Summary: Een proef waarbij ontwikkelaars van nieuwe medicijnen bij meerdere medicijnautoriteiten in Europa tegelijk wetenschappelijk ...

Date: 01/07/2025

**Title:** [Voorwaardelijke handelsvergunning voor behandeling bloedkanker](https://www.cbg-meb.nl/actueel/nieuws/2025/06/23/voorwaardelijke-handelsvergunning-voor-behandeling-bloedkanker)

Summary: Het medicijn Zemcelpro mag een voorwaardelijke handelsvergunning krijgen voor de behandeling van volwassenen met bloedkanker Het ...

Date: 23/06/2025

**Title:** [Voorwaardelijke goedkeuring voor medicijn tegen bepaalde vorm van leververvetting](https://www.cbg-meb.nl/actueel/nieuws/2025/06/20/voorwaardelijke-goedkeuring-voor-medicijn-tegen-bepaalde-vorm-van-leververvetting)

Summary: Het medicijn Rezdiffra mag een voorwaardelijke handelsvergunning krijgen Rezdiffra is een medicijn voor volwassenen met een ...

Date: 20/06/2025

**Title:** [Oogziekte NAION is zeldzame bijwerking van semaglutide](https://www.cbg-meb.nl/actueel/nieuws/2025/06/06/oogziekte-naion-is-zeldzame-bijwerking-van-semaglutide)

Summary: De zeldzame oogziekte NAION is een zeer zeldzame bijwerking van semaglutide Dat is de conclusie van het onderzoek van ...

Date: 06/06/2025

**Title:** [Column 'Over medicijnen': Vervangen, verminderen, verfijnen](https://www.cbg-meb.nl/actueel/nieuws/2025/06/04/column-over-medicijnen-vervangen-verminderen-verfijnen)

Summary: Als je medicijnen ontwikkelt, dan zijn tot nu toe dierproeven nodig Om informatie over de veiligheid van medicijnen te ...

Date: 04/06/2025

**Title:** [Collegedag 2025: de veranderende rol van data en patiënt](https://www.cbg-meb.nl/actueel/nieuws/2025/06/02/cbg-collegedag-2025-de-veranderende-rol-van-data-en-patient)

Summary: De toekomst van medicijnbeoordeling stond maandag 19 mei centraal tijdens de jaarlijkse CBG Collegedag Sprekers uit de ...

Date: 02/06/2025

**Title:** [Measures to minimise risk of suicidal thoughts with finasteride and dutasteride medicines](https://www.moh.gov.cy/Moh/phs/phs.nsf/All/3C843076C13D6E25C2258CAC002AFCF6?OpenDocument)

Summary: Measures to minimise risk of suicidal thoughts with finasteride and dutasteride medicines  
Suicidal thoughts confirmed as side effect of finasteride tablets; no direct link found for dutasteride  
Following an EU-wide review of available data on finasteride and dutasteride medicines, EMA’s safety committee, PRAC, has confirmed suicidal ideation (suicidal thoughts) as a side effect of finasteride 1 and 5 mg tablets.

Date: 17/06/2025

**Title:** [EMA recommends non-renewal of authorisation of Duchenne muscular dystrophy medicine Translarna](https://www.moh.gov.cy/Moh/phs/phs.nsf/All/45D6AFC48726EEB2C2258B640025EDD9?OpenDocument)

Summary: No summary available

Date: 24/07/2024

**Title:** [CHESSMEN, the Joint Action to mitigate medicine’s shortages](https://www.moh.gov.cy/Moh/phs/phs.nsf/All/CC9A61154D97C7F3C22589590027F4A2?OpenDocument)

Summary: No summary available

Date: 17/02/2023

**Title:** [Urgent Field Safety Notice for Citra-Lock S 4% by Sterisets Medical Products](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2025/33610-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Injections / Infusions / Transfusions / Dialysis - infusion technology Reference 33610/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Citra-Lock S 4% by Sterisets Medical Products 2025.07.31 PDF, 166KB, File does not meet accessibility standards

Date: 31/07/2025

**Title:** [Urgent Field Safety Notice for Smart MDI Monitor Procedure Pack Kit by Medtronic Minimed](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/10/2025/34575-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Medical electronics / Electromedical devices - electric blood glucose meters Reference 34575/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Smart MDI Monitor Procedure Pack Kit by Medtronic Minimed 2025.07.31 PDF, 440KB, File does not meet accessibility standards

Date: 31/07/2025

**Title:** [Urgent Field Safety Notice for WATCHMAN TruSeal Zugangssystem, WATCHMAN FXD Curve Zugangssystem by Boston Scientific Corporation Marlborough](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2025/34704-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Injections / Infusions / Transfusions / Dialysis - catheters Reference 34704/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for WATCHMAN TruSeal Zugangssystem, WATCHMAN FXD Curve Zugangssystem by Boston Scientific Corporation Marlborough 2025.07.31 PDF, 380KB, File does not meet accessibility standards

Date: 31/07/2025

**Title:** [Urgent Field Safety Notice for ORBIS Medication by DH Healthcare GmbH](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/09/2025/32927-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Medical data processing (software) - others Reference 32927/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for ORBIS Medication by DH Healthcare GmbH 2025.07.31 PDF, 555KB, File does not meet accessibility standards

Date: 31/07/2025

**Title:** [Downloads Iris Institute - Terms and conditions for downloading (PDF, 258 kB)](https://www.bfarm.de/SharedDocs/Downloads/EN/Code-Systems/Iris/iris-terms-conditions-download.pdf?__blob=publicationFile)

Summary: Downloads Iris Institute - Terms and conditions for downloading Downloads Iris Institute - Terms and conditions for downloading (PDF, 258 kB) PDF, 257KB, File is accessible

Date: 31/07/2025

**Title:** [Urgent Field Safety Notice for Corpuls3, Corpulse3 Touch by GS Electromedical Devices G. Stample GmbH](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/10/2025/32474-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Medical electronics / Electromedical devices - electrotherapy Reference 32474/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for corpuls3, corpuls3 Touch by GS Elektromedizinische Geräte G. Stemple GmbH 2025.07.30 PDF, 183KB, File does not meet accessibility standards

Date: 30/07/2025

**Title:** [Urgent Field Safety Notice for XtremeCT by SCANCO Medical AG](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/17/2025/32612-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Radiological technology - CT scanners Reference 32612/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for XtremeCT by SCANCO Medical AG 2025.07.30 PDF, 353KB, File does not meet accessibility standards

Date: 30/07/2025

**Title:** [Urgent Field Safety Notice for CORIN mobile operating tables by Maquet GmbH](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2025/31945-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Surgical equipment/ Anaesthesia - surgical equipment Reference 31945/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for CORIN mobile operating tables by Maquet GmbH 2025.07.30 PDF, 182KB, File does not meet accessibility standards

Date: 30/07/2025

**Title:** [Projects in the field of medical devices](https://www.bfarm.de/EN/BfArM/Tasks/Research/Safety-of-medical-devices/_artikel.html?nn=986784)

Summary: No summary available

Date: 29/07/2025

**Title:** [Urgent Field Safety Notice for CORFLO / CORTRAK 2 by Avanos Medical (früher: Halyard Health Inc.)](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2025/33848-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Injections / Infusions / Transfusions / Dialysis - probes Reference 33848/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for CORFLO / CORTRAK 2 by Avanos Medical (früher: Halyard Health Inc.) 2025.07.29 PDF, 313KB, File does not meet accessibility standards

Date: 29/07/2025

**Title:** [Urgent Field Safety Notice for HALF PIN L120MM D4.0MM THREAD D4.0XL18MM PACK OF 2 by Orthofix SRL](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2025/34188-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Non-active implants - bone surgery Reference 34188/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for HALF PIN L120MM D4.0MM THREAD D4.0XL18MM PACK OF 2 by Orthofix SRL 2025.07.29 PDF, 309KB, File does not meet accessibility standards

Date: 29/07/2025

**Title:** [Urgent Field Safety Notice for Medumat Standard 2 by WEINMANN Emergency Medical Technology GmbH + Co. KG](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2025/33307-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Surgical equipment/ Anaesthesia - anaesthesia and medical gas supply Reference 33307/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Medumat Standard 2 by WEINMANN Emergency Medical Technology GmbH + Co. KG 2025.07.29 PDF, 197KB, File does not meet accessibility standards

Date: 29/07/2025

**Title:** [Urgent Field Safety Notice for Dexcom G7 Continuous Glucose Monitoring System by Dexcom, Inc](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/10/2025/31739-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Medical electronics / Electromedical devices - electric blood glucose meters Reference 31739/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Dexcom G7 Continuous Glucose Monitoring System by Dexcom, Inc 2025.07.29 PDF, 566KB, File does not meet accessibility standards

Date: 29/07/2025

**Title:** [Urgent Field Safety Notice for LinkSymphoKnee System, Tibial Component, Modular by Waldemar Link GmbH & Co. KG](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2025/34142-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Non-active implants - bone surgery Reference 34142/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for LinkSymphoKnee System, Tibial Component, Modular by Waldemar Link GmbH & Co. KG 2025.07.29 PDF, 2MB, File does not meet accessibility standards

Date: 29/07/2025

**Title:** [Urgent Field Safety Notice for Tracoe Vario ExtractTracheostomy Tube with cuff by TRACOE medical GmbH Nieder-Olm](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2025/33945-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Surgical equipment/ Anaesthesia - anaesthesia and medical gas supply Reference 33945/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Tracoe Vario ExtractTracheostomy Tube with cuff by TRACOE medical GmbH Nieder-Olm 2025.07.29 PDF, 199KB, File does not meet accessibility standards

Date: 29/07/2025

**Title:** [Urgent Field Safety Notice for Access High Sensitivity Troponin I Reagent by Beckman Coulter Inc.](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/08/2025/41368-24_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group In-vitro diagnostics - immunological products Reference 41368/24 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Access High Sensitivity Troponin I Reagent by Beckman Coulter Inc. 2025.07.29 PDF, 309KB, File does not meet accessibility standards

Date: 29/07/2025

**Title:** [Urgent Field Safety Notice for SOPHIE by Fritz Stephan GmbH](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2025/33273-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Surgical equipment/ Anaesthesia - anaesthesia and medical gas supply Reference 33273/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for SOPHIE by Fritz Stephan GmbH 2025.07.28 PDF, 466KB, File does not meet accessibility standards

Date: 28/07/2025

**Title:** [Urgent Field Safety Notice for Unterarmgestütze Magic-Soft by REBOTEC Rehabilitationsmittel GmbH](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/15/2025/31907-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Orthopaedic / Rehabilitation technology - daily living aids Reference 31907/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Unterarmgestütze Magic-Soft by REBOTEC Rehabilitationsmittel GmbH 2025.07.28 PDF, 257KB, File does not meet accessibility standards

Date: 28/07/2025

**Title:** [Urgent Field Safety Notice for Extension line for single use DI75 und DI150 by Zibo Qiaosend Medical Articles Co., Ltd](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2025/31904-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Injections / Infusions / Transfusions / Dialysis - infusion technology Reference 31904/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Extension line for single use DI75 und DI150 by Zibo Qiaosend Medical Articles Co., Ltd 2025.07.28 PDF, 111KB, File does not meet accessibility standards

Date: 28/07/2025

**Title:** [Radiation Protection Act](https://www.bfarm.de/EN/Medicinal-products/Clinical-trials/Radiation-Protection-Act/_artikel.html?nn=986784)

Summary: No summary available

Date: 25/07/2025

**Title:** [Urgent Field Safety Notice for Celsite Babyport by B. Braun Medical S.A.S.](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2025/33527-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Non-active implants - special implants Reference 33527/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Celsite Babyport by B. Braun Medical S.A.S. 2025.07.25 PDF, 207KB, File does not meet accessibility standards

Date: 25/07/2025

**Title:** [Urgent Field Safety Notice for Poweo 200 with electrical suspension by SCALEO MEDICAL](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/02/2025/30311-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group General equipment for medical treatment - ward equipment and equipment for emergency medical services Reference 30311/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Poweo 200 with electrical suspension by SCALEO MEDICAL 2025.07.25 PDF, 704KB, File does not meet accessibility standards

Date: 25/07/2025

**Title:** [Paediatric Committee (PDCO)](https://www.bfarm.de/EN/BfArM/EU-and-International/PDCO-Committee/_artikel.html?nn=986784)

Summary: No summary available

Date: 25/07/2025

**Title:** [Reporting Recalls](https://www.bfarm.de/SharedDocs/Formulare/EN/MedicalDevices/fsca_reports.pdf?__blob=publicationFile)

Summary: No summary available

Date: 24/07/2025

**Title:** [Code-Search: ICD-10-GM online](https://www.bfarm.de/EN/Code-systems/Classifications/ICD/ICD-10-GM/Code-search/_artikel.html?nn=986784)

Summary: No summary available

Date: 24/07/2025

**Title:** [Urgent Field Safety Notice for TruSystem 7000 by Baxter Medical Systems GmbH + Co. KG](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2025/29812-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Surgical equipment/ Anaesthesia - surgical equipment Reference 29812/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for TruSystem 7000 by Baxter Medical Systems GmbH + Co. KG 2025.07.23 PDF, 1MB, File does not meet accessibility standards

Date: 23/07/2025

**Title:** [Urgent Field Safety Notice for IPC HANDPIECE - POWEREASE DRIVER by Medtronic Xomed Inc.](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2025/33091-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Surgical equipment/ Anaesthesia - surgical equipment Reference 33091/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for IPC HANDPIECE - POWEREASE DRIVER by Medtronic Xomed Inc. 2025.07.23 PDF, 424KB, File does not meet accessibility standards

Date: 23/07/2025

**Title:** [Information for marketing authorisation holders: current information on submission for step 3](https://www.bfarm.de/SharedDocs/Downloads/EN/Drugs/licensing/folgeverfahren/elektrAeA/Instruction_for_Feedback_via_PharmNetBund_step_3.pdf?__blob=publicationFile)

Summary: Active substance: various The European Medicines Agency (EMA), the Heads of Medicines Authorities (HMA) and the Coordination Group on Mutual Recognition Procedures and Decentralized Procedures (CMDh) have published documents related to the implementation of the Article 5(3) procedure of Regulation (EC) No 726/2004 on nitrosamine impurities in human medicinal products. These documents are updated on a regular basis. The latest versions are published on the CMDh homepage: Heads of Medicines Agencies: Nitrosamine impurities (hma.eu) Step 3 of the risk assessment procedure outlines the marketing authorisations (MA) to be updated if necessary. Marketing authorisation holders (MAH) are requested to submit any...

Date: 23/07/2025

**Title:** [Urgent Field Safety Notice for Pinnacle Radiation Therapy Planning System by Philips Medical Systems (Cleveland), Inc. Gainesville](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/18/2025/24651-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Radiotherapy / Radiation protection - radiotherapy treatment planning systems Reference 24651/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Pinnacle Radiation Therapy Planning System by Philips Medical Systems (Cleveland), Inc. Gainesville 2025.07.22 PDF, 521KB, File does not meet accessibility standards

Date: 22/07/2025

**Title:** [Urgent Field Safety Notice for Mölnlycke Procedure Pak by Mölnlycke Health Care AB (Moldal)](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2025/32688-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Surgical equipment/ Anaesthesia - surgical equipment Reference 32688/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Mölnlycke Procedure Pak by Mölnlycke Health Care AB (Molndal) 2025.07.22 PDF, 509KB, File does not meet accessibility standards

Date: 22/07/2025

**Title:** [Urgent Field Safety Notice for Sharesource Adequest by Baxter Healthcare S. (Opfikon)](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2025/29876-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Injections / Infusions / Transfusions / Dialysis - dialysis technology Reference 29876/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Sharesource Adequest by Baxter Healthcare S. (Opfikon) 2025.07.22 PDF, 208KB, File does not meet accessibility standards

Date: 22/07/2025

**Title:** [Urgent Field Safety Notice for X-Ray Interventional Systems by Canon Medical Systems Corporation](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/17/2025/32718-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Radiological technology - radiological equipment for vascular diagnostics Reference 32718/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for X-Ray Interventional Systems by Canon Medical Systems Corporation 2025.07.22 PDF, 144KB, File does not meet accessibility standards

Date: 22/07/2025

**Title:** [Urgent Field Safety Notice for OtoLase by Boston Scientific Corporation Marlborough](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/14/2025/32445-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Optics / Precision engineering - laser technology Reference 32445/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for OtoLase by Boston Scientific Corporation Marlborough 2025.07.22 PDF, 231KB, File does not meet accessibility standards

Date: 22/07/2025

**Title:** [Urgent Field Safety Notice for POLYPERF by PEROUSE MEDICAL (IVRY LE TEMPLE)](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2025/30047-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Injections / Infusions / Transfusions / Dialysis - injection kits Reference 30047/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for POLYPERF by PEROUSE MEDICAL (IVRY LE TEMPLE) 2025.07.21 PDF, 882KB, File does not meet accessibility standards

Date: 21/07/2025

**Title:** [Urgent Field Safety Notice for Vasoview Hemopro 2 Endoscopic Vessel Harvesting System by Maquet Cardiovascular](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/14/2025/09399-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Optics / Precision engineering - endoscopes Reference 09399/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for Vasoview Hemopro 2 Endoscopic Vessel Harvesting System by Maquet Cardiovascular 2025.07.21 PDF, 836KB, File does not meet accessibility standards

Date: 21/07/2025

**Title:** [Urgent Field Safety Notice for VITROS Chemistry Products Ca Slides by Ortho-Clinical Diagnostics, Inc.](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/08/2025/32038-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group In-vitro diagnostics - equipment / products for clinical chemistry Reference 32038/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for VITROS Chemistry Products Ca Slides by Ortho-Clinical Diagnostics, Inc. 2025.07.18 PDF, 260KB, File does not meet accessibility standards

Date: 18/07/2025

**Title:** [Urgent Field Safety Notice for SIGNA Artist, Discovery MR450 1.5T, Optima MR450w 1.5T, SIGNA Architect, SIGNA Premier, Discovery MR750 3.0T, Discovery MR750w 3.0T, SIGNA Hero, SIGNA PET/MR by GE MEDICAL SYSTEMS LLC / GE HANGWEI MEDICAL SYSTEMS CO. LTD / GE HEALTHCARE JAPAN CORPORATION](https://www.bfarm.de/SharedDocs/Kundeninfos/EN/04/2025/32170-25_kundeninfo_en.pdf?__blob=publicationFile)

Summary: Product group Electromedical fields - equipment for MR tomography Reference 32170/25 For further information as well as details concerning the device please see the enclosed Advisory Notice of the manufacturer. Urgent Field Safety Notice for SIGNA Artist, Discovery MR450 1.5T, Optima MR450w 1.5T, SIGNA Architect, SIGNA Premier, Discovery MR750 3.0T, Discovery MR750w 3.0T, SIGNA Hero, SIGNA PET/MR by GE MEDICAL SYSTEMS LLC / GE HANGWEI MEDICAL SYSTEMS CO. LTD / GE HEALTHCARE JAPAN CORPORATION 2025.07.18 PDF, 321KB, File does not meet accessibility standards

Date: 18/07/2025

**Title:** [Commission adopts EU4Health Work Programme 2025](https://ec.europa.eu/newsroom/sante/newsletter-archives/65776)

Summary: nan

Date: 23/07/2025

**Title:** [Strengthening health resilience: new initiative for mpox testing and sequencing in Africa launched](https://health.ec.europa.eu/latest-updates/strengthening-health-resilience-new-initiative-mpox-testing-and-sequencing-africa-launched-2025-07-30_en)

Summary: nan

Date: 30/07/2025

**Title:** [Are you working in any of these public health areas? Only one month left to submit your proposal](https://health.ec.europa.eu/latest-updates/are-you-working-any-these-public-health-areas-only-one-month-left-submit-your-proposal-2025-07-22_en)

Summary: nan

Date: 22/07/2025

**Title:** [Registration - EUHPP Live Webinar: Outcomes from RE-SAMPLE (17 November 2025, 14.30-16.30 CET)](https://health.ec.europa.eu/latest-updates/registration-euhpp-live-webinar-outcomes-re-sample-17-november-2025-1430-1630-cet-2025-07-29_en)

Summary: nan

Date: 29/07/2025

**Title:** [Videos - Patient Journeys on Hereditary Spastic Paraplegias (HSPs)](https://health.ec.europa.eu/publications/patient-journeys-hereditary-spastic-paraplegias-hsps_en)

Summary: nan

Date: 29/07/2025

**Title:** [Adoption of Commission Delegated Regulation (EU) 2025/788 amending Delegated Regulation (EU) 2023/2197 as regards the date of application](https://health.ec.europa.eu/medical-devices-sector/new-regulations_en)

Summary: nan

Date: 29/07/2025

**Title:** [Outcome of the Implementation dialogue on biocides with Commissioner Olivér Várhelyi (15 July 2025)](https://health.ec.europa.eu/latest-updates/outcome-implementation-dialogue-biocides-commissioner-oliver-varhelyi-15-july-2025-2025-07-30_en)

Summary: nan

Date: 30/07/2025

**Title:** [Adoption of Decision (EU) 2025/1324 on expert panels in the field of medical devices](https://eur-lex.europa.eu/eli/dec_impl/2025/1324/oj/eng)

Summary: nan

Date: 08/07/2025

**Title:** [Working Groups](https://health.ec.europa.eu/latest-updates/working-groups-2025-07-30_en)

Summary: nan

Date: 30/07/2025

**Title:** [Boosting health resilience: enhancing the Union Civil Protection Mechanism with strategic health funding](https://health.ec.europa.eu/latest-updates/boosting-health-resilience-enhancing-union-civil-protection-mechanism-strategic-health-funding-2025-07-17_en)

Summary: nan

Date: 17/07/2025

**Title:** [Minutes - Board of Member States on ERNs – Extraordinary meeting (10 June 2025)](https://health.ec.europa.eu/latest-updates/minutes-board-member-states-erns-extraordinary-meeting-10-june-2025-2025-07-18_en)

Summary: nan

Date: 18/07/2025

**Title:** [Minutes - HTACG - Subgroup for Joint Scientific Consultations (11 June 2025)](https://health.ec.europa.eu/events/htacg-subgroup-joint-scientific-consultations-2025-06-11_en)

Summary: nan

Date: 11/07/2025

**Title:** [Report on the implementation of the EU Global Health Strategy](https://health.ec.europa.eu/latest-updates/report-implementation-eu-global-health-strategy-2025-07-10_en)

Summary: nan

Date: 10/07/2025

**Title:** [Video recordings - EU health technology assessment: Advent of a new era of collaboration (2 July 2025)](https://health.ec.europa.eu/events/eu-health-technology-assessment-advent-new-era-collaboration-2025-07-02_en)

Summary: nan

Date: 10/07/2025

**Title:** [Minutes - Meeting of the ERN Board of Member States and ERN coordinators (Rome, 22 May 2025)](https://health.ec.europa.eu/events/board-member-states-erns-30th-meeting-2025-05-22_en)

Summary: nan

Date: 10/07/2025

**Title:** [Flash Report - PHEG sub-group on NCD prevention (10 July 2025)](https://health.ec.europa.eu/latest-updates/flash-report-pheg-sub-group-ncd-prevention-10-july-2025-2025-07-10_en)

Summary: nan

Date: 10/07/2025

**Title:** [Minutes - 36th meeting of the Expert Group on Health Systems Performance Assessment (16 June 2025)](https://health.ec.europa.eu/latest-updates/minutes-36th-meeting-expert-group-health-systems-performance-assessment-16-june-2025-2025-07-10_en)

Summary: nan

Date: 10/07/2025

**Title:** [SCCS - Final Scientific Advice on Benzophenone-2 (BP-2) and Benzophenone-5 (BP-5)](https://health.ec.europa.eu/latest-updates/sccs-final-scientific-advice-benzophenone-2-bp-2-and-benzophenone-5-bp-5-2025-06-30_en)

Summary: nan

Date: 30/06/2025

**Title:** [SCCS - Scientific Opinion on Hydroxyapatite (nano) - Submission IV](https://health.ec.europa.eu/latest-updates/sccs-scientific-opinion-hydroxyapatite-nano-submission-iv-2025-07-01_en)

Summary: nan

Date: 01/07/2025

**Title:** [SCCS - Scientific Opinion on Hydroxyapatite (nano) - Submission IV](https://health.ec.europa.eu/latest-updates/sccs-scientific-opinion-hydroxyapatite-nano-submission-iv-2025-07-01-0_en)

Summary: nan

Date: 01/07/2025

**Title:** [Stakeholders’ Consultation on EudraLex Volume 4 - Good Manufacturing Practice Guidelines: Chapter 4, Annex 11 and New Annex 22](https://health.ec.europa.eu/consultations/stakeholders-consultation-eudralex-volume-4-good-manufacturing-practice-guidelines-chapter-4-annex_en)

Summary: nan

Date: 07/07/2025

**Title:** [Recording and presentation - EUHPP Live Webinar: Natural disasters and climate change the risks of wildfires for respiratory health (4 July 2025)](https://health.ec.europa.eu/latest-updates/recording-and-presentation-euhpp-live-webinar-natural-disasters-and-climate-change-risks-wildfires-2025-07-07_en)

Summary: nan

Date: 07/07/2025

**Title:** [EU Sets Out New Plan to Boost Health Crisis Readiness](https://health.ec.europa.eu/latest-updates/eu-sets-out-new-plan-boost-health-crisis-readiness-2025-07-09_en)

Summary: nan

Date: 09/07/2025

**Title:** [SCCS - Minutes of the Working Group meeting on Cosmetic Ingredients of 25 June 2025](https://health.ec.europa.eu/latest-updates/sccs-minutes-working-group-meeting-cosmetic-ingredients-25-june-2025-2025-07-09_en)

Summary: nan

Date: 09/07/2025

**Title:** [SCCS - Minutes of the 11th plenary meeting, Luxembourg, 26 June 2025](https://health.ec.europa.eu/latest-updates/sccs-minutes-11th-plenary-meeting-luxembourg-26-june-2025-2025-07-09_en)

Summary: nan

Date: 09/07/2025

**Title:** [MDCG 2025-7 - Position Paper: Timelines of implementation of ‘Master UDI-DI’ to contact lenses and spectacle frames, spectacle lenses and ready-to-wear reading spectacles](https://health.ec.europa.eu/latest-updates/mdcg-2025-7-position-paper-timelines-implementation-master-udi-di-contact-lenses-and-spectacle-2025-07-10_en)

Summary: nan

Date: 10/07/2025

**Title:** [Strengthening supply chain of anti-D immunoglobulins](https://www.ema.europa.eu/en/news/strengthening-supply-chain-anti-d-immunoglobulins)

Summary: EMA and the Heads of Medicines Agencies (HMA), through the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) , have issued recommendations to address vulnerabilities in the...

Date: 04/07/2025

**Title:** [Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 2-5 June 2025](https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-2-5-june-2025)

Summary: PRAC concludes eye condition NAION is a very rare side effect of semaglutide medicines Treatment with semaglutide should be stopped if NAION occurs EMA’s safety committee (PRAC) has concluded its revi...

Date: 06/06/2025

**Title:** [New guideline on inclusion of pregnant and breastfeeding individuals in clinical trials](https://www.ema.europa.eu/en/news/new-guideline-inclusion-pregnant-breastfeeding-individuals-clinical-trials)

Summary: EMA has released for public consultation a new guideline providing recommendations on how to include and/or retain pregnant and breastfeeding people in clinical trials. The goal is to ensure developer...

Date: 04/06/2025

**Title:** [EMA closed 9 June](https://www.ema.europa.eu/en/news/ema-closed-9-june)

Summary: The European Medicines Agency (EMA) is closed from 18:00 on Friday 6 June 2025 until 08:30 on Tuesday 10 June 2025. The product emergency hotline is available outside working hours and on public holid...

Date: 05/06/2025

**Title:** [2024 annual report is published](https://www.ema.europa.eu/en/news/2024-annual-report-published)

Summary: EMA’s annual report 2024 published today gives insights into the Agency’s strategic priorities and contributions to public and animal health in the European Union (EU). The digital report outlines the...

Date: 10/06/2025

**Title:** [PRAC concludes eye condition NAION is a very rare side effect of semaglutide medicines Ozempic, Rybelsus and Wegovy](https://www.ema.europa.eu/en/news/prac-concludes-eye-condition-naion-very-rare-side-effect-semaglutide-medicines-ozempic-rybelsus-wegovy)

Summary: This news announcement was revised on 13 June 2025 to delete the reference to the European Commission issuing a legally binding decision on the procedure. EMA’s safety committee (PRAC) has concluded i...

Date: 13/06/2025

**Title:** [Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 10-12 June 2025](https://www.ema.europa.eu/en/news/meeting-highlights-committee-veterinary-medicinal-products-cvmp-10-12-june-2025)

Summary: The Committee re-elected Dr Frida Hasslung Wikström from Sweden as its Vice-chair for a further 3-year mandate. CVMP opinions on veterinary medicinal products The Committee adopted by consensus a posi...

Date: 13/06/2025

**Title:** [First vaccine against swine dysentery disease recommended for approval](https://www.ema.europa.eu/en/news/first-vaccine-against-swine-dysentery-disease-recommended-approval)

Summary: EMA has issued a positive opinion for the approval of a vaccine named Biobhyo, indicated to protect pigs from swine dysentery, a disease that causes dysenteric diarrhoea in pigs. No vaccine is current...

Date: 13/06/2025

**Title:** [EMA Management Board: highlights of June 2025 meeting](https://www.ema.europa.eu/en/news/ema-management-board-highlights-june-2025-meeting)

Summary: Management Board meets the African Medicines Agency Governing Board The Management Board welcomed the African Medicines Agency (AMA) Governing Board and heads of African national agencies as observers...

Date: 13/06/2025

**Title:** [First treatment against liver scarring caused by a type of ‘fatty liver disease’](https://www.ema.europa.eu/en/news/first-treatment-against-liver-scarring-caused-type-fatty-liver-disease)

Summary: EMA has recommended granting a conditional marketing authorisation in the European Union (EU) for Rezdiffra (resmeritom) for the treatment of adults with noncirrhotic metabolic dysfunction-associated ...

Date: 20/06/2025

**Title:** [Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 16-19 June 2025](https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-16-19-june-2025)

Summary: 13 new medicines recommended for approval EMA’s human medicines committee (CHMP) recommended 13 medicines for approval at its June 2025 meeting. The committee recommended granting a marketing authoris...

Date: 20/06/2025

**Title:** [New stem cell therapy to treat patients with blood cancers](https://www.ema.europa.eu/en/news/new-stem-cell-therapy-treat-patients-blood-cancers)

Summary: EMA has recommended granting a conditional marketing authorisation in the European Union (EU) for Zemcelpro (dorocubicel / unexpanded umbilical cord cells) to treat adults with haematological malignan...

Date: 20/06/2025

**Title:** [EMA starts review of sodium oxybate in alcohol dependence](https://www.ema.europa.eu/en/news/ema-starts-review-sodium-oxybate-alcohol-dependence)

Summary: EMA’s human medicines committee (CHMP) has started a review of medicines containing sodium oxybate used in people with alcohol dependency to treat alcohol withdrawal syndrome and to support long‑term ...

Date: 20/06/2025

**Title:** [Ixchiq: temporary restriction on vaccinating people 65 years and older to be lifted](https://www.ema.europa.eu/en/news/ixchiq-temporary-restriction-vaccinating-people-65-years-older-be-lifted)

Summary: EMA’s safety committee (PRAC) has completed its review of Ixchiq (a live attenuated chikungunya vaccine), following reports of serious side effects. The previous temporary restriction on vaccinating p...

Date: 11/07/2025

**Title:** [Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 7 – 10 July 2025](https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-7-10-july-2025)

Summary: Vaccine to be used only when there is a significant chikungunya risk and after careful consideration of the benefits and risks EMA’s safety committee (PRAC) has completed its review of Ixchiq, a live ...

Date: 11/07/2025

**Title:** [Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 15-17 July 2025](https://www.ema.europa.eu/en/news/meeting-highlights-committee-veterinary-medicinal-products-cvmp-15-17-july-2025)

Summary: CVMP opinions on veterinary medicinal products The Committee adopted by consensus a positive opinion for a marketing authorisation from Axience for Hemosyvet (etamsylate) for prevention and treatment ...

Date: 18/07/2025

**Title:** [EMA Paediatric Committee elects Sabine Scherer as its new chair](https://www.ema.europa.eu/en/news/ema-paediatric-committee-elects-sabine-scherer-its-new-chair)

Summary: At its July 2025 meeting, EMA’s , elected Sabine Scherer from Germany as its new chair for a three-year mandate, beginning in September 2025. Dr Scherer takes over from Dr Aylward, from the in Ireland...

Date: 24/07/2025

**Title:** [Ixchiq: temporary restriction on vaccinating people 65 years and older to be lifted](https://www.ema.europa.eu/en/news/ixchiq-temporary-restriction-vaccinating-people-65-years-older-be-lifted-0)

Summary: On 24 July 2025, EMA’s human medicines committee (CHMP) endorsed the recommendation of the Agency’s safety committee (PRAC) following a review of serious side effects of Ixchiq (a live attenuated chik...

Date: 25/07/2025

**Title:** [New treatment for Niemann-Pick type C disease](https://www.ema.europa.eu/en/news/new-treatment-niemann-pick-type-c-disease)

Summary: EMA has recommended granting a marketing authorisation in the European Union (EU) for Aqneursa (levacetylleucine) for the treatment of neurological manifestations of Niemann-Pick type C (NPC) disease ...

Date: 25/07/2025

**Title:** [New injection for easier prevention of HIV infection in the EU and worldwide](https://www.ema.europa.eu/en/news/new-injection-easier-prevention-hiv-infection-eu-worldwide)

Summary: EMA has recommended granting a marketing authorisation in the European Union (EU) for Yeytuo (lenacapavir) for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the ris...

Date: 25/07/2025

**Title:** [First reformulation of an inhaled medicine with environmentally friendly gas propellant](https://www.ema.europa.eu/en/news/first-reformulation-inhaled-medicine-environmentally-friendly-gas-propellant)

Summary: EMA has recommended a change in the composition of Trixeo Aerosphere and its duplicate product Riltrava Aerosphere to replace the existing gas propellant with a low global warming potential (GWP) gas ...

Date: 25/07/2025

**Title:** [Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 21-24 July 2025](https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-21-24-july-2025)

Summary: 13 new medicines recommended for approval EMA’s human medicines committee (CHMP) recommended 13 medicines for approval at its July 2025 meeting. The committee recommended granting a marketing authoris...

Date: 25/07/2025

**Title:** [FUCIDINE 250 mg COMPRIMIDOS RECUBIERTOS CON PELICULA , 10 comprimidos (NR: 39143, CN: 697148)](nan)

Summary: Resultado fuera de especificaciones en impurezas detectado en estudios de estabilidad. Cadena de distribución y dispensación. Defecto de calidad que no supone un riesgo vital para el paciente

Date: 29/07/2025

**Title:** [Allergovit 123 Parietaria 100% suspensión inyectable formato varias presentaciones](nan)

Summary: Resultado fuera de especificaciones en el parámetro de actividad residual alergénica detectado en estudios de estabilidad. Allergopharma España SLU contactará con los profesionales sanitarios afectados para la recuperación de unidades. Defecto de calidad que no supone un riesgo vital para el paciente.

Date: 22/07/2025

**Title:** [COLIRCUSI GENTADEXA 5 MG/ML+ 1 MG/ML+ 0,5 MG/ML COLIRIO/GOTAS ÓTICAS EN SOLUCIÓN 1 frasco de 10 ml (NR: 51174, CN: 672096)](nan)

Summary: No se puede garantizar su esterilidad debido a problemas de contaminación microbiológica en la planta de fabricación. Cadena de distribución y dispensación. Defecto de calidad que no supone un riesgo vital para el paciente.

Date: 11/07/2025

**Title:** [COSDUO 20 MG/ML + 5 MG/ML COLIRIO EN SOLUCION 1 frasco de 5 ml (NR: 82086, CN: 716318)](nan)

Summary: No se puede garantizar su esterilidad debido a problemas de contaminación microbiológica en la planta de fabricación. Cadena de distribución y dispensación. Defecto de calidad que no supone un riesgo vital para el paciente.

Date: 11/07/2025

**Title:** [BENTIFEN 0,25mg/ml COLIRIO EN SOLUCION, 1 frasco de 5 ml (NR: 63618, CN: 653304)](nan)

Summary: No se puede garantizar su esterilidad debido a problemas de contaminación microbiológica en la planta de fabricación. Cadena de distribución y dispensación. Defecto de calidad que no supone un riesgo vital para el paciente.

Date: 04/07/2025

**Title:** [LUDIOMIL, COMPRIMIDOS RECUBIERTOS CON PELÍCULA, varias presentaciones](nan)

Summary: Detección de una impureza por encima de su límite establecido. Cadena de distribución y dispensación. Defecto de calidad que no supone un riesgo vital para el paciente

Date: 30/06/2025

**Title:** [KIMMTRAK 100 MICROGRAMOS/0,5 ML CONCENTRADO PARA SOLUCION PARA PERFUSION, 1 vial de 0,5 ml (NR: 1221630001, CN: 759433)](nan)

Summary: Resultado fuera de especificación en el ensayo de potencia, detectado en estudios de estabilidad. Cadena de distribución y dispensación/hospitales. Defecto de calidad que no supone un riesgo vital para el paciente

Date: 13/06/2025

**Title:** [BILAXTEN 6 MG/ML COLIRIO EN SOLUCION, 1 frasco de 5 ml (NR: 88089, CN: 758305)](nan)

Summary: Detección de partículas visibles por precipitación del principio activo. Cadena de distribución y dispensación. Defecto de calidad que no supone un riesgo vital para el paciente

Date: 29/05/2025

**Title:** [BISOPROLOL PENSA 2,5 MG COMPRIMIDOS EFG, 28 comprimidos (Blister PVC/PVDC/Al) (NR: 81435, CN: 713616)](nan)

Summary: Detección de una impureza por encima de su límite establecido. Cadena de distribución y dispensación. Defecto de calidad que no supone un riesgo vital para el paciente

Date: 21/05/2025

**Title:** [DULOXETINA PENSA PHARMA 30 MG CAPSULAS DURAS GASTRORRESISTENTES EFG , 28 cápsulas (Blister PVC/PVDC-ALUMINIO) (NR: 79370, CN: 704749)](nan)

Summary: Detección de una impureza por encima de su límite establecido. Cadena de distribución y dispensación. Defecto de calidad que no supone un riesgo vital para el paciente

Date: 08/05/2025

**Title:** [TOPIRAMATO TEVA 200 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG, 60 comprimidos (NR: 68933, CN: 659269)](nan)

Summary: Obtención de resultado fuera de especificaciones en el ensayo de contenido durante los estudios de estabilidad en curso. Cadena de distribución y dispensación. Defecto de calidad que no supone un riesgo vital para el paciente

Date: 02/04/2025

**Title:** [CELSIOR SOLUCION PARA LA CONSERVACION DE ORGANOS, 4 bolsas de 1.000 ml](nan)

Summary: Incumplimiento de normas de correcta fabricación del fabricante Institut Georges Lopez. Cadena de distribución y dispensación/hospitales. Defecto de calidad que no supone un riesgo vital para el paciente

Date: 02/04/2025

**Title:** [CEFIXIMA MABO COMPRIMIDOS RECUBIERTOS CON PELICULA EFG, varias presentaciones](nan)

Summary: Incumplimiento de las normas de correcta fabricación del fabricante Nectar LifeSciences Limited, Unit VI, India. Cadena de distribución y dispensación. Defecto de calidad que no supone un riesgo vital para el paciente

Date: 14/03/2025

**Title:** [TACROLIMUS STADAFARMA, CAPSULAS DURAS DE LIBERACION PROLONGADA, varias presentaciones](nan)

Summary: Posible obtención de resultados fuera de especificaciones en el ensayo de contenido durante los estudios de estabilidad en curso. Cadena de distribución y dispensación. Defecto de calidad que no supone un riesgo vital para el paciente

Date: 12/03/2025

**Title:** [VENLAFAXINA RETARD TEVA 75 mg CAPSULAS DURAS DE LIBERACION PROLONGADA EFG , 30 cápsulas (NR: 69851, CN: 661052)](nan)

Summary: Prospecto no actualizado. Cadena de distribución y dispensación. Defecto de calidad que no supone un riesgo vital para el paciente

Date: 10/03/2025

**Title:** [Pellets de testosterona y de estradiol, FÓRMULA MAGISTRAL](nan)

Summary: nan

Date: 04/03/2025

**Title:** [Fórmulas magistrales incluidas en el anexo de la alerta farmacéutica R\_06/2025](nan)

Summary: nan

Date: 27/02/2025

**Title:** [NEUPOGEN 30 MU (0,3 mg/ml) SOLUCION INYECTABLE , 5 viales de 1 ml (NR: 59102, CN: 845826)](nan)

Summary: nan

Date: 25/02/2025

**Title:** [Pellets de testosterona y de estradiol, FÓRMULA MAGISTRAL](nan)

Summary: nan

Date: 17/02/2025

**Title:** [E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials: Draft Guidance for Industry](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e21-inclusion-pregnant-and-breastfeeding-women-clinical-trials)

Summary: E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials: Draft Guidance for Industry

Date: 21/07/2025

**Title:** [Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products Guidance for Industry](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-bsufa-products-guidance-industry)

Summary: Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products Guidance for Industry

Date: 18/07/2025

**Title:** [Development of Cancer Drugs for Use in Novel Combination - Determining the Contribution of the Individual Drugs’ Effects: Draft Guidance for Industry](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-cancer-drugs-use-novel-combination-determining-contribution-individual-drugs-effects)

Summary: Development of Cancer Drugs for Use in Novel Combination - Determining the Contribution of the Individual Drugs’ Effects: Draft Guidance for Industry

Date: 17/07/2025

**Title:** [Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-volume-parenteral-drug-products-and-pharmacy-bulk-packages-parenteral-nutrition-aluminum)

Summary: Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations

Date: 03/07/2025

**Title:** [Myelodysplastic Syndromes: Developing Drug and Biological Products for Treatment: Draft Guidance for Industry](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/myelodysplastic-syndromes-developing-drug-and-biological-products-treatment)

Summary: Myelodysplastic Syndromes: Developing Drug and Biological Products for Treatment: Draft Guidance for Industry

Date: 02/07/2025

**Title:** [Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases – Questions and Answers: Guidance for Industry](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/antibacterial-therapies-patients-unmet-medical-need-treatment-serious-bacterial-diseases-questions)

Summary: Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases – Questions and Answers: Guidance for Industry

Date: 26/06/2025

**Title:** [Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/early-lyme-disease-manifested-erythema-migrans-developing-drugs-treatment)

Summary: Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment

Date: 26/06/2025

**Title:** [Unique Device Identifier Requirements for Combination Products: Draft Guidance for Industry](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identifier-requirements-combination-products)

Summary: Unique Device Identifier Requirements for Combination Products: Draft Guidance for Industry

Date: 25/06/2025

**Title:** [Conducting Remote Regulatory Assessments Questions and Answers: Guidance for Industry](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-remote-regulatory-assessments-questions-and-answers)

Summary: Conducting Remote Regulatory Assessments Questions and Answers: Guidance for Industry

Date: 24/06/2025

**Title:** [Q1 Stability Testing of Drug Substances and Drug Products: Draft Guidance for Industry](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q1-stability-testing-drug-substances-and-drug-products)

Summary: Q1 Stability Testing of Drug Substances and Drug Products: Draft Guidance for Industry

Date: 23/06/2025

**Title:** [Post-Warning Letter Meetings Under GDUFA](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/post-warning-letter-meetings-under-gdufa)

Summary: Post-Warning Letter Meetings Under GDUFA

Date: 20/06/2025

**Title:** [ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/andas-pre-submission-facility-correspondence-related-prioritized-generic-drug-submissions)

Summary: ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions

Date: 16/06/2025

**Title:** [M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/m11-technical-specification-clinical-electronic-structured-harmonised-protocol)

Summary: M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol

Date: 06/06/2025

**Title:** [M11 Template: Clinical Electronic Structured Harmonised Protocol (CeSHarP)](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/m11-template-clinical-electronic-structured-harmonised-protocol-cesharp)

Summary: M11 Template: Clinical Electronic Structured Harmonised Protocol (CeSHarP)

Date: 05/06/2025

**Title:** [Recommendations for Complying With Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs: Draft Guidance for Industry](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-complying-over-counter-monograph-procedure-minor-changes-c001-minor-changes-solid)

Summary: Recommendations for Complying With Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs: Draft Guidance for Industry

Date: 04/06/2025

**Title:** [EMA: Chapter 4 - new Requirements for GMP Documentation?](https://www.gmp-compliance.org/gmp-news/ema-chapter-4-new-requirements-for-gmp-documentation)

Summary: Since 07 July 2025, three new draft guidance documents have been available on the EMA website, which can be commented on until 07 October 2025. These include Chapter 4, Annex 11 and Annex 22.

Date: 30/07/2025

**Title:** [Swissmedic/EMA: M4Q(R2) Guideline published for Comment](https://www.gmp-compliance.org/gmp-news/swissmedic-ema-m4qr2-guideline-published-for-comment)

Summary: The draft guideline "THE COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE: QUALITY M4Q(R2)" of the ICH was published on the ICH website in May 2025. The EMA and Swissmedic have now also published the draft guideline on their websites and set the comment periods until 24 October 2025.

Date: 30/07/2025

**Title:** [Annex 11 Draft - First Analysis](https://www.gmp-compliance.org/gmp-news/annex-11-draft-first-analysis)

Summary: On 07 July 2025, the EU Commission published 3 drafts of the EU GMP Guidance Annex 11 “Computerised Systems”, the new Annex 22 “Artificial Intelligence” and Chapter 4 “Documentation”. Here is an initial analysis of the Annex 11 draft.

Date: 30/07/2025

**Title:** [EDQM publishes three revised Texts on Pharmaceutical Water](https://www.gmp-compliance.org/gmp-news/edqm-publishes-three-revised-texts-on-pharmaceutical-water)

Summary: At its 182nd meeting in June 2025, the European Pharmacopoeia Commission (EPC) adopted three revised texts on pharmaceutical water: Water for injection (0169); Purified water (0008); Total organic carbon in water for pharmaceutical purposes (2.2.44). Read more.

Date: 30/07/2025

**Title:** [US Manufacturer buys ‘Pharmaceutical Water’ in Grocery Store](https://www.gmp-compliance.org/gmp-news/us-manufacturer-buys-pharmaceutical-water-in-grocery-store)

Summary: During an inspection of a US manufacturer of OTC products in March 2025, the FDA identified serious violations of GMP requirements for finished medicinal products. Among other issues, the manufacturer had purchased the water for its production from a grocery store. This resulted in a warning letter from the FDA. Continue reading.

Date: 30/07/2025

**Title:** [VDI updates Cleanroom Guidelines 2083 Sheets 4.1 and 4.2](https://www.gmp-compliance.org/gmp-news/vdi-updates-cleanroom-guidelines-2083-sheets-4-1-and-4-2)

Summary: The Verein Deutscher Ingenieure (VDI) has updated two guidelines from the VDI 2083 series and published them for comment. VDI 2083 4.1 describes the planning, construction and initial commissioning of cleanrooms, while VDI 2083 4.2 covers the energy efficiency of cleanrooms. Read more.

Date: 30/07/2025

**Title:** [WHO: TRS 1060 Nitrosamine Guideline published](https://www.gmp-compliance.org/gmp-news/who-trs-1060-nitrosamine-guideline-published)

Summary: In April 2025, the WHO published the new guideline ‘TRS 1060 - Annex 2: WHO good practice considerations for the prevention and control of nitrosamines in pharmaceutical products’ on its website, which must be taken into account by manufacturers and packagers of excipients, active ingredients, processing aids and finished medicinal products. It should be noted that WHO Annex 2 is to be regarded as a supplement to the existing GMP guidelines and their requirements with regard to nitrosamines, as set out, for example, in ICH M7 (R2).

Date: 30/07/2025

**Title:** [German Draft Act to amend Cannabis Prescription](https://www.gmp-compliance.org/gmp-news/german-draft-act-to-amend-cannabis-prescription)

Summary: The draft act from the German Federal Ministry of Health (Bundesministerium für Gesundheit - BMG) is intended to concretise the Medical Cannabis Act (Medizinal-Cannabisgesetz - MedCanG). Among other things, the draft stipulates that cannabis flowers may only be prescribed after personal contact between a doctor and the patient.

Date: 24/07/2025

**Title:** [Revised USP Chapter <561> Articles of Botanical Origin](https://www.gmp-compliance.org/gmp-news/revised-usp-chapter-561-articles-of-botanical-origin)

Summary: A revised version of USP chapter <561> Articles of Botanical Origin (ABOs) has been published in the Pharmacopeial Forum. The comment deadline is 30 September 2025.

Date: 24/07/2025

**Title:** [USP HMC Publishes Final Cannabis Flower Monograph](https://www.gmp-compliance.org/gmp-news/usp-hmc-publishes-final-cannabis-flower-monograph)

Summary: Following the revised draft chapter issued last year, the USP Herbal Medicines Compendium (HMC) published the Final Authorized Version 1.0 of its Cannabis Species Inflorescence Monograph.

Date: 24/07/2025

**Title:** [New HPTLC Chapter Proposed for The International Pharmacopoeia](https://www.gmp-compliance.org/gmp-news/new-hptlc-chapter-proposed-for-the-international-pharmacopoeia)

Summary: The World Health Organization (WHO) has published a new general chapter "1.18 High-performance thin-layer chromatography" (HPTLC) to be included in The International Pharmacopoeia. The draft is currently open for public consultation. Comments can be submitted via the WHO platform until 09 September 2025.

Date: 23/07/2025

**Title:** [WHO: TRS 1060 Excipients GMP Guideline published](https://www.gmp-compliance.org/gmp-news/who-trs-1060-excipients-gmp-guideline-published)

Summary: In April 2025, the WHO published the new TRS 1060 guideline package on its website. This includes, for example, "TRS 1060 - Annex 3: WHO good manufacturing practices for excipients used in pharmaceutical products", which addresses the requirements for excipients used in the pharmaceutical industry.

Date: 23/07/2025

**Title:** [Shocking Conditions at Indian pharmaceutical Manufacturer](https://www.gmp-compliance.org/gmp-news/shocking-conditions-at-indian-pharmaceutical-manufacturer)

Summary: The FDA inspection at an Indian manufacturer revealed serious violations of GMP requirements, in particular unsustainable hygienic conditions in the production and storage areas.

Date: 23/07/2025

**Title:** [Swissmedic updates Risk Assessment of Nitrosamines in Active Substances and finished Medicinal Products](https://www.gmp-compliance.org/gmp-news/swissmedic-updates-risk-assessment-of-nitrosamines-in-active-substances-and-finished-medicinal-products)

Summary: Swissmedic has published new provisions for the assessment of possible nitrosamine impurities, taking into account international methods with the aim of assessing the carcinogenic potential of nitrosamines and setting limits.

Date: 23/07/2025

**Title:** [FDA: Complete Response Letters published](https://www.gmp-compliance.org/gmp-news/fda-complete-response-letters-published)

Summary: In July, the U.S. FDA (U.S. Food and Drug Administration) published an announcement on its website regarding the publication of a large number of so-called "Complete Response Letters (CRLs)". It is already mentioned that further CRLs are to follow in the future.

Date: 23/07/2025

**Title:** [WHO: TRS 1060 regulatory Guidelines published](https://www.gmp-compliance.org/gmp-news/who-trs-1060-regulatory-guidelines-published)

Summary: In April 2025, the WHO published annexes to its current Technical Report Series (TRS) 1060 on its website, including 'Annex 7: Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products' and 'Annex 8: Collaborative registration procedure between WHO and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified vector control products'.

Date: 22/07/2025

**Title:** [AQCG Organises One-Day Track at PharmaLab 2025](https://www.gmp-compliance.org/gmp-news/aqcg-organises-one-day-track-at-pharmalab-2025)

Summary: PharmaLab Congress – the event for all pharmaceutical laboratory sectors – will take place from 24–26 November 2025 in Düsseldorf/Neuss. This year, the ECA Analytical Quality Control Group (AQCG) will organise a dedicated one-day conference track. The draft programme is now available.

Date: 22/07/2025

**Title:** [ICH publishes Training Materials on Q2(R2) and Q14](https://www.gmp-compliance.org/gmp-news/ich-publishes-training-materials-on-q2r2-and-q14)

Summary: On 8 July 2025, the ICH published Training Modules 1 to 7 on ICH Q2(R2) “Validation of Analytical Procedures” and ICH Q14 “Analytical Procedure Development.” The files are available for download on the ICH website.

Date: 22/07/2025

**Title:** [AQCG welcomes two new Board Members](https://www.gmp-compliance.org/gmp-news/aqcg-welcomes-two-new-board-members)

Summary: The ECA Analytical Quality Control Group (AQCG) is pleased to announce recent changes to the Board. As of June 2025, Dr Amanda Guiraldelli Mahr has joined the Board. Lance Smallshaw has been serving as a member since November 2024.

Date: 22/07/2025

**Title:** [Free Webinar on Sampling and Sample Management: Recording & Q&A Document](https://www.gmp-compliance.org/gmp-news/free-webinar-on-sampling-and-sample-management-recording-q-a-document)

Summary: A free one-hour webinar on ECA’s new Guidance on Sampling and Sample Management was held on 17 June 2025 for all members of the Analytical Quality Control Group (AQCG). After the event, the speaker, Dr Christopher Burgess, answered the submitted questions in writing. The resulting Q&A document, containing 39 questions and answers, is now available in the members’ area. If you haven’t seen it yet: the webinar recording and presentation slides are also accessible.

Date: 22/07/2025

**Title:** [Analytical Quality Group Developments January through April 2025](https://www.gmp-compliance.org/gmp-news/analytical-quality-group-developments-january-through-april-2025)

Summary: Find out what the ECA Analytical Quality Control Group was working on and accomplished in the first four months of 2025 - in the latest report.

Date: 22/07/2025

**Title:** [ICH E20 Draft Guideline on Adaptive Design for Clinical Trials](https://www.gmp-compliance.org/gmp-news/ich-e20-draft-guideline-on-adaptive-design-for-clinical-trials)

Summary: The ICH E20 draft Guideline on “Adaptive Design for Clinical Trials” has reached Step 2b of the ICH Process and entered the Step 3 public consultation period. The EU deadline for comments is 30 November 2025.

Date: 17/07/2025

**Title:** [Update on ICH Guidelines E21 & E22](https://www.gmp-compliance.org/gmp-news/update-on-ich-guidelines-e21-e22)

Summary: The ICH is currently working on two new Efficacy Guidelines: E21 on Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials and E22 on General Considerations for Patient Preference Studies.

Date: 17/07/2025

**Title:** [Glass Containers for Pharmaceutical Use](https://www.gmp-compliance.org/gmp-news/glass-containers-for-pharmaceutical-use)

Summary: A revised version of Ph. Eur. chapter 3.2.1. Glass containers for pharmaceutical use has been published in Pharmeuropa 37.3. The comment deadline is 30 September 2025.

Date: 17/07/2025

**Title:** [Inadequate Sampling and Component Testing Highlighted in FDA Warning Letter](https://www.gmp-compliance.org/gmp-news/inadequate-sampling-and-component-testing-highlighted-in-fda-warning-letter)

Summary: An FDA inspection revealed serious CGMP violations related to sampling, testing, and quality oversight at a U.S.-based drug manufacturer, underscoring the critical importance of scientifically sound sampling strategies.

Date: 16/07/2025

**Title:** [EMA publishes new Product-Specific Bioequivalence Guidance](https://www.gmp-compliance.org/gmp-news/ema-publishes-new-product-specific-bioequivalence-guidance)

Summary: The European Medicines Agency (EMA) has added new entries to its “Product-specific bioequivalence guidance” section, publishing updated guidelines for individual products.

Date: 16/07/2025

**Title:** [Revision of USP Chapter <1039> Chemometrics Published for Comments](https://www.gmp-compliance.org/gmp-news/revision-of-usp-chapter-1039-chemometrics-published-for-comments)

Summary: In Pharmacopeial Forum 51(4), the USP has published a major revision of General Chapter <1039> Chemometrics for public comment. The update reflects the rapid evolution of the field, particularly driven by developments in machine learning and AI.

Date: 16/07/2025

**Title:** [Proposal for new USP Chapter <318> NMR Monomer Ratio Determination for Lactide-Glycolide Polymers](https://www.gmp-compliance.org/gmp-news/proposal-for-new-usp-chapter-318-nmr-monomer-ratio-determination-for-lactide-glycolide-polymers)

Summary: In the Pharmacopeial Forum, PF 51(4), a proposal for a new USP General Chapter <318> Nuclear Magnetic Resonance Spectroscopy Monomer Ratio Determination for Lactide–Glycolide Polymers has been published for public comment. Developed by the Excipients Test Methods Expert Committee, the chapter introduces a validated proton NMR method to quantify the monomer ratio in ring-opening copolymers of DL- or L-lactide and glycolide.

Date: 16/07/2025

**Title:** [New USP Chapter <1221> on Ongoing Procedure Performance Verification (OPPV) Published for Comment](https://www.gmp-compliance.org/gmp-news/new-usp-chapter-1221-on-ongoing-procedure-performance-verification-oppv-published-for-comment)

Summary: In Pharmacopeial Forum 51(4), the USP proposes a new General Chapter <1221> Ongoing Procedure Performance Verification. As Stage 3 of the Analytical Procedure Life Cycle (<1220>), the chapter introduces a risk-based approach to ensure consistent method performance during routine use. The draft is open for public comment until 30 September 2025.

Date: 16/07/2025

**Title:** [Content of an Audit Trail / Must an Audit Trail be printable?](https://www.gmp-compliance.org/gmp-news/content-of-an-audit-trail-must-an-audit-trail-be-printable)

Summary: The requirements for an audit trail can now be found almost everywhere in the relevant pharmaceutical regulations. Six experts from industry and regulatory authorities answer an extensive catalog of questions from various topic areas. Questions 1 and 2: From an inspector's perspective, what are the minimum requirements for the content of an audit trail and must an audit trail be printable?

Date: 16/07/2025

**Title:** [Final FDA Guidance on Remote Regulatory Assessments](https://www.gmp-compliance.org/gmp-news/final-fda-guidance-on-remote-regulatory-assessments)

Summary: The FDA published the final Guidance for Industry Conducting Remote Regulatory Assessments - Questions and Answers. The final guidance describes how FDA will use Remote Regulatory Assessments (RRAs) for FDA-regulated products.

Date: 16/07/2025

**Title:** [New USP Chapter <1245> Compaction Simulation published](https://www.gmp-compliance.org/gmp-news/new-usp-chapter-1245-compaction-simulation-published)

Summary: The new chapter <1245> Compaction Simulation in the USP is a newly added chapter that describes procedures for simulating tableting. It was first published with USP 47 - NF 42, First Supplement and, like all USP chapters with a number > 999, is considered informative. Read more here.

Date: 16/07/2025

**Title:** [New Swissmedic Technical Interpretation on Returns of Medicinal Products](https://www.gmp-compliance.org/gmp-news/new-swissmedic-technical-interpretation-on-returns-of-medicinal-products)

Summary: Swissmedic has published a new Technical Interpretation (TI) entitled "Requirements for the return of medicinal products" (I-SMI.TI.28e). The document defines the minimum requirements for wholesalers handling medicinal products returned by retailers, particularly with regard to the time limits that must be observed between delivery and return of the medicinal products.

Date: 15/07/2025

**Title:** [Two new GDP Non-Compliance Reports from Austria and Ireland published in the EudraGMDP database](https://www.gmp-compliance.org/gmp-news/two-new-gdp-non-compliance-reports-from-austria-and-ireland-published-in-the-eudragmdp-database)

Summary: Two new GDP Non-Compliance Reports from Austria and Ireland have been published in the EudraGMDP database. Both authorities document violations of the EU GDP guidelines and have revoked the Wholesale Distribution Authorisation (WDA) of the respective companies.

Date: 15/07/2025

**Title:** [Reminder: Participate in the GDP Implementation Survey until 31 July 2025](https://www.gmp-compliance.org/gmp-news/reminder-participate-in-the-gdp-implementation-survey-until-31-july-2025)

Summary: As previously reported, the European GDP Association (GDPA) is currently conducting a survey on the topic of GDP. If you have not yet participated, you can still complete the online questionnaire until 31 July.

Date: 15/07/2025

**Title:** [PDA Publishes Results of Transportation Validation Benchmarking Survey](https://www.gmp-compliance.org/gmp-news/pda-publishes-results-of-transportation-validation-benchmarking-survey)

Summary: The Parenteral Drug Association (PDA) has published the results of its 2025 Transportation Validation Benchmarking Survey. The survey aimed to gather industry benchmarking data on transportation qualification strategies within the pharmaceutical and biopharmaceutical industry.

Date: 15/07/2025

**Title:** [EMA Policy on the Publication of Clinical Data](https://www.gmp-compliance.org/gmp-news/ema-policy-on-the-publication-of-clinical-data)

Summary: The EMA has published a revised version of the guideline on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use.

Date: 10/07/2025

**Title:** [New Ph. Eur. Chapter for Estragole Determination](https://www.gmp-compliance.org/gmp-news/new-ph-eur-chapter-for-estragole-determination)

Summary: A new European Pharmacopoeia (Ph. Eur.) chapter 2.8.27. Determination of Estragole has been published in Pharmeuropa 37.3. The comment deadline is 30 September 2025.

Date: 10/07/2025

**Title:** [EMA Reflection Paper on Data Recommendations for Herbal Medicinal Products](https://www.gmp-compliance.org/gmp-news/ema-reflection-paper-on-data-recommendations-for-herbal-medicinal-products)

Summary: The European Medicines Agency (EMA) published a draft "Reflection paper on data recommendations for herbal medicinal products (HMPs) and traditional herbal medicinal products (THMPs) used in children and adolescents". The paper is open for public consultation until 31 August 2025.

Date: 10/07/2025

**Title:** [Drafts of EU GMP Guideline Annex 11, Annex 22 and Chapter 4 released for comment](https://www.gmp-compliance.org/gmp-news/drafts-of-eu-gmp-guideline-annex-11-annex-22-and-chapter-4-released-for-comment)

Summary: The long-awaited drafts of the EU GMP Guide Annex 11, Annex 22 and Chapter 4 were published by the EU Commission for comment on 7 July 2025.

Date: 09/07/2025

**Title:** [Phenolic Antioxidants in Plastic Materials](https://www.gmp-compliance.org/gmp-news/phenolic-antioxidants-in-plastic-materials)

Summary: A new Ph. Eur. chapter 2.5.46. Phenolic antioxidants in plastic materials has been published in Pharmeuropa 37.3. The comment deadline is 30 September 2025.

Date: 09/07/2025

**Title:** [The USP has revised the General Chapter <1231> on Pharmaceutical Water](https://www.gmp-compliance.org/gmp-news/the-usp-has-revised-the-general-chapter-1231-on-pharmaceutical-water)

Summary: In the Pharmacopoeial Forum PF 51(4), the USP has published the draft revision of chapter <1231> "Water for Pharmaceutical Purposes". See the proposed changes to the general water chapter.

Date: 09/07/2025

**Title:** [USP: Chapter <1029> Good Documentation Guidelines and Data Integrity published for comment](https://www.gmp-compliance.org/gmp-news/usp-chapter-1029-good-documentation-guidelines-and-data-integrity-published-for-comment)

Summary: The chapter "<1029> Good Documentation Guidelines and Data Integrity" has been published for comment on the website of the USP Pharmacopeial Forum since the beginning of July 2025. Comments and remarks on this draft, which is based on the previous version "<1029> Good Documentation Guidelines" from May 2018, can be submitted until September 30, 2025.

Date: 09/07/2025

**Title:** [ICH M4Q Guideline Updated](https://www.gmp-compliance.org/gmp-news/ich-m4q-guideline-updated)

Summary: The draft of the updated guideline of the ICH entitled 'THE COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE: QUALITY M4Q(R2)' was published in May 2025 and is now available for public comment.

Date: 02/07/2025

**Title:** [FDA Warning Letter: Missing Testing, No Stability Data, and Inadequate Raw Material Controls](https://www.gmp-compliance.org/gmp-news/fda-warning-letter-missing-testing-no-stability-data-and-inadequate-raw-material-controls)

Summary: A recent FDA Warning Letter highlights GMP violations at a U.S. manufacturer of over-the-counter (OTC) drug products, including missing microbiological testing, lack of stability data, and inadequate raw material controls.

Date: 02/07/2025

**Title:** [EFPIA Report on Current Inspections](https://www.gmp-compliance.org/gmp-news/efpia-report-on-current-inspections)

Summary: The EFPIA has published its "Annual Regulatory GMP/GDP Inspection Survey 2024 Data", containing some interesting results that not everyone may have expected.

Date: 02/07/2025

**Title:** [GMP non-Compliance Reports for two Cannabis Sites](https://www.gmp-compliance.org/gmp-news/gmp-non-compliance-reports-for-two-cannabis-sites)

Summary: Malta's Medicines Authority recently issued two GMP non-compliance statements: One to a manufacturer of cannabis-based medicinal products and another to a Quality Control testing laboratory for the analytical testing of non-sterile dosage forms (specifically for medical Cannabis products).

Date: 01/07/2025

**Title:** [IPEC: Revised Risk Assessment Guide for Pharmaceutical Excipients](https://www.gmp-compliance.org/gmp-news/ipec-revised-risk-assessment-guide-for-pharmaceutical-excipients)

Summary: In May 2025, the IPEC International Pharmaceutical Excipients Council Europe (IPEC Europe) announced the new Version 1 of its “IPEC Risk Assessment Guide for Pharmaceutical Excipients - Risk Assessment for Excipient Manufacturers (Version 1, 2025)” on its website.

Date: 25/06/2025

**Title:** [Is Knowledge Management a Part of the Pharmaceutical Quality System?](https://www.gmp-compliance.org/gmp-news/is-knowledge-management-a-part-of-the-pharmaceutical-quality-system)

Summary: To make it short: yes, it is. Although Knowledge Management is not a formal GMP requirement, ICH Q10 lists Knowledge Management as an "enabler" for an effective pharmaceutical quality system.

Date: 25/06/2025

**Title:** [FDA Warning Letter: "Memory-Based Manufacturing" and Lack of Analytical Testing](https://www.gmp-compliance.org/gmp-news/fda-warning-letter-memory-based-manufacturing-and-lack-of-analytical-testing)

Summary: A recent FDA Warning Letter reveals severe GMP breaches at a U.S. drug manufacturer, including the absence of written procedures, reliance on undocumented processes, and a failure to perform basic analytical testing such as identity, strength, and microbiological checks prior to product release.

Date: 25/06/2025

**Title:** [Deficiencies in the Water System: Warning Letter to US Manufacturers of OTC Products](https://www.gmp-compliance.org/gmp-news/deficiencies-in-the-water-system-warning-letter-to-us-manufacturers-of-otc-products)

Summary: The FDA inspection of the US manufacturer of OTC products already took place in January 2025. The FDA criticized laboratory tests, missing microbiological specifications and the Quality Unit, which had not fulfilled its responsibilities. The water system in particular also showed serious deficiencies. Read more.

Date: 25/06/2025

**Title:** [USP: Comments possible on the Topic "Process Analytical Technology"](https://www.gmp-compliance.org/gmp-news/usp-comments-possible-on-the-topic-process-analytical-technology)

Summary: The new general chapter "<1037> Process Analytical Technology-Theory and Practice" and the two related stimuli articles "Process Analytical Technology I-Theory of Sampling in PAT" and "Process Analytical Technology II-Implementation of Real-Time Release Testing" of the USP have been published on the website of the Pharmacopeial Forum for comments.

Date: 18/06/2025

**Title:** [FDA Warning Letter Highlights Analytical Deficiencies: Lack of Release Testing and Unsupported Expiry Dates](https://www.gmp-compliance.org/gmp-news/fda-warning-letter-highlights-analytical-deficiencies-lack-of-release-testing-and-unsupported-expiry-dates)

Summary: In a recent Warning Letter, the U.S. Food and Drug Administration (FDA) criticizes major analytical GMP violations observed during an inspection at a Chinese drug manufacturing facility. These include a lack of release testing and unsupported expiry dates for products intended for the U.S. market.

Date: 18/06/2025

**Title:** [EMA/CMDh: Nitrosamine Q&A Document updated](https://www.gmp-compliance.org/gmp-news/ema-cmdh-nitrosamine-q-a-document-updated)

Summary: The Q&A document "Questions and answers for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products", which was prepared jointly by the EMA and the CMDh, has been updated once again and published in the new revision 22 on the EMA website.

Date: 18/06/2025

**Title:** [FDA Warning Letter with Supplier Qualification Observations](https://www.gmp-compliance.org/gmp-news/fda-warning-letter-with-supplier-qualification-observations)

Summary: A US company received a Warning Letter because of problems at their CMO. FDA points out that companies should have a robust qualification process for CMOs.

Date: 18/06/2025

**Title:** [USP Draft Chapter for E&Ls in Parenteral Drug Products](https://www.gmp-compliance.org/gmp-news/usp-draft-chapter-for-e-ls-in-parenteral-drug-products)

Summary: The USP is expanding the Extractables and Leachables (E&Ls) Chapter Series <1664>: The draft chapter <1664.2> Parenteral Drug Products (Intramuscular, Intravenous, and Subcutaneous), has just been officially published.

Date: 17/06/2025

**Title:** [EMA Implementation of ICH E6, M11 & M12](https://www.gmp-compliance.org/gmp-news/ema-implementation-of-ich-e6-m11-m12)

Summary: The European Medicines Agency has announced the implementation of various ICH guidelines. Gaps that were previously covered by European documents will also be closed by supplementary papers. Moreover, the EMA has set up dedicated websites for the implementaion of the ICH E6, M11 and M12 guidelines.

Date: 17/06/2025

**Title:** [USP informs about Monographs affected by the Revision of NMR Chapters <761> and <1761>](https://www.gmp-compliance.org/gmp-news/usp-informs-about-monographs-affected-by-the-revision-of-nmr-chapters-761-and-1761)

Summary: Revisions to USP Chapters <761> Nuclear Magnetic Resonance Spectroscopy and <1761> Nuclear Magnetic Resonance Spectroscopy—Theory and Practice were proposed for comment in PF 49(5) and are scheduled to become official on 1 December 2025. The USP has now identified other documentary standards that reference these chapters and has published a list of monographs that will be revised accordingly.

Date: 11/06/2025

**Title:** [Root Cause Investigations criticised at EU Company](https://www.gmp-compliance.org/gmp-news/root-cause-investigations-criticised-at-eu-company)

Summary: A Warning Letter was issued to a Dutch company, also because root cause determinations and CAPAs were deemed inadequate.

Date: 11/06/2025

**Title:** [Warning Letter to Chinese Manufacturer due to serious Sterility and Hygiene Deficiencies](https://www.gmp-compliance.org/gmp-news/warning-letter-to-chinese-manufacturer-due-to-serious-sterility-and-hygiene-deficiencies)

Summary: The FDA found serious GMP deficiencies during an inspection of a Chinese pharmaceutical manufacturer in November 2024. These include, above all, inadequate hygiene and ensuring the sterility of the products. For example, medicinal products were labelled as 'sterile' although neither sterilisation nor sterility tests were carried out.

Date: 11/06/2025

**Title:** [Swissmedic differentiates GMP Scope for Manufacturing and Preparation for Administration](https://www.gmp-compliance.org/gmp-news/swissmedic-differentiates-gmp-scope-for-manufacturing-and-preparation-for-administration)

Summary: Swissmedic has published an urgent revision to the regulations of Good Manufacturing Practice for medicinal products in small quantities in the Swiss Pharmacopoeia (Ph. Helv.). The revision relates in particular to the distinction under therapeutic products legislation between manufacturing and preparation for administration.

Date: 11/06/2025

**Title:** [Booklet "ICH Q7 Side-by-Side Comparison" updated](https://www.gmp-compliance.org/gmp-news/booklet-ich-q7-side-by-side-comparison-updated)

Summary: The booklet "ICH Q7 Side-by-Side Comparison" compares the requirements of the "ICH Q7 Guideline - GMP for Active Pharmaceutical Ingredients" to the interpretations of the revised "How to do"- Document - Interpretation of ICH Q7 Guide and "Review form" (Version 17) and explains the requirements of the guideline.

Date: 11/06/2025

**Title:** [APIC: Update of the Nitrosamine Guide](https://www.gmp-compliance.org/gmp-news/apic-update-of-the-nitrosamine-guide)

Summary: The guideline 'Additional guidance on the assessment on the risk assessment for presence of N-nitrosamines in APIs', first published in February 2020, has now been revised by a subgroup of the 'APIC Nitrosamines Task Force' and recently published in its latest version on the APIC website. The document is now called 'Nitrosamine Risk Management: Guidance for API Manufacturers' and has been extensively updated.

Date: 11/06/2025

**Title:** [New MHRA Blog Post: Supplying Medicines to Ships, Aircraft and Oil Platforms](https://www.gmp-compliance.org/gmp-news/new-mhra-blog-post-supplying-medicines-to-ships-aircraft-and-oil-platforms)

Summary: A new article titled “A Voyage in Good Distribution Practice (GDP): The Aviation and Marine Sectors” has been published on the MHRA Inspectorate blog. In this post, the Medicines and Healthcare products Regulatory Agency (MHRA) outlines key regulatory expectations, licensing requirements, delivery procedures, and specific considerations for recalls and repackaging when supplying medicines to the aviation and marine sectors – two environments that present unique logistical and compliance challenges.

Date: 10/06/2025

**Title:** [Questions and Answers from the ECA Webinar "GDP Update 2025" - Part 3](https://www.gmp-compliance.org/gmp-news/questions-and-answers-from-the-eca-webinar-gdp-update-2025-part-3)

Summary: Around 60 participants attended the ECA Webinar "GDP Update 2025" in March. Many interesting aspects were discussed in the Q&A session. After the event, the speaker, Dr. Christian Grote-Westrick, answered the submitted questions in writing. We have compiled a selection of these questions and answers for you – read Part 3 here.

Date: 10/06/2025

**Title:** [Meet the GDPA Board Members at the GDP Forum in Barcelona](https://www.gmp-compliance.org/gmp-news/meet-the-gdpa-board-members-at-the-gdp-forum-in-barcelona)

Summary: The upcoming GDP Forum will be held on 25 and 26 June 2025 in Barcelona, Spain. Several Board Members of the European GDP Association are part of the speakers team. Find out here which topics will be covered at the GDP Forum.

Date: 10/06/2025

**Title:** [Swissmedic Technical Interpretation: What Counts as a Major Change in GDP?](https://www.gmp-compliance.org/gmp-news/swissmedic-technical-interpretation-what-counts-as-a-major-change-in-gdp)

Summary: Swissmedic has published Version 3.0 of its Technical Interpretation "Notifications according to Article 41, MPLO". The document outlines which major changes must be reported to Swissmedic and provides additional clarification on the notification process. While the guidance primarily addresses manufacturers, it also includes several important points relevant to companies operating in the GDP environment.

Date: 10/06/2025

**Title:** [MHRA informes about Validity Date of UK issued GDP Certificates](https://www.gmp-compliance.org/gmp-news/mhra-informes-about-validity-date-of-uk-issued-gdp-certificates)

Summary: In a recent blog post, the MHRA Inspectorate outlined its approach to the validity of GMP and GDP certificates issued in the UK. While GMP certificates may be updated based on a new desk-based compliance assessment, GDP certificates will not be automatically extended in 2025.

Date: 10/06/2025

**Title:** [ICH: New Guideline for Stabilities](https://www.gmp-compliance.org/gmp-news/ich-new-guideline-for-stabilities)

Summary: The draft guideline "STABILITY TESTING OF DRUG SUBSTANCES AND DRUG PRODUCTS" of the ICH was published in April 2025 and is now available for public comment.

Date: 04/06/2025

**Title:** [FAQs regarding Cross Contamination](https://www.gmp-compliance.org/gmp-news/faqs-regarding-cross-contamination)

Summary: The topic of cross contamination is still in focus, as the FDA Warning Letters of the last 1-2 years show. It is therefore also discussed in some conferences and seminars. Questions are repeatedly asked in this context, and we are happy to provide you with possible answers.

Date: 04/06/2025

**Title:** [EDQM: Update of Guideline "How to read a CEP"](https://www.gmp-compliance.org/gmp-news/edqm-update-of-guideline-how-to-read-a-cep)

Summary: In May, the first revision of the guideline "How to read a CEP (PA/PH/CEP (15) 31, 1R)" was published on the EDQM website. It mainly contains updates resulting from the introduction of CEP 2.0 in 2023.

Date: 04/06/2025

**Title:** [Become a speaker at the ECA AI Conference on 5/6 November 2025](https://www.gmp-compliance.org/gmp-news/become-a-speaker-at-the-eca-ai-conference-on-5-6-november-2025)

Summary: Artificial Intelligence (AI) is increasingly finding its way into the pharmaceutical industry. In light of the expected EU GMP Guide Annex 22 on AI, the ECA will be organising an AI conference in Copenhagen on 5/6 November 2025. Become a speaker at the conference and submit a proposal for a contribution. Details can be found here.

Date: 04/06/2025

**Title:** [ISO 13485/EU GMP Guideline Part I Matrix exclusively for delegates at the GMP & GDP Forum](https://www.gmp-compliance.org/gmp-news/iso-13485-eu-gmp-guideline-part-i-matrix-exclusively-for-delegates-at-the-gmp-gdp-forum)

Summary: For combination products the quality requirements for the medicinal product part are fixed in the EU in the EU GMP Guidance Part I. For the medical device part the ISO standard 13485 is relevant. How to bring them together?

Date: 04/06/2025

**Title:** [GMP Deficiencies at French Sterile Manufacturer](https://www.gmp-compliance.org/gmp-news/gmp-deficiencies-at-french-sterile-manufacturer)

Summary: In November 2024, the US FDA inspected a French sterile manufacturer of prescription and OTC medicines. The inspectors found significant GMP violations. Deficiencies were cited in the handling of complaints, the microbiological control of aseptic processes and the cleaning and maintenance of production equipment.

Date: 04/06/2025

**Title:** [Use of real-world evidence in regulatory decision making – EMA (European Medicines Agency) publishes review of its studies](https://www.ema.europa.eu/documents/report/real-world-evidence-framework-support-eu-regulatory-decision-making-report-experience-gained_.pdf, https://www.encepp.eu/encepp/openAttachment/studyResult/42289, https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/covid-19-public-health-emergency-international-concern-2020-23/monitoring-covid-19-medicines#observational-research-section, https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance-overview#measuring-the-impact-of-pharmacovigilance-activities-(updated)-section, https://www.ema.europa.eu/en/about-us/how-we-work/big-data/data-analysis-real-world-interrogation-network-darwin-eu, https://www.ema.europa.eu/en/events/multi-stakeholder-workshop-real-world-data-rwd-quality-real-world-evidence-rwe-use, https://www.ema.europa.eu/documents/report/real-world-evidence-framework-support-eu-regulatory-decision-making-report-experience-gained_.pdf, https://www.hma.eu/about-hma/recently-published.html, https://www.hma.eu/about-hma/recently-published.html, https://twitter.com/EMA_News)

Summary: Overseen by the EMA (European Medicines Agency) EMA - HMA (Heads of Medicines Agencies) HMA Big Data Steering Group, EMA (European Medicines Agency) EMA and EMRN (European Medicines Regulator Network) EMRN are working towards setting up a sustainable framework that...

Date: nan

**Title:** [ICH E2B(R3) Q&As, Implementation Guide, and Appendix I (G) Reach Step 4 of the ICH Process](https://www.ich.org/news/ich-e2br3-qas-implementation-guide-and-appendix-i-g-reach-step-4-ich-process)

Summary: nan

Date: 30/07/2025

**Title:** [ICH E20 Step 2 Presentation Now Available on the ICH Website](https://www.ich.org/news/ich-e20-step-2-presentation-now-available-ich-website)

Summary: nan

Date: 11/07/2025

**Title:** [ICH Q2(R2)/Q14 IWG Training Materials Now Available on the ICH Website](https://www.ich.org/news/ich-q2r2q14-iwg-training-materials-now-available-ich-website)

Summary: nan

Date: 09/07/2025

**Title:** [ICH M4Q(R2) Step 2 Presentation Now Available on the ICH Website](https://www.ich.org/news/ich-m4qr2-step-2-presentation-now-available-ich-website)

Summary: nan

Date: 27/06/2025

**Title:** [ICH E20 Draft Guideline is Available Now on the ICH Website](https://www.ich.org/news/ich-e20-draft-guideline-available-now-ich-website)

Summary: nan

Date: 25/06/2025

**Title:** [ICH E21 Step 2 Presentation Now Available on the ICH Website](https://www.ich.org/news/ich-e21-step-2-presentation-now-available-ich-website)

Summary: nan

Date: 12/06/2025

**Title:** [Recent warning from UK authorities following adverse reactions to cosmetic procedures involving botulinum toxin](https://www.hpra.ie/news-events/news/article/recent-warning-from-uk-authorities-following-adverse-reactions-to-cosmetic-procedures-involving-botulinum-toxin)

Summary: The HPRA is aware of a recent safety alert  
Opens in new window  
issued by the UK Health Security Agency (UKHSA) warning people to be aware of the signs and symptoms of botulism.

Date: 29/07/2025

**Title:** [TPO added to European Union list of prohibited ingredients](https://www.hpra.ie/news-events/news/article/tpo-added-to-european-union-list-of-prohibited-ingredients)

Summary: On 12 May 2025, the EU Commission published legislation, known as the 7th CMR Omnibus Regulation, to add 22 new substances to the list of ingredients prohibited for use in cosmetics.

Date: 29/07/2025

**Title:** [Further deferral of prescription requirement for antiparasitic veterinary medicines in food-producing animals](https://www.hpra.ie/news-events/news/article/further-deferral-of-prescription-requirement-for-antiparasitic-veterinary-medicines-in-food-producing-animals)

Summary: The Minister for Agriculture, Food and the Marine, has further deferred the requirement for a veterinary prescription for anti-parasitic veterinary medicines used in food-producing animal species until 1 December 2025.

Date: 28/07/2025

**Title:** [Revised Good Clinical Practice Guideline ICH E6 (R3)](https://www.hpra.ie/news-events/news/article/revised-good-clinical-practice-guideline-ich-e6-(r3))

Summary: The revised International Council for Harmonisation (ICH) Guideline for Good Clinical Practice (GCP), ICH E6(R3), will become effective in the EU on 23 July 2025.

Date: 23/07/2025

**Title:** [Heads of Competent Authorities for Medical Devices (CAMD) release consensus statement on reform of the EU regulatory framework for medical devices](https://www.hpra.ie/news-events/news/article/heads-of-competent-authorities-for-medical-devices-(camd)-release-consensus-statement-on-reform-of-the-eu-regulatory-framework-for-medical-devices)

Summary: National Competent Authorities have endorsed a consensus statement  
Opens in new window  
and shared it with the European Commission on the reform of the EU regulatory framework for medical devices.

Date: 14/07/2025

**Title:** [EMA webinar – Redesigned CTIS training material for sponsor users](https://www.hpra.ie/news-events/news/article/ema-webinar---redesigned-ctis-training-material-for-sponsor-users)

Summary: The EMA will publish a revised Sponsor Handbook for the Clinical Trials Information System (CTIS) on the EMA website  
Opens in new window  
on 9 July 2025.

Date: 08/07/2025

**Title:** [Clinical trials involving IVD performance studies – coordinated assessment pilot](https://www.hpra.ie/news-events/news/article/clinical-trials-involving-ivd-performance-studies---coordinated-assessment-pilot)

Summary: Clinical trial sponsors are invited to express their interest in Phase 1 of the COMBINE Project 1 pilot.

Date: 27/06/2025

**Title:** [Deferral of prescription requirement for antiparasitic veterinary medicines in food-producing animals](https://www.hpra.ie/news-events/news/article/deferral-of-prescription-requirement-for-antiparasitic-veterinary-medicines-in-food-producing-animals)

Summary: The Minister for Agriculture, Food and the Marine, has further deferred the requirement for a veterinary prescription for anti-parasitic veterinary medicines used in food-producing animal species until 1 September 2025.

Date: 09/06/2025

**Title:** [Regulation of chemical-unlike biological substances used in food-producing species](https://www.hpra.ie/news-events/news/article/regulation-of-chemical-unlike-biological-substances-used-in-food-producing-species)

Summary: On 3 June 2025, the EU Commission published a number of legal acts relating to the regulation of residues of chemical-unlike biological substances.

Date: 06/06/2025

**Title:** [Urgent warning of fraudulent websites and adverts promoting illegal medicines](https://www.hpra.ie/news-events/news/article/urgent-warning-of-fraudulent-websites-and-adverts-promoting-illegal-medicines)

Summary: The HPRA today states that it has identified a significant increase in recent weeks of online content making false claims whilst promoting medicines, medical devices and cosmetics.

Date: 29/05/2025

**Title:** [Minimum service from 21 July till 4 August](https://www.ima.is/frettir/minimum-service-from-21-july-till-4-august/)

Summary: The services that are mostly affected are as follows: Requests submitted on or after, 21 July 2025, will be received on 5 August The Icelandic Medicines Agency strives to answer requests within four weeks from submission but applicants may expect delays during the summer months Slots for 2026 are no...

Date: 23/06/2025

**Title:** [Watch out for the sun when taking certain drugs](https://santesecu.public.lu/fr/actualites/2025/juillet/photosensibilisation-medicamenteuse.html)

Summary: The pharmacovigilance service of the pharmacy and medication division (DPM) wishes to recall the importance of vigilance in the face of photosensitization reactions that can occur after taking certain commonly used drugs and draw attention to ...

Date: 25/07/2025

**Title:** [World Hepatitis Day: Luxembourg intensifies its mobilization against a silent epidemic](https://santesecu.public.lu/fr/actualites/2025/juillet/journee-mondiale-hepatite.html)

Summary: On the occasion of World Day against Hepatitis, celebrated every July 28, the Ministry of Health and Social Security recalls the importance of prevention, screening and access to treatments to effectively fight hepatitis ...

Date: 25/07/2025

**Title:** [Analysis of the reassuring Steinfort communal water network: absence of legionella](https://santesecu.public.lu/fr/actualites/2025/juillet/absence-legionellose-steinfort.html)

Summary: The Ministry of Health and Social Security and the Municipality of Steinfort informs the population that the analyzes carried out on the drinking water supply network as well as in the two Steinfort and Kleinbettingen reservoirs ...

Date: 22/07/2025

**Title:** [Situation point concerning cases of legionellosis detected in Steinfort](https://santesecu.public.lu/fr/actualites/2025/juillet/cas-legionellose-steinfort.html)

Summary: The Ministry of Health and Social Security was informed in the evening of Thursday, July 10, that cases of legionellosis had been detected in unusual numbers. Seven cases of pneumonia caused by the bacteria Legionella ...

Date: 15/07/2025

**Title:** [Successful inaugural flight - The Griffin drone carries a blood sample by air](https://santesecu.public.lu/fr/actualites/2025/juillet/drone-griffin-inauguration.html)

Summary: A major advance for medical logistics in Luxembourg: today, the Griffin project drone successfully made its very first official flight, transporting a blood sample by the air, from Robert Schuman Hospitals (Kirchberg) to the Laboratories Reunited ...

Date: 10/07/2025

**Title:** [Working visit of the new Director General of the DG Hera at the National Crisis Center in Senningen](https://santesecu.public.lu/fr/actualites/2025/juillet/visite-travail-hera.html)

Summary: As part of his visit to Luxembourg, Florika Fink-Hooijer, recently appointed Director General of the DG Hera (Health Emergency, Preparedness & Response Authority) of the European Commission, was greeted at the National Crisis Center in Senningen. This meeting ...

Date: 03/07/2025

**Title:** [Red alert confirmed for this afternoon - gradual improvement of the conditions expected this evening](https://santesecu.public.lu/fr/actualites/2025/juillet/alerte-rouge.html)

Summary: The weather assessment unit evaluation unit (CERI) again met on Wednesday, July 2, 2025 in the morning in order to take stock of the evolution of the weather situation. The developments announced yesterday are confirmed: maximum temperatures reach ...

Date: 02/07/2025

**Title:** [Heat notice - CERI: Red vigilance trigger for Wednesday July 2, 2025](https://santesecu.public.lu/fr/actualites/2025/juillet/avis-chaleur-vigilance-rouge.html)

Summary: The bad weather and flooding risk assessment cell (CERI) met at the end of the morning in order to analyze the meteorological situation announced by Meteolux for the day of July 2. Selon les prévisions, un niveau de vigilance rouge est attendu entre...

Date: 01/07/2025

**Title:** [Heat notice - Orange vigilance announced for tomorrow July 1, 2025: Reminder of behavior to adopt](https://santesecu.public.lu/fr/actualites/2025/juin/avis-chaleur-vigilance-orange.html)

Summary: Due to the advice of heat (orange vigilance) issued by Meteolux for the whole country this Tuesday, July 1, between 12:00 p.m. and 9:00 p.m., with maximum temperatures provided between 32 and 35 degrees, and insofar as temperatures ...

Date: 30/06/2025

**Title:** [High heat: the Ministry of Health and Social Security calls for vigilance and recalls the good gestures to adopt](https://santesecu.public.lu/fr/actualites/2025/juin/fortes-chaleurs.html)

Summary: A period of hot weather is planned in the coming days. The Ministry of Health and Social Security reminds the population some recommendations to protect themselves and protect the most vulnerable. Adopt the right reflexes: drink ...

Date: 27/06/2025

**Title:** [Martine Deprez to the Council of Health Ministers in Luxembourg](https://santesecu.public.lu/fr/actualites/2025/juin/epsco.html)

Summary: Dated June 20, 2025, the Minister of Health and Social Security, Martine Deprez, took part in the EPSCO council in her health training in Luxembourg. European Health Ministers have debated several ...

Date: 20/06/2025

**Title:** [EPSCO Consulting: a strong commitment from Luxembourg ministers for a Europe putting people at the center of actions](https://santesecu.public.lu/fr/actualites/2025/juin/conseil-epsco.html)

Summary: Georges Mischo, Minister of Labor, Martine Deprez, Minister of Health and Social Security, and Max Hahn, Minister of Family, Solidarity, Living Ensemble and Home, participated on June 19, 2025 in Reunion ...

Date: 20/06/2025

**Title:** [Presentation of honorary distinctions by the Ministry of Health and Social Security](https://santesecu.public.lu/fr/actualites/2025/juin/remise-distinctions-honorifiques-2025.html)

Summary: As of June 18, 2025, the Minister of Health and Social Security, Martine Deprez, gave honorary medals to collaborators from the Ministry of Health and Social Security and ...

Date: 19/06/2025

**Title:** [18th edition of the Occupational Safety and Health Forum](https://santesecu.public.lu/fr/actualites/2025/juin/forum-securite-sante-travail.html)

Summary: On June 19, 2025 will be held, from 9:00 a.m. to 4:30 p.m., the 18th edition of the Forum Sécurité-santé at work (SST), in the premises of the Chamber of Commerce. Under the theme of "security and health in the face of the challenges of a world ...

Date: 16/06/2025

**Title:** [Establishment of an internal reporting channel for whistleblowers.](https://santesecu.public.lu/fr/actualites/2025/juin/lanceur-dalerte-guichet-lu.html)

Summary: The Ministry of Health and Social Security sets up an internal reporting channel for whistleblowers. As part of its transparency and integrity policy, the ministry announces the implementation of a ...

Date: 06/06/2025

**Title:** [Publication of European and national reports on drugs 2025: inventory and public health issues](https://santesecu.public.lu/fr/actualites/2025/juin/rapport-relis-2025.html)

Summary: The 30ᵉ European report on drugs, published by the Agency of the European Union on Drugs (EUDA), as well as the National Drug Report 2025 (RELIS), developed by the Euda National Focal Point and published by Management ...

Date: 05/06/2025

**Title:** [MHRA outlines intent to speed up patient access to innovative medical devices](https://www.gov.uk/government/news/mhra-outlines-intent-to-speed-up-patient-access-to-innovative-medical-devices)

Summary: Statement of Policy Intent sets out initial thinking on a new Early Access service to help patients benefit sooner from innovative medical devices that address unmet clinical needs.

Date: 31/07/2025

**Title:** [MHRA CEO Lawrence Tallon welcomes Life Sciences Sector Plan](https://www.gov.uk/government/news/mhra-ceo-lawrence-tallon-welcomes-life-sciences-sector-plan)

Summary: The Life Sciences Sector plan was released today (16 July 2025)

Date: 16/07/2025

**Title:** [Five non-executive directors reappointed to the Medicines and Healthcare products Regulatory Agency Board](https://www.gov.uk/government/news/five-non-executive-directors-reappointed-to-the-medicines-and-healthcare-products-regulatory-agency-board)

Summary: Two board members have been reappointed for two years, while three others have had their term extended by a year.

Date: 17/07/2025

**Title:** [MHRA approves adrenaline nasal spray - the first needle-free emergency treatment for anaphylaxis in the UK](https://www.gov.uk/government/news/mhra-approves-adrenaline-nasal-spray-the-first-needle-free-emergency-treatment-for-anaphylaxis-in-the-uk)

Summary: The Medicines and Healthcare products Regulatory Agency (MHRA) has today, 18 July 2025, approved adrenaline (epinephrine) nasal spray (EURneffy) to be used for the emergency treatment of serious allergic reactions, known as …

Date: 18/07/2025

**Title:** [MHRA’s 2024–25 Annual Report and Accounts and Impact Report show progress on safety, innovation, and regulatory excellence](https://www.gov.uk/government/news/mhras-2024-25-annual-report-and-accounts-and-impact-report-show-progress-on-safety-innovation-and-regulatory-excellence)

Summary: The Medicines and Healthcare products Regulatory Agency (MHRA) has published its 2024–25 Annual Report and Accounts, and accompanying Impact Report.

Date: 21/07/2025

**Title:** [The MHRA and the global flu vaccine: How the UK is helping shape the world’s flu vaccine](https://www.gov.uk/government/news/the-mhra-and-the-global-flu-vaccine-how-the-uk-is-helping-shape-the-worlds-flu-vaccine)

Summary: Ensuring the seasonal flu vaccine is ready, safe and effective involves months of international planning, testing and collaboration

Date: 22/07/2025

**Title:** [MHRA announces proposals to improve access to world’s best medical devices for patients and to boost economic growth in Britain’s med tech sector](https://www.gov.uk/government/news/mhra-announces-proposals-to-improve-access-to-worlds-best-medical-devices-for-patients-and-to-boost-economic-growth-in-britains-med-tech-sector)

Summary: The MHRA has now published the government’s response to its public consultation on future routes to market for medical devices - designed to modernise regulation

Date: 22/07/2025

**Title:** [Cutting-edge personalised treatments, made while you wait, will deliver specialised care to patients more quickly](https://www.gov.uk/government/news/cutting-edge-personalised-treatments-made-while-you-wait-will-deliver-specialised-care-to-patients-more-quickly)

Summary: New regulations effective today will make it faster and easier for cutting-edge cancer treatments and personalised gene therapies to be made right where patients are treated.

Date: 23/07/2025

**Title:** [Summer ready: MHRA issues updated guidance on medicines and medical devices during holiday season](https://www.gov.uk/government/news/summer-ready-mhra-issues-updated-guidance-on-medicines-and-medical-devices-during-holiday-season)

Summary: As the UK enters the heart of summer – with temperatures rising and families holidaying – the Medicines and Healthcare products Regulatory Agency (MHRA) is reinforcing essential safety advice for anyone using medicines or me…

Date: 23/07/2025

**Title:** [Yellow Card centre launched in Northern Ireland to strengthen patient safety](https://www.gov.uk/government/news/yellow-card-centre-launched-in-northern-ireland-to-strengthen-patient-safety)

Summary: A new regional centre to promote Yellow Card reporting has been launched in Belfast today.

Date: 24/07/2025

**Title:** [Tofersen approved by the MHRA to treat rare inherited form of motor neurone disease](https://www.gov.uk/government/news/tofersen-approved-by-the-mhra-to-treat-rare-inherited-form-of-motor-neurone-disease)

Summary: New genetic therapy approved for SOD1-ALS brings targeted treatment option to patients in the UK

Date: 28/07/2025

**Title:** [Mirvetuximab soravtansine approved to treat adult patients who have ovarian, fallopian tube or primary peritoneal cancer](https://www.gov.uk/government/news/mirvetuximab-soravtansine-approved-to-treat-adult-patients-who-have-ovarian-fallopian-tube-or-primary-peritoneal-cancer)

Summary: The approval is supported by a study involving 453 adults with advanced platinum-resistant cancers of the ovary, fallopian tubes and the peritoneum that were FRα positive

Date: 28/07/2025

**Title:** [MHRA seizes 7.7 million doses of illegal medicines and removes hundreds of illegal online listings as part of Operation Pangea](https://www.gov.uk/government/news/mhra-seizes-77-million-doses-of-illegal-medicines-and-removes-hundreds-of-illegal-online-listings-as-part-of-operation-pangea)

Summary: Operation Pangea brings together health regulators, customs authorities, law enforcement agencies, and private sector partners to tackle the threat posed by global criminal networks

Date: 25/06/2025

**Title:** [If you take a GLP-1 medicine and have been hospitalised by acute pancreatitis, the Yellow Card Biobank wants to hear from you](https://www.gov.uk/government/news/if-you-take-a-glp-1-medicine-and-have-been-hospitalised-by-acute-pancreatitis-the-yellow-card-biobank-wants-to-hear-from-you)

Summary: GLP-1 medicines are licensed for Type 2 diabetes and weight management, and include the branded products Ozempic, Mounjaro and Wegovy

Date: 26/06/2025

**Title:** [AI Airlock, CERSIs and a new global AI network for health regulators](https://www.gov.uk/government/news/ai-airlock-cersis-and-a-new-global-ai-network-for-health-regulators)

Summary: Med Tech Regs blog, June 2025: A focus on Software and AI.

Date: 27/06/2025

**Title:** [MHRA approves aumolertinib to treat non-small cell lung cancer](https://www.gov.uk/government/news/mhra-approves-aumolertinib-to-treat-non-small-cell-lung-cancer)

Summary: As with all products, we will keep its safety under close review

Date: 03/06/2025

**Title:** [Women on “skinny jabs” must use effective contraception, MHRA urges in latest guidance](https://www.gov.uk/government/news/women-on-skinny-jabs-must-use-effective-contraception-mhra-urges-in-latest-guidance)

Summary: Anyone who suspects that they’ve had an adverse reaction to their weight loss or diabetes medicine or suspects it is not a genuine product, should report it to the MHRA.

Date: 05/06/2025

**Title:** [Helping bring phage medicines to UK patients – guidance for industry](https://www.gov.uk/government/news/helping-bring-phage-medicines-to-uk-patients-guidance-for-industry)

Summary: Bacteriophages – viruses that selectively fight bacteria – may offer new hope in fighting infections and tackling antimicrobial resistance.

Date: 05/06/2025

**Title:** [MHRA launches new digital hub in Leeds to drive innovation and regional growth](https://www.gov.uk/government/news/mhra-launches-new-digital-hub-in-leeds-to-drive-innovation-and-regional-growth)

Summary: The new hub will strengthen the MHRA’s work with regional partners and boost the UK’s digital health and life sciences sector.

Date: 06/06/2025

**Title:** [Chikungunya vaccine (IXCHIQ) temporarily paused in people aged 65 and over as precautionary measure](https://www.gov.uk/government/news/chikungunya-vaccine-ixchiq-temporarily-paused-in-people-aged-65-and-over-as-precautionary-measure)

Summary: This is a precautionary measure while the MHRA conducts the safety review.

Date: 09/06/2025

**Title:** [NHS red tape blitz delivers game-changing new cancer treatment](https://www.gov.uk/government/news/nhs-red-tape-blitz-delivers-game-changing-new-cancer-treatment)

Summary: Patients to benefit from new era in cancer treatment, as the government slashes red tape to unleash life-saving innovation.

Date: 10/06/2025

**Title:** [First major overhaul of medical device regulation comes into force across Great Britain](https://www.gov.uk/government/news/first-major-overhaul-of-medical-device-regulation-comes-into-force-across-great-britain)

Summary: New Post-Market Surveillance (PMS) regulations have taken effect across Great Britain, requiring medical device manufacturers to proactively monitor the safety and performance of their products once on the market.

Date: 16/06/2025

**Title:** [Fast, Expert and Open – how the MHRA is poised to become a global leader in risk-proportionate regulation](https://www.gov.uk/government/news/fast-expert-and-open-how-the-mhra-is-poised-to-become-a-global-leader-in-risk-proportionate-regulation)

Summary: New MHRA CEO puts safety, accelerated access and innovation at the centre of agency’s refreshed strategic direction.

Date: 18/06/2025

**Title:** [MHRA approves UK’s first anti-PD-1 monoclonal antibody for treatment of aggressive form of lung cancer](https://www.gov.uk/government/news/mhra-approves-uks-first-anti-pd-1-monoclonal-antibody-for-treatment-of-aggressive-form-of-lung-cancer)

Summary: As with all products, we will keep its safety under close review

Date: 20/06/2025

**Title:** [AI breakthroughs drive expansion of ‘Airlock’ testing programme to support AI-powered healthcare innovation](https://www.gov.uk/government/news/ai-breakthroughs-drive-expansion-of-airlock-testing-programme-to-support-ai-powered-healthcare-innovation)

Summary: MHRA opens second round of applications to test cutting-edge AI medical technologies following successful pilot phase.

Date: 23/06/2025

**Title:** [UK MHRA leads safe use of AI in healthcare as first country in new global network](https://www.gov.uk/government/news/uk-mhra-leads-safe-use-of-ai-in-healthcare-as-first-country-in-new-global-network)

Summary: The MHRA will help shape international rules for AI in healthcare – speeding up access to safe, effective technologies into the NHS and worldwide.

Date: 24/06/2025

**Title:** [MHRA publishes final Business Plan for 2023-2026 Corporate Plan](https://www.gov.uk/government/news/mhra-publishes-final-business-plan-for-2023-2026-corporate-plan)

Summary: The new Business Plan sets out priorities for 2025–26: Protecting public safety and maintaining public trust; delivering efficient, predictable services through regulatory excellence; being an agile organisation that drives …

Date: 25/06/2025

**Title:** [MHRA approves nogapendekin alfa inbakicept to treat adult patients with non-muscle invasive bladder cancer](https://www.gov.uk/government/news/mhra-approves-nogapendekin-alfa-inbakicept-to-treat-adult-patients-with-non-muscle-invasive-bladder-cancer)

Summary: The Medicines and Healthcare products Regulatory Agency (MHRA) has today, 4 July 2025, approved nogapendekin alfa inbakicept (Anktiva) for adults with BCG-unresponsive non-muscle invasive bladder cancer, where the disease re…

Date: 04/07/2025

**Title:** [MHRA approves elinzanetant to treat moderate to severe vasomotor symptoms (hot flushes) caused by menopause](https://www.gov.uk/government/news/mhra-approves-elinzanetant-to-treat-moderate-to-severe-vasomotor-symptoms-hot-flushes-caused-by-menopause)

Summary: The Medicines and Healthcare products Regulatory Agency (MHRA) has today, 8 July, become the first regulator in the world to approve elinzanetant (Lynkuet) for the treatment of moderate to severe vasomotor symptoms (hot flus…

Date: 08/07/2025

**Title:** [Don’t let the heatwave affect your medicines: Three important tips from the MHRA](https://www.gov.uk/government/news/dont-let-the-heatwave-affect-your-medicines-three-important-tips-from-the-mhra)

Summary: Essential advice on protecting your medicines during extreme heat and staying safe this summer.

Date: 10/07/2025

**Title:** [Government to align with European specifications on high risk in vitro diagnostic devices to reduce regulatory burden](https://www.gov.uk/government/news/government-to-align-with-european-specifications-on-high-risk-in-vitro-diagnostic-devices-to-reduce-regulatory-burden)

Summary: The specifications will establish standards for high-risk diagnostic tests while creating consistency with European regulations

Date: 10/07/2025

**Title:** [MHRA approves sebetralstat (Ekterly) to treat hereditary angioedema (HAE) attacks in patients aged 12 and over](https://www.gov.uk/government/news/mhra-approves-sebetralstat-ekterly-to-treat-hereditary-angioedema-hae-attacks-in-patients-aged-12-and-over)

Summary: The Medicines and Healthcare products Regulatory Agency (MHRA) has today, 15 July 2025, approved sebetralstat (Ekterly) for the treatment of hereditary angioedema (HAE) attacks in adults and adolescents aged 12 years and old…

Date: 15/07/2025

**Title:** [Consultation on the International Council for Harmonisation Guideline E20 for adaptive clinical trial design](nan)

Summary: The MHRA is consulting with UK stakeholders to gather feedback and comments on ICH E20, a new international guideline.

Date: 24/07/2025

**Title:** [MHRA Strategy for Improving Safety Communications](nan)

Summary: The MHRA’s strategy for Improving Safety Communications for 2024 to 2027.

Date: 17/09/2024

**Title:** [Consultation on the International Council for Harmonisation ICH M15 Guideline for Model Informed Drug Development (MIDD)](nan)

Summary: The ICH Expert Working Group for ICH M15 (EWG) has been drafting the ICH M15 MIDD guideline. The MHRA attended the EWG meetings and participated in the drafting group.

Date: 10/01/2025

**Title:** [Draft guidance on individualised mRNA cancer immunotherapies](nan)

Summary: We are seeking feedback on our new draft guideline on individualised mRNA cancer immunotherapies, a new type of cancer treatment being tested in clinical trials. This will help us to clarify and streamline pathways for bring…

Date: 03/02/2025

**Title:** [MHRA consultation on statutory fees - proposals on ongoing cost recovery](nan)

Summary: Consultation on proposals to update the MHRA's statutory fees to ensure they continue to recover their costs.

Date: 06/03/2025

**Title:** [Consultation on the International Council for Harmonisation (ICH) M13B Guideline on Bioequivalence for Immediate-Release Solid Oral Dosage Forms](nan)

Summary: The ICH Expert Working Group (EWG) for ICH M13B has been drafting the second guideline in the series which describes the scientific and technical aspects of study design and data analysis to support bioequivalence (BE) asses…

Date: 09/05/2025

**Title:** [Consultation on the International Council for Harmonisation ICH E6 (R3) Guideline for Good Clinical Practice Annex-2](nan)

Summary: The ICH Expert Working Group for ICH E6(R3) (EWG) has been updating the ICH E6(R2) GCP guideline. The MHRA represents the Pharmaceutical Inspection Co-operation Scheme (PIC/s) in the EWG.

Date: 12/05/2025

**Title:** [MHRA draft guideline on the use of external control arms based on real-world data to support regulatory decisions](nan)

Summary: We invite feedback on the clarity and wording of our new draft guideline on the use of external control arms based on real-world data to support regulatory decisions.

Date: 20/05/2025

**Title:** [Consultation on the International Council for Harmonisation (ICH) E21 Guideline on the Inclusion of Pregnant and Breast-feeding Individuals in Clinical Trials](nan)

Summary: The MHRA is consulting with UK stakeholders to gather feedback and comments on a new international guideline for the appropriate inclusion and/or retention of pregnant and/or breast-feeding individuals in clinical trials of …

Date: 03/07/2025

**Title:** [Common specification requirements for in vitro diagnostic devices](nan)

Summary: MHRA seeks views on possible amendments to the Medical Devices Regulations 2002 to include common specification requirements for manufacturers of IVD devices.

Date: 10/07/2025

**Title:** [Medicines and Medical Devices Act 2021 – Stakeholder survey](nan)

Summary: We invite feedback on the operation and impact of the human medicines and medical devices legislation as part of a statutory review required under the Medicines and Medical Devices Act 2021.

Date: 21/07/2025

**Title:** [Consultation on Medical Devices Regulations: Routes to market and in vitro diagnostic devices](nan)

Summary: The MHRA is inviting members of the public to provide their views on proposed changes to the regulatory framework for medical devices.

Date: 22/07/2025

**Title:** [Consultation on the International Council for Harmonisation (ICH) E6 (R3) Good Clinical Practice (GCP) Guidelines](nan)

Summary: The Medicines and Healthcare products Regulatory Agency (MHRA) became a full member of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in May 2022 and is consulting w…

Date: 26/05/2023

**Title:** [Consultation on proposal to make Aquiette 2.5mg Tablets (oxybutynin hydrochloride) available from pharmacies](nan)

Summary: Public consultation on a set of proposals to make Aquiette 2.5mg Tablets (oxybutynin hydrochloride) available from pharmacies

Date: 03/07/2023

**Title:** [Consultation on how MHRA communicate with healthcare professionals to improve medicines and medical devices’ safety](nan)

Summary: The MHRA is reviewing its approach to engagement with healthcare professionals to improve the safety of medicines and medical devices.

Date: 11/12/2023

**Title:** [How should we engage and involve patients and the public in our work](nan)

Summary: Work is ongoing to address the comments and feedback from respondents to the consultation. Publication of our report on the consultation has been delayed in light of the Agency’s response during the ongoing coronavirus situa…

Date: 15/06/2020

**Title:** [British Pharmacopoeia Commission: triennial review](nan)

Summary: Seeks views on the role and performance of the British Pharmacopoeia Commission (BPC)

Date: 26/03/2015

**Title:** [Proposal to allow wider access to naloxone for use in emergencies](nan)

Summary: The MHRA is asking for feedback on a proposal to allow wider access to naloxone for the purpose of saving life in an emergency.

Date: 26/06/2015

**Title:** [Regulatory fees for medicines: 2016 to 2017 and fees for online sellers of medicines](nan)

Summary: This consultation seeks views on the reduction of some fees for the regulation of medicines and the introduction of fees for online sellers of medicines (MLX 389).

Date: 22/10/2015

**Title:** [Classification of Ibuprofen Seven Plus 200mg/5ml Oral Suspension](nan)

Summary: MHRA is asking for feedback on proposals to change the legal classification of Ibuprofen Seven Plus 200mg/5ml Oral Suspension

Date: 15/03/2016

**Title:** [Regulatory fees for e-cigarettes](nan)

Summary: MHRA is asking for feedback on proposals to introduce proportionate fees for getting a notification from MHRA to put an e-cigarette on the market in the UK.

Date: 25/04/2016

**Title:** [Proposal on increases and additions to current medical devices fees](nan)

Summary: We are seeking views on amending fees for the regulation of medical devices. Please tell us what you think.

Date: 06/02/2017

**Title:** [Proposal to make Maloff Protect 250mg/100mg film-coated tablets available from Pharmacies](nan)

Summary: We are considering making Maloff Protect anti-malaria tablets available to buy from pharmacies. We always want to involve the public and healthcare professionals in decision that affect them. We want to know what you think a…

Date: 03/07/2017

**Title:** [Reclassification of Otrivine extra dual relief nasal spray solution (ARM 90)](nan)

Summary: MHRA is asking for feedback on proposals to change the legal classification of Otrivine extra dual relief nasal spray solution from prescription only medicine (POM) to pharmacy only (P).

Date: 05/07/2017

**Title:** [Classification of Nasonex Allergy Control Nasal Spray](nan)

Summary: We want to know what you think about our proposal to Nasonex Allergy Control Nasal Spray available without prescription.

Date: 10/07/2017

**Title:** [Proposal to make Arthriex 750mg and 1500mg film-coated tablets available from Pharmacies](nan)

Summary: We are considering making Arthriex 750mg and 1500mg film-coated tablets available to buy from pharmacies. We always want to involve the public and healthcare professionals in decisions that affect them. We want to know what …

Date: 14/07/2017

**Title:** [Proposal to make Dovonex Psoriasis Ointment available from Pharmacies](nan)

Summary: We are considering making Dovonex Psoriasis 50 microgram/g Ointment available to buy from pharmacies. We always want to involve the public and healthcare professionals in decisions that affect them. We want to know what you …

Date: 17/08/2017

**Title:** [Proposal to make Sildenafil 50mg film-coated tablets available from Pharmacies](nan)

Summary: We are considering making Sildenafil 50mg film-coated tablets available to buy from pharmacies. We always want to involve the public and healthcare professionals in decisions that affect them. We want to know what you think …

Date: 28/11/2017

**Title:** [Post-implementation Review of the Human Medicines Regulations 2012 (MLX 391)](nan)

Summary: We are reviewing the impact of the Human Medicines Regulations 2012 (‘the 2012 Regulations’). This is part of a wider exercise within government to test the impact of legislation five years after implementation.

Date: 05/12/2017

**Title:** [Government response to report on Brexit and medicines, medical devices and substances of human origin](nan)

Summary: Command paper responding to the Health and Social Care Committee's report 'Brexit: medicines, medical devices and substances of human origin'.

Date: 23/05/2018

**Title:** [Implementing ‘safety features’ under the Falsified Medicines Directive](nan)

Summary: This consultation invites views on the proposed steps we intend to take to make sure the UK meets its obligations to transpose the 'safety features' provisions of the Falsified Medicines Directive (FMD).

Date: 24/12/2018

**Title:** [Proposal to make Colourstart Test 65mcg Cutaneous Patch available from general sales outlets without prescription](nan)

Summary: We are considering making Colourstart Test 65mcg Cutaneous Patch available to buy without prescription from retail outlets. We always want to involve the public and healthcare professionals in decisions that affect them. W…

Date: 01/08/2019

**Title:** [Consultation on guidance on the safe use of bed rails](nan)

Summary: We are asking for views on a new draft version on our guidance for users, carers and staff on the safe use of bed rails.

Date: 02/08/2019

**Title:** [Strategy for pharmacopoeial public quality standards for biological medicines](nan)

Summary: We are developing a strategy for the creation of pharmacopoeial public quality standards for biological medicines. We would like your input regarding how they are used & can be improved as well as feedback on our draft s…

Date: 16/09/2019

**Title:** [Consultation on Acnecide face gel and face wash](nan)

Summary: We are seeking views on a proposal to make Acnecide Face 5% w/w Gel and Acnecide Face Wash 5% w/w Gel available from general sales outlets.

Date: 23/09/2019

**Title:** [MHRA consultation on EU exit no-deal legislative proposals](nan)

Summary: This consultation seeks your views on how the Medicines and Healthcare products Regulatory Agency’s (MHRA) legislation and regulatory processes would have to be modified in the event of the UK not securing a deal with the EU…

Date: 09/10/2019

**Title:** [Consultation on the application of Analytical Quality by Design (AQbD) principles to pharmacopoeial standards for medicines](nan)

Summary: This consultation asks for views on the application of AQbD principles to pharmacopoeial standards for medicinal products.

Date: 12/08/2020

**Title:** [Access Consortium statement on COVID-19 vaccines evidence](nan)

Summary: The medicine regulators from Australia, Canada, Singapore, Switzerland and the United Kingdom (Access Consortium) have discussed the regulatory evidence requirements for COVID-19 vaccine approvals and considerations for post…

Date: 07/01/2021

**Title:** [MHRA draft guidance on the licensing of biosimilar products](nan)

Summary: We want your comments on the clarity and wording of our new guidance

Date: 10/05/2021

**Title:** [Nuromol Dual Action Pain Relief 200mg/500mg tablets (ibuprofen/paracetamol): public consultation](nan)

Summary: The MHRA is asking for views on a proposal to make Nuromol Dual Action Pain Relief 200mg/500mg tablets (ibuprofen/paracetamol) available without prescription in general sales outlets, such a supermarkets.

Date: 13/05/2021

**Title:** [MHRA Patient Involvement Strategy consultation](nan)

Summary: We’re looking for views from patients and the public on how we engage with them.

Date: 24/05/2021

**Title:** [Lovima 75 microgram film-coated tablets (Desogestrel): Public Consultation](nan)

Summary: A 3-week consultation on a proposal to make Lovima 75 microgram film-coated tablets (Desogestrel) available from pharmacies.

Date: 08/07/2021

**Title:** [Hana 75 microgram film-coated tablets (Desogestrel): Public Consultation](nan)

Summary: A 3-week public consultation on a proposal to make Hana 75 microgram film-coated tablets (Desogestrel) available from pharmacies.

Date: 08/07/2021

**Title:** [Pharmacy dispensing models and displaying prices on medicines](nan)

Summary: Seeks views on proposed changes to the Human Medicines Regulations and the Medicines Act.

Date: 11/11/2021

**Title:** [Access Consortium statement on COVID-19 medicines](nan)

Summary: The medicines regulators from Australia, Canada, Singapore, Switzerland and the United Kingdom (Access Consortium) have discussed the continued need for COVID-19 medicines that are safe, effective and of high quality

Date: 14/12/2021

**Title:** [MHRA draft guidance on randomised controlled trials generating real-world evidence to support regulatory decisions](nan)

Summary: We want your comments on the clarity and wording of our new guidance

Date: 16/12/2021

**Title:** [Early Access to Medicines Scheme (EAMS) Consultation](nan)

Summary: We're looking for your views and comments on our proposed legislative changes to clarify the legal basis for EAMS.

Date: 02/02/2022

**Title:** [Consultation on the future regulation of medical devices in the United Kingdom](nan)

Summary: We're looking for your views on how medical devices will be regulated across the United Kingdom (UK) in the future.

Date: 26/06/2022

**Title:** [Consultation on proposal to make Gina 10 microgram vaginal tablets (Estradiol) available from pharmacies](nan)

Summary: Public consultation on a set of proposals to make Gina 10 microgram vaginal tablets (Estradiol) available from pharmacies.

Date: 20/07/2022

**Title:** [Consultation on a new Code of Practice for the Expert Advisory Committees](nan)

Summary: We are consulting on a set of proposals to improve and strengthen the Code of Practice for experts who provide advice on which decisions about the regulation of medicines and medical devices are based, to ensure that experts…

Date: 08/09/2022

**Title:** [Point of Care Consultation](nan)

Summary: We’d value your views to help shape the introduction of a new regulatory framework for products supplied at the point of care.

Date: 25/01/2023

**Title:** [Consultation on proposals for changes to the Medicines and Healthcare products Regulatory Agency’s statutory fees](nan)

Summary: The aim of this consultation is to seek the views of stakeholders on proposals for changes to the Medicines and Healthcare products Regulatory Agency’s statutory fees.

Date: 31/01/2023

**Title:** [Original pack dispensing and supply of medicines containing sodium valproate](nan)

Summary: Public consultation on proposals to allow pharmacists to dispense prescription medicines in original packaging, in particular those containing sodium valproate.

Date: 19/03/2023

**Title:** [Consultation on proposals for legislative changes for clinical trials](nan)

Summary: We are consulting on a set of proposals to improve and strengthen the UK clinical trials legislation to help us make the UK the best place to research and develop safe and innovative medicines

Date: 21/03/2023

**Title:** [Isotretinoin: call for information to be considered as part of an expert review](nan)

Summary: Call for information to support a review of isotretinoin, a treatment for severe acne. This review is being undertaken by the Medicines and Healthcare products Regulatory Agency with advice from the Commission on Human Medic…

Date: 28/04/2023

**Title:** [Consultation on end to the European Commission Decision Reliance Procedure](nan)

Summary: This is a consultation on a statutory instrument to amend the Human Medicines Regulations 2012 to remove the provision which provides the legal basis to the European Commission Decision Reliance Procedure (ECDRP).

Date: 21/12/2023

**Title:** [MHRA Public consultation on the proposal to make Codeine Linctus available as a prescription-only medicine (POM)](nan)

Summary: The Medicines and Healthcare Products Regulatory Agency (MHRA) have launched a public consultation to propose reclassification of Codeine Linctus to prescription-only medicine.

Date: 20/02/2024

**Title:** [Framework agreement between DHSC and the Medicines and Healthcare products Regulatory Agency](nan)

Summary: Describes the working relationship between the Department of Health and Social Care and the Medicines and Healthcare products Regulatory Agency.

Date: 21/03/2024

**Title:** [Impact of AI on the regulation of medical products](nan)

Summary: Implementing the Artificial Intelligence (AI) White Paper principles.

Date: 30/04/2024

**Title:** [Consultation on the International Council for Harmonisation (ICH) M14](nan)

Summary: Consultation on the ICH E2D(R1) guidelines on General principles on plan, design, and analysis of pharmacoepidemiological studies that utilise real-world data for safety assessment of medicines.

Date: 29/08/2024

**Title:** [Drug search on dmp.no is upgraded](https://www.dmp.no/nyheter/legemiddelsok.no-er-utilgjengelig-ny-side)

Summary: Drug search is currently inaccessible due to upgrading. In the meantime, you still have access to our drug data, for example via the Common Catalog.

Date: 21/07/2025

**Title:** [New strength on rybelsus tablets](https://www.dmp.no/nyheter/rybelsus-ny-styrke)

Summary: The new tablets have changed so that the active substance is better absorbed in the body. New and lower forces therefore produce the same effect as the original higher forces. In a transitional period, both old and new tablets will be available.

Date: 24/07/2025

**Title:** [EU hearing on updating GMP rules for documentation, computer systems and artificial intelligence](https://www.dmp.no/nyheter/eu-horing-om-oppdatering-av-gmp-regler-for-dokumentasjon-datasystemer-og-kunstig-intelligens)

Summary: The European Commission's revision of the GMP guidelines respond to a long-reported need from both the pharmaceutical industry and the authorities. The consultation is particularly relevant to interest organizations representing drug involvement.

Date: 09/07/2025

**Title:** [Important information to anyone preparing documentation packages for method assessment](https://www.dmp.no/nyheter/viktig-informasjon-til-alle-som-utarbeider-dokumentasjonspakker-til-metodevurdering)

Summary: From September 1, 2025, DMP takes a major step towards more accurate and relevant assessment of new drugs and medical equipment. Then it will be mandatory to use the new Norwegian EQ-5D-5L tariff when documenting health-related quality of life for adults.

Date: 09/07/2025

**Title:** [Resolution provision for ipidacrin](https://www.dmp.no/nyheter/vedtak-om-utleveringsbestemmelse-for-ipidakrin)

Summary: DMP makes a decision on extradition provision for the active ingredient ipidacrin.

Date: 08/07/2025

**Title:** [Error in medical systems when requesting ADHD medication](https://www.dmp.no/nyheter/feil-i-journalsystemer-ved-rekvirering-av-adhd-medisiner)

Summary: An error has occurred in the prescribing module affecting the requisition of certain drugs with the active substance methylphenidathicrochloride in certain forces. Automatic dosage suggestions (short dose) are missing, but dosage can be specified in free text.

Date: 03/07/2025

**Title:** [Norwegian drug standards 2025.2 are published](https://www.dmp.no/nyheter/norske-legemiddelstandarder-2025.2-er-publisert)

Summary: Norwegian drug standards (NLS) contain an overview of all standards, pharmacopé monographs, for raw materials, drug forms and pharmaceutical preparations that apply to Norway.

Date: 01/07/2025

**Title:** [Hearing - Proposal for the introduction of delivery provision for IPTAKOPAN](https://www.dmp.no/nyheter/horing--forslag-om-innforing-av-utleveringsbestemmelse-for-iptakopan)

Summary: DMP, on consultation, submits a proposal for the introduction of a delivery provision for the active substance IPTAKOPAN.

Date: 30/06/2025

**Title:** [Extraordinary publication of party until 01.07.2025](https://www.dmp.no/nyheter/ekstraordinar-publisering-av-fest-til-01.07.2025)

Summary: Errors have been detected in the Fest file for July 1, which was published June 27. DMP has now corrected the error, and asks all users to download complete extraction to ensure updated and correct information.

Date: 30/06/2025

**Title:** [Changing the process of submitting documentation to method assessment from September 1](https://www.dmp.no/nyheter/endrer-prosessen-for-innsending-av-dokumentasjon-til-metodevurdering--fra-1.-september)

Summary: From September 1, 2025, the company must notify DMP no later than three months before submission of documentation. August 22, we hold an information meeting on the changes.

Date: 27/06/2025

**Title:** [Ventizolve nasal spray is approved as a non -prescription drug with compulsory guidance in pharmacies](https://www.dmp.no/nyheter/ventizolve-nesespray-er-godkjent-som-reseptfritt-legemiddel-med-obligatorisk-veiledning-i-apotek)

Summary: From July 1, 2025, Ventizolve nasal spray is approved as a non -prescription drug with compulsory guidance in pharmacies. Ventizolve nasal spray is a life -saving drug for emergency treatment of opioids overdoses.

Date: 27/06/2025

**Title:** [Greater action revealed smuggling of illegal and false drugs](https://www.dmp.no/nyheter/storaksjon-avdekket-smugling-av-ulovlige-og-falske-legemidler)

Summary: In an international action, the Customs Administration, in collaboration with the Directorate for Medical Products, has revealed larger amounts of drugs tried to be imported by private individuals who are suspected of conducting business activities, as well as websites offering illegal drugs.

Date: 27/06/2025

**Title:** [New supervisors for the treatment of scabies](https://www.dmp.no/nyheter/nye-veiledere-for-behandling-av-skabb)

Summary: Together with the Institute of Public Health, the Swedish Medicines Agency has prepared new supervisors for health professionals and patients for the treatment of scabies.

Date: 16/09/2021

**Title:** [Hemovigilance seminar November 13 - Keep the date!](https://www.dmp.no/nyheter/hemovigilansseminaret-2025)

Summary: This year's hemovigilance seminar will be held on November 13 at 09.00-16.00. The meeting is physically conducted in DMP's premises at Helsfyr, but it will also be possible to participate digitally. Program and information about registration is coming.

Date: 26/06/2025

**Title:** [Regulatory Information Meeting May 8](https://www.dmp.no/nyheter/regulatorisk-informasjonsmote-8.-mai-2025)

Summary: DMP organized an information meeting on May 8. Here you will find the program and presentations that were held at the meeting.

Date: 17/03/2025

**Title:** [Control revealed illegal advertising in online pharmacy](https://www.dmp.no/nyheter/dmp-advarer-mot-intravenos-behandling-med-nad2)

Summary: In April, the Directorate for Medical Products conducted a check on the information available about 4 various non -prescription drugs, and illegal advertising was found at 15 online pharmacies.

Date: 24/06/2025

**Title:** [New about medicines No. 8 2025](https://www.dmp.no/nyheter/nytt-om-legemidler-nr.-8-2025)

Summary: Themes in this edition: Risk of suicidal thoughts when using finasteride against hair loss and enlarged prostate. Rosuvastatin - Multiple indications granted  
pre -approved refund

Date: 24/06/2025

**Title:** [Hearing - Suggestions for changes to the drug regulations](https://www.dmp.no/nyheter/horing--forslag-om-endringer-i-narkotikaforskriften)

Summary: On behalf of the Ministry of Health and Care Services, the Directorate for Medical Products (DMP) sends on Friday, June 20, on consultation proposals for amendments to the drug regulations.

Date: 20/06/2025

**Title:** [Seminar on uncertainty in method assessment and price agreements](https://www.dmp.no/nyheter/seminar-om-usikkerhet-i-metodevurdering-og-prisavtaler)

Summary: Area Director Einar Andreassen made a speech at the seminar and explained that the assessments DMP makes will be challenging when there is uncertainty related to documentation of the effect of the methods.

Date: 20/06/2025

**Title:** [DMP warns MOT intravenous treatment with NAD](https://www.dmp.no/nyheter/dmp-advarer-mot-intravenos-behandling-med-nad)

Summary: There are no approved drugs for intravenous treatment with NAD, and no documentation showing that this treatment is safe. Such treatment can therefore lead to health hazards.

Date: 18/06/2025

**Title:** [Consultation-Clinical testing of GMO drug TCR T-cell therapy aimed at TDT for therapy resistant leukemia or lymphoma](https://www.dmp.no/nyheter/horing--klinisk-utproving-av-gmo-legemidlet-tcr-t-celle-terapi-rettet-mot-tdt-for-terapiresistent-leukemi-eller-lymfom)

Summary: Application for release for research purposes of drug TDT-3 consisting of genetically modified organisms (GMO) for clinical testing on patients, has been sent for consultation. Consultation deadline: 24.06.2025.

Date: 17/06/2025

**Title:** [Change of criteria for blood donation](https://www.dmp.no/nyheter/endring-i-kriterier-for-blodgivning)

Summary: Persons who have previously been excluded from blood donation due to long -term stays in the UK may now be blood donors, provided that other criteria are met.

Date: 13/06/2025

**Title:** [New online solution for pH. Eur. from 12th edition July 2025](https://www.dmp.no/nyheter/ny-online-losning-for-ph.-eur.-fra-12.-utgave-juli-2025)

Summary: The European pharmacopeen comes in a new online solution from July 1. This means new access method and that everyone must have new users. You can participate in webinars for more information on July 1 or July 3.

Date: 12/06/2025

**Title:** [Information meeting on HTA Regulation June 18](https://www.dmp.no/nyheter/informasjonsmote-om-hta-forordning-18.-juni)

Summary: DMP, the secretariat for new methods and the pharmaceutical industry (LMI) organizes an information meeting on HTAR - the EU Regulation for European Cooperation on Method Assessments. The meeting is intended for the pharmaceutical industry.

Date: 12/06/2025

**Title:** [Eye disease is considered very rare side effect when using semaglutid](https://www.dmp.no/nyheter/mistanke-om-sjelden-bivirkning-ved-bruk-av-semaglutid)

Summary: European drug authorities (EMA) recommends that the eye disease NAION be listed as a very rare side effect of semaglutide.

Date: 16/12/2024

**Title:** [Risk of cardiovascular disease by long-term use of ▼ mysimba](https://www.dmp.no/nyheter/Risiko-for-hjerte-og-karsykdommer-ved-langtidsbruk-av-Mysimba)

Summary: The risk of cardiovascular disease using ▼ Mysimba (naltrexone/bupropion) is not fully clarified in patients treated for more than one year.

Date: 03/06/2025

**Title:** [New about drugs no. 7 2025](https://www.dmp.no/nyheter/nytt-om-legemidler-nr.-7-2025)

Summary: The pandemic increased awareness of how vulnerable global supply chains of drugs can be. National emergency stocks increase security of supply for important drugs.

Date: 03/06/2025

**Title:** [FDA warns firms for CGMP, QSR violations; online retailers cited for selling unapproved drugs](https://www.raps.org/news-and-articles/news-articles/2025/7/fda-warns-firms-for-cgmp,-qsr-violations;-online-r)

Summary: The US Food and Drug Administration (FDA) has cited several manufacturers for failing to conform to current good manufacturing practices (CGMP) and quality system regulation (QSR) requirements. The agency also warned several online retailers for illegally marketing Schedule II stimulants, opioids, and benzodiazepines. Macsen Drugs The agency sent a warning letter to Indian drug maker Macsen Drugs last March, stating that it failed to ensure the manufacture of i...

Date: 31/07/2025

**Title:** [Recon: Moderna to layoff 10% of staff; Trump pressures drugmakers to cut US prices](https://www.raps.org/news-and-articles/news-articles/2025/7/recon-moderna-to-layoff-10-of-staff-trump-pressur)

Summary: Welcome to Regulatory Reconnaissance, your regulatory news and intelligence briefing. In Focus: US NIH is shrinking the number of research projects it funds due to a new Trump policy ( STAT ) FDA chief says NIH ‘brewed up a virus that killed 20 million people’ ( The Hill ) Senate confirms Trump nominee to lead CDC ( The Hill ) Trump drove firing of FDA official ( Politico ) Inside the fall of Vinay Prasad at the FDA ( STAT ) US vaccination rates for measles, other...

Date: 31/07/2025

**Title:** [Euro Roundup: Notified bodies propose EU-level medtech coordination and support structure](https://www.raps.org/news-and-articles/news-articles/2025/7/euro-roundup-notified-bodies-propose-eu-level-medt)

Summary: Notified bodies have shared their vision for the future governance of the medical device sector in the European Union, making the case for a central structure that reduces duplication, streamlines decision-making and provides a single interface for stakeholders. Team-NB, the European association of medtech notified bodies, published the paper with NBCG-Med, a notified body coordination group established as part of the medtech regulations. The groups framed their prop...

Date: 31/07/2025

**Title:** [Connected OBDS and regulatory implications in the US](https://www.raps.org/news-and-articles/news-articles/2025/7/connected-obds-and-regulatory-implications-in-the)

Summary: This article discusses the current and future market for on-body delivery systems (OBDS), the current regulatory pathways for drug delivery systems, future connectivity trends, and the regulatory implications of “connected OBDS” in the US. Keywords – artificial intelligence, combination products, drug delivery systems, machine learning Introduction On-body delivery systems are the future of drug delivery systems, improving patient care while mitigating ...

Date: 31/07/2025

**Title:** [Investment in quality management can reduce defects and recalls, FDA says](https://www.raps.org/news-and-articles/news-articles/2025/7/investment-in-quality-management-can-reduce-defect)

Summary: Companies that invest in quality management initiatives can incur lower costs related to defects, waste, and recalls compared to those that do not make such investments, according to a white paper published by the US Food and Drug Administration’s (FDA) Office of Pharmaceutical Quality (OPQ) on Tuesday. Additionally, FDA stated that investing in quality management can lead to public health benefits, such as improved supply chain reliability and a reduction in drug sh...

Date: 30/07/2025

**Title:** [FDA unveils FY 2026 user fee rates](https://www.raps.org/news-and-articles/news-articles/2025/7/fda-unveils-fy-2026-user-fee-rates)

Summary: The US Food and Drug Administration (FDA) has published its user fee rates for fiscal year 2026 across its prescription drug, generic drug, biosimilar, and medical device programs. The rates are calculated by factoring in the agency’s resources against the number of applications it expects to receive over the next fiscal cycle based on historical trends. The FDA has yet to publish its rates for its over-the-counter monograph drug program, but this article will be upd...

Date: 30/07/2025

**Title:** [Navigating the transition: Implementing the new EU CTR in the pharmaceutical industry](https://www.raps.org/news-and-articles/news-articles/2025/7/navigating-the-transition-implementing-the-new-eu)

Summary: This article explores the transition to the EU Clinical Trials Regulation (EU CTR), focusing on the operational challenges sponsors and applicants faced. Key topics include harmonizing country-specific documents prior to transition submissions, operational and functionality issues within the Clinical Trials Information System (CTIS), transparency requirements, and the need for regular updates on guidance and Q&A documents during the transition period. The article highlight...

Date: 30/07/2025

**Title:** [Experts offer advice on avoiding common warning letter citations](https://www.raps.org/news-and-articles/news-articles/2025/7/experts-offer-advice-on-avoiding-common-warning-le)

Summary: Experts said that good manufacturing practice (GMP) violations, including inadequate procedures, insufficient training, and problems with data integrity, were commonly cited by US Food and Drug Administration investigators during drug and medical device facility inspections and offered advice on how to avoid enforcement actions related to these violations. The experts spoke at a webinar sponsored by ProPharma and Hyman Phelps and McNamara, which focused on inspection...

Date: 29/07/2025

**Title:** [Device makers seek flexibility, clarity in Q-sub electronic submission guidance](https://www.raps.org/news-and-articles/news-articles/2025/7/device-makers-seek-flexibility,-clarity-in-q-sub-e)

Summary: Medtech industry stakeholders said they want greater clarity and flexibility in the US Food and Drug Administration’s (FDA) recent draft guidance on submitting questions electronically to the agency under its Q-Submission program. In May, the Center for Devices and Radiological Health (CDRH) published a draft guidance on FDA's expectations for medtech sponsors who submit pre-submissions (pre-subs) electronically to regulators as part of the agency's Q-submission prog...

Date: 29/07/2025

**Title:** [Manufacturers largely met May DSCSA deadline without major issues, experts say](https://www.raps.org/news-and-articles/news-articles/2025/6/experts-manufacturers-largely-met-may-dscsa-deadli)

Summary: Supply chain experts said that most manufacturers successfully implemented the enhanced tracing requirements outlined in the Drug Supply Chain Security Act (DSCSA) by the 27 May deadline without significant issues. In addition, they said that wholesalers are optimistic about meeting the upcoming deadline of 27 August, which marks the end of the exemption period. Eric Marshall, executive director of the Partnership for DSCSA Governance (PDG), and Tish Pahl, an attorn...

Date: 29/07/2025

**Title:** [Recon: Sarepta resumes shipments of Elevidys for ambulatory patients; Merck to cut costs by $3B](https://www.raps.org/news-and-articles/news-articles/2025/7/recon-sarepta-resumes-shipments-of-elevidys-for-am)

Summary: Welcome to Regulatory Reconnaissance, your regulatory news and intelligence briefing. In Focus: US NIH is shrinking the number of research projects it funds due to a new Trump policy ( STAT ) FDA permits use of Sarepta Therapeutics’ Duchenne therapy in younger patients after short-lived halt ( STAT ) ( Reuters ) FDA approves PTC’s rare genetic disease drug ( Endpoints ) Post-Hoc: Is this what a political FDA looks like? ( Endpoints ) Medical group urges Kennedy not...

Date: 29/07/2025

**Title:** [FDA, ASCO propose principles for proper dosing in cancer drug development](https://www.raps.org/news-and-articles/news-articles/2025/7/fda,-asco-propose-principles-for-proper-dosing-in)

Summary: The US Food and Drug Administration (FDA) and the American Society of Clinical Oncology (ASCO) have laid out several principles for cancer drug developers to ensure more nuanced dosing. The principles are intended to help sponsors develop drugs that are better tolerated by patients who otherwise might suffer from long-term exposure and toxicity. Historically, cancer drugs have used the maximum tolerated dose (MTD) or the highest dosage administered in the dose-escala...

Date: 28/07/2025

**Title:** [7-year FDA review finds improved GCP compliance](https://www.raps.org/news-and-articles/news-articles/2025/7/7-year-fda-review-finds-improved-gcp-compliance)

Summary: A study of routine good clinical practice (GCP) inspections between 2017 and 2023 found a declining number of Form 483s flagging violations at clinical trial sites and a very low number requiring official action (0.3%), US Food and Drug Administration (FDA) officials report. During the seven-year period, there were 2,386 inspections of clinical trials requested as part of reviews of Center for Drug Evaluation and Research (CDER) marketing applications, according to t...

Date: 28/07/2025

**Title:** [Asia-Pacific Roundup: DRAP publishes guidance on trials, biosimilarity studies of drugs made in Pakistan](https://www.raps.org/news-and-articles/news-articles/2025/7/asia-pacific-roundup-drap-publishes-guidance-on-tr)

Summary: The Drug Regulatory Authority of Pakistan (DRAP) has published guidance on the requirement for clinical trials or biosimilarity studies to support the registration of locally manufactured biological medicines. DRAP said its staff created the document to provide a better illustration of data requirements for clinical trials of locally manufactured biological drugs. The guidance applies to companies that intend to seek marketing authorization of such products. DRAP sai...

Date: 28/07/2025

**Title:** [Recon: GSK pays $500M upfront to Hengrui for rights to several drugs; PE firms offer $3B to buy Bavarian Nordic](https://www.raps.org/news-and-articles/news-articles/2025/7/recon-gsk-pays-$500m-upfront-to-hengrui-for-rights)

Summary: Welcome to Regulatory Reconnaissance, your regulatory news and intelligence briefing. In Focus: US New analysis predicts sprawling effects of proposed NIH budget cuts ( STAT ) Trump targets supervised consumption of drugs and harm reduction in executive order ( STAT ) Did a drug prevent this man’s ALS? ( STAT ) FDA 'Expert Panels' Raise Concerns of Evading Regulations, Ethics ( MedPage Today ) US Health, Tech Officials to Launch Data-Sharing Plan ( Bloomberg ) FDA...

Date: 28/07/2025

**Title:** [This Week at FDA: Expert panels draw criticism, HHS seeks to define ultra-processed foods](https://www.raps.org/news-and-articles/news-articles/2025/7/this-week-at-fda-expert-panels-draw-criticism,-hhs)

Summary: Welcome to another installment of This Week at FDA, your weekly source for updates—big and small—on FDA, drug, and medical device regulation and what we’re reading from around the web. This week, FDA faced criticism over several recent expert panel meetings, top US health officials said they want to cooperate with industry rather than forcing it to change, and FDA and the Department of Agriculture (USDA) are looking for input on how to define ultra-processed foods. S...

Date: 25/07/2025

**Title:** [EMA proposes reflection paper on using external controls to generate evidence](https://www.raps.org/news-and-articles/news-articles/2025/7/ema-proposes-reflection-paper-on-using-external-co)

Summary: The European Medicines Agency (EMA) plans to release a reflection paper regarding when external controls can be used to generate evidence to support regulatory decisions on drug approvals. The agency noted that there is currently a lack of regulatory guidance in this area within Europe. The paper states that while randomized controlled trials are considered the "gold standard" for evaluating the benefits and risks of medicines in regulatory decision-making, there ar...

Date: 25/07/2025

**Title:** [FDA white paper encourages adoption of selective safety data collection](https://www.raps.org/news-and-articles/news-articles/2025/7/fda-white-paper-encourages-adoption-of-selective-s)

Summary: The US Food and Drug Administration’s (FDA) Center for Drug Evaluation and Research (CDER) this week released a white paper aimed at encouraging the use of selective safety data collection (SSDC). This approach is designed to simplify the data gathering process for drugs that have well-established safety profiles with the goal of reducing the collection of non-serious adverse events (AEs) that are unlikely to provide significant additional insights into drug safety. ...

Date: 25/07/2025

**Title:** [EMA: Drug repurposing efforts saw limited success during pilot](https://www.raps.org/news-and-articles/news-articles/2025/7/ema-drug-repurposing-efforts-saw-limited-success-d)

Summary: The European Medicines Agency (EMA) said researchers working to repurpose out-of-patent drugs face significant challenges, such as interpreting the available data to support a regulatory application for a new use. They also noted that during clinical trials, they faced challenges developing the right inclusion/ exclusion criteria, isolating the drug's effects in a trial that used combination therapy, and choosing the right primary endpoint. In a report on the agency’...

Date: 24/07/2025

**Title:** [Questions remain as FDA opens submissions for new priority voucher program](https://www.raps.org/news-and-articles/news-articles/2025/7/questions-remain-as-fda-opens-submissions-for-new)

Summary: The US Food and Drug Administration (FDA) on Tuesday said it will select up to five drugmakers to participate in the Commissioner’s National Priority Voucher (CNPV) pilot in the program’s first year and offered new details about the program’s terms. Legal experts who spoke to Focus said there could be legal challenges to the program or the selection of participants, especially given the limited number of vouchers available, and noted that there are still unanswered...

Date: 24/07/2025

**Title:** [Euro Roundup: EU committee calls for CMA to reflect burden of green legislation](https://www.raps.org/news-and-articles/news-articles/2025/7/euro-roundup-eu-committee-calls-for-cma-to-reflect)

Summary: A European Parliament committee has proposed changing the draft Critical Medicines Act (CMA) to reflect the impact environmental measures have on drug supply. The Committee on the Environment, Climate and Food Safety submitted the proposals in response to the European Commission’s proposed framework for strengthening the availability and security of supply of critical medicinal products. The proposals are intended to stop overlapping environmental and chemical legisl...

Date: 24/07/2025

**Title:** [Recon: Novartis, Matchpoint sign $1B deal to develop anti-inflammatory drugs; FDA reinstated a quarter of jobs cut by DOGE, Makary says](https://www.raps.org/news-and-articles/news-articles/2025/7/recon-novartis-matchpoint-sign-$1b-deal-to-develo)

Summary: Welcome to Regulatory Reconnaissance, your regulatory news and intelligence briefing. In Focus: US FDA reinstated roughly a quarter of initial DOGE job cuts ( Politico Pro ) HHS Secretary RFK Jr. accepts recommendations to drop thimerosal from U.S. flu vaccines ( STAT ) Alnylam CEO: Congress must pass the MINI Act to protect future biotech breakthroughs ( STAT ) Medical groups and US states work to circumvent Kennedy's vaccine decisions ( Reuters ) Exclusive: Sarep...

Date: 24/07/2025

**Title:** [RAPS honors 9 regulatory professionals and one organization with 2025 awards](https://www.raps.org/news-and-articles/news-articles/2025/7/raps-honors-9-regulatory-professionals-and-one-org)

Summary: RAPS has recognized nine distinguished professionals and one organization with awards for their work to support the regulatory profession and advance public health. Recipients will be honored at RAPS Convergence 2025 , which will take place on 7-9 October in Pittsburgh, PA. The 2025 RAPS Award winners are: The Founder's Award The Founder’s Award is the profession’s highest honor, recognizing exemplary regulatory professionals who have shaped regulatory policy an...

Date: 24/07/2025

**Title:** [MHRA’s framework point-of-care personalized medicine goes into effect](https://www.raps.org/news-and-articles/news-articles/2025/7/mhra-s-framework-point-of-care-personalized-medici)

Summary: The UK Medicines and Healthcare products Regulatory Agency's (MHRA) new framework, which allows certain personalized breakthrough medicines to be administered at the point of care to patients, went into effect on Wednesday. The agency said the regulation is the first of its kind and will significantly speed up the availability of treatments such as cell and gene therapy (CGT) products. "Patients will receive faster access to life-saving, personalized treatments made ...

Date: 23/07/2025

**Title:** [CBO: NIH budget cuts, slower FDA reviews would have significant impact on drug development](https://www.raps.org/news-and-articles/news-articles/2025/7/cbo-nih-budget-cuts,-slower-fda-reviews-would-have)

Summary: The US Congressional Budget Office (CBO) says a permanent cut to the National Institutes of Health (NIH) budget and extending drug review times at the Food and Drug Administration (FDA) would likely have significant detrimental effects on bringing new drugs to market, though the effects might not be immediately evident. CBO is a nonpartisan federal agency that responds to economic and budgetary questions from congressional leaders and their offices. On 18 July, it re...

Date: 22/07/2025

**Title:** [FDA warns Glenmark for failure to investigate dissolution failures](https://www.raps.org/news-and-articles/news-articles/2025/7/fda-warns-glenmark-for-failure-to-investigate-diss)

Summary: Glenmark Pharmaceuticals is once again under scrutiny from the US Food and Drug Administration (FDA) due to violations of good manufacturing practices (GMP). The issues are related to an investigation that found the company’s extended-release potassium chloride tablets did not dissolve properly. Additionally, the company failed to conduct stability testing and did not validate its testing methods. The company’s site in Madhya Pradesh, India, was inspected in early to...

Date: 22/07/2025

**Title:** [MHRA to move forward with medical device reliance plans](https://www.raps.org/news-and-articles/news-articles/2025/7/mhra-to-move-forward-with-medical-device-reliance)

Summary: The UK Medicines and Healthcare products Regulatory Agency (MHRA) plans to propose an indefinite recognition of CE-marked medical devices and new pathways to get devices on the market that have already been vetted by Australia, Canada, and the US later this year. The announcement is part of the agency's efforts to use international reliance to regulate products while reducing its administrative burdens. On 22 July, MHRA announced it had reviewed feedback from stakeho...

Date: 22/07/2025

**Title:** [Latin America Roundup: Mexico formalizes regulatory reliance strategy](https://www.raps.org/news-and-articles/news-articles/2025/7/latin-america-roundup-mexico-formalizes-regulatory)

Summary: On 18 July, Mexico’s health ministry took a leap toward harmonization of regulatory requirements for medicines, publishing new guidelines that allow its medicines agency to honor decisions by WHO-listed regulatory authorities and permanent members of the International Council for Harmonization (ICH). The guidelines cover new molecules, generic medications, biological medications, and other biological products including vaccines. They also cover devices, for ...

Date: 22/07/2025

**Title:** [Recon: FDA rejects Replimune’s oncolytic virus drug over study issues; Sarepta to halt shipments of Duchenne gene therapy](https://www.raps.org/news-and-articles/news-articles/2025/7/recon-fda-rejects-replimune-s-oncolytic-virus-drug)

Summary: Welcome to Regulatory Reconnaissance, your regulatory news and intelligence briefing. In Focus: US Drugmakers are racing to help patients stay awake — and could also make billions ( STAT ) Study of GLP-1 guidelines for teens points to potential for influence from drugmakers ( STAT ) In surprise reversal, Sarepta Therapeutics says it will pause shipments of Duchenne gene therapy ( STAT ) ( Reuters ) US begins organ-transplant reform as 'signs of life' found before so...

Date: 22/07/2025

**Title:** [What these 6 regulatory leaders learned at the RAPS Kellogg Executive Development Program](https://www.raps.org/news-and-articles/news-articles/2024/3/regulatory-affairs-leadership-training)

Summary: When you advance to a senior role in regulatory affairs, the skills you use daily begin to change. The skills you applied at the beginning of your regulatory career were probably narrow, focusing on specific regulatory requirements and supporting individual projects. When you advance into a leadership position in regulatory affairs, those things still matter. After all, getting safe and effective products to market is still the goal. But in a regulatory affairs lead...

Date: 22/07/2025

**Title:** [FDA names biotech entrepreneur, Stanford professor as new CDER chief](https://www.raps.org/news-and-articles/news-articles/2025/7/fda-names-biotech-entrepreneur,-stanford-professor)

Summary: After weeks of anticipation, the US Food and Drug Administration (FDA) has announced that George Tidmarsh, a Stanford University adjunct professor and biotech industry veteran, will lead its drug center. On 21 July, FDA Commissioner Marty Makary notified staff in an email reviewed by Focus that Tidmarsh has been appointed director of the Center for Drug Evaluation and Research (CDER). He touted Tidmarsh’s more than 30 years of experience in biotechnology, clinical ...

Date: 21/07/2025

**Title:** [FDA panel debates label change on SSRI use during pregnancy](https://www.raps.org/news-and-articles/news-articles/2025/7/fda-panel-debates-label-change-on-ssri-use-during)

Summary: A US Food and Drug Administration (FDA) panel convened on Monday to explore the impact of selective serotonin reuptake inhibitors (SSRIs) on fetal development, with some panel members proposing that the labeling for SSRIs be changed to include a warning about adverse maternal and fetal risks during pregnancy. At times, members of the FDA expert roundtable on SSRIs and pregnancy disagreed on the effectiveness of SSRIs in treating anxiety and depression, whether they s...

Date: 21/07/2025

**Title:** [Trump gives device sterilizers two more years to comply with EtO limits](https://www.raps.org/news-and-articles/news-articles/2025/7/trump-gives-device-sterilizers-two-more-years-to-c)

Summary: President Donald Trump issued an executive order (EO) last week granting a two-year extension for medical device sterilization facilities to comply with the new limits for ethylene oxide (EtO) for device sterilization. The action was taken to avert potential device shortages and reflects a belief within the administration that the technology needed to cut emissions to the required levels is not widely available. Last year, the Environmental Protection Agency (EPA) is...

Date: 21/07/2025

**Title:** [Recon: FDA panel votes against Otsuka, Lundbeck PTSD drug; Biogen announces $2B upgrades to NC facilities](https://www.raps.org/news-and-articles/news-articles/2025/7/recon-fda-panel-votes-against-otsuka-lundbeck-pts)

Summary: Welcome to Regulatory Reconnaissance, your regulatory news and intelligence briefing. In Focus: US FDA taps biotech veteran George Tidmarsh to lead drug center ( STAT ) ( Reuters ) A sloppy report on mifepristone is being used to undermine the FDA — and the biotech industry ( STAT ) The FDA’s new SSRI experts have long questioned antidepressant use ( Endpoints ) Otsuka, Lundbeck’s PTSD Drug Fails to Win US FDA Panel Support ( Bloomberg ) ( Reuters ) Gene therapy ma...

Date: 21/07/2025

**Title:** [Asia-Pacific Roundup: India’s CDSCO shares guidance on seeking clearance to export new drugs](https://www.raps.org/news-and-articles/news-articles/2025/7/asia-pacific-roundup-india-s-cdsco-shares-guidance)

Summary: The Central Drugs Standard Control Organization (CDSCO) has shared guidance on obtaining a certificate to export new drugs from India. Companies need a no-objection certificate from CDSCO zonal offices to export new drugs. The certificates are required for exports of both approved and unapproved products but cannot be used to authorize the shipment of narcotics, psychotropic substances, and banned drugs. CDSCO’s guidance describes a two-step process for obtaini...

Date: 21/07/2025

**Title:** [340 Global Regulators, Health Authorities and Industry Partners Gather in Sydney for Australia Regulatory Device Summit 2025](https://www.raps.org/news-and-articles/news-articles/2025/7/australia-regulatory-device-summit-2025-recap)

Summary: Sydney, AU — 21 July 2025 —The Regulatory Affairs Professionals Society (RAPS) and the Medical Technology Association of Australia (MTAA ) just concluded the Australia Regulatory Device Summit 2025 , held at the ICC Sydney 17-18 July. The Summit, which attracted 340 attendees from 12 countries and 5 continents, addressed Australian regulatory reforms and international harmonization. The event also offered participants insights and access to representatives from organis...

Date: 21/07/2025

**Title:** [This Week at FDA: FDA revokes food standards, says no to WHO pandemic regulation, and more](https://www.raps.org/news-and-articles/news-articles/2025/7/this-week-at-fda-fda-revokes-food-standards,-says)

Summary: Welcome to another installment of This Week at FDA, your weekly source for updates—big and small—on FDA, drug, and medical device regulation and what we’re reading from around the web. This week, the Food and Drug Administration (FDA) said it is revoking dozens of food standards, the US government rejected a regulation from the World Health Organization (WHO) that it says would impose on its sovereignty during future pandemics, and CDER Director Vinay Prasad justified mRNA...

Date: 18/07/2025

**Title:** [FDA finalizes guidance for efficient biosimilars meetings, per BsUFA III](https://www.raps.org/news-and-articles/news-articles/2025/7/fda-finalizes-guidance-for-efficient-biosimilars-m)

Summary: The US Food and Drug Administration (FDA) published on 18 July a final, 23-page guidance document clarifying how sponsors may formally meet with the agency regarding the development and review of their biosimilars, including interchangeable products. The latest reauthorization of the Biosimilar User Fee Act (BsUFA III) included performance goals for efficiently and predictably managing formal meetings between FDA and sponsors. “The good meeting management practices...

Date: 18/07/2025

**Title:** [Panel urges FDA to remove boxed warning on women’s hormone therapy](https://www.raps.org/news-and-articles/news-articles/2025/7/panel-urges-fda-to-remove-boxed-warning-on-women-s)

Summary: An advisory panel on Thursday urged the US Food and Drug Administration (FDA) to remove the boxed warnings on labels for vaginal estrogen products and asserted there is a lack of data to support the warnings. Further, they said the warnings wrongly deter patients and providers from using the products. The panel was convened by FDA Commissioner Marty Makary to discuss hormone therapy for menopausal women, a subject of particular interest to Makary. However, the discus...

Date: 17/07/2025

**Title:** [Euro Roundup: EMA identifies need to adapt frameworks, processes to accommodate AI](https://www.raps.org/news-and-articles/news-articles/2025/7/euro-roundup-ema-identifies-need-to-adapt-framewor)

Summary: The European medicines regulatory network’s AI Observatory has shared its first annual report alongside a compilation of examples of AI use and a horizon scanning document. Officials set up the AI Observatory to capture and share experience and trends in AI to inform the work of the European Medicines Regulatory Network. The European Medicines Agency (EMA) published a set of documents from the AI Observatory last week, revealing a need to adapt frameworks and process...

Date: 17/07/2025

**Title:** [Recon: BMS, Pfizer to sell Eliquis direct to patients at a discount; Sarepta to layoff 500 staff as it adds boxed warning for DMD gene therapy](https://www.raps.org/news-and-articles/news-articles/2025/7/recon-bms-pfizer-to-sell-eliquis-direct-to-patien)

Summary: Welcome to Regulatory Reconnaissance, your regulatory news and intelligence briefing. In Focus: US Senators reveal how much Lilly, Pfizer paid telehealth companies ( STAT ) FDA advisers vote against combination therapies of GSK's blood cancer drug ( Reuters ) Bristol-Myers and Pfizer to Offer Blockbuster Blood Thinner at Discount ( The Wall Street Journal ) Trump’s Medicare agency to speed up clawback of $7.8 billion in hospital drug payments ( STAT ) RFK Jr.’s FDA...

Date: 17/07/2025

**Title:** [FDA issues guidance on developing cancer drugs in combination with other treatments](https://www.raps.org/news-and-articles/news-articles/2025/7/fda-issues-guidance-on-developing-cancer-drugs-in)

Summary: The US Food and Drug Administration (FDA) has issued draft guidance on developing cancer drugs intended for use in combination with other therapies. The guidance focuses on demonstrating each drug's contribution to the overall treatment. “Combination therapy in oncology is an important treatment modality. Scientific advances have increased our understanding of the pathophysiological processes that underlie many cancers,” according to the draft guidance. “This increas...

Date: 16/07/2025

**Title:** [UK sets plan to be Euro life sciences leader by 2030](https://www.raps.org/news-and-articles/news-articles/2025/7/uk-sets-plan-to-be-euro-life-sciences-leader-by-20)

Summary: The UK government has announced an ambitious plan to become the leading life sciences economy in Europe in five years and the third most important global life sciences economy by 2035. The plan includes significant reforms to the Medicines & Healthcare products Regulatory Agency (MHRA). On 16 July, the UK government published its Life Sciences Sector Plan, which lays out specific steps and metrics it wants to achieve over the next decade to advance the country's medi...

Date: 16/07/2025

**Title:** [Challenges and best practices in planning and executing PMCF surveys](https://www.raps.org/news-and-articles/news-articles/2025/7/challenges-and-best-practices-in-planning-and-exec)

Summary: Postmarket clinical follow-up (PMCF) surveys are a proven method for collecting the data used for EU Medical Device Regulation (EU MDR) submissions, but there is limited guidance on survey procedure and use. This article explores the challenges in planning and executing high-quality Level 4 and general/usability Level 8 PMCF surveys, as outlined in Appendix III of the Medical Device Coordination Group (MDCG) 2020-6 guidance document. It addresses poor survey design, insuff...

Date: 16/07/2025

**Title:** [MDCG outlines timeline for complying with new UDI-DI for contact lenses and glasses](https://www.raps.org/news-and-articles/news-articles/2025/7/mdcg-outlines-timeline-for-complying-with-new-udi)

Summary: The European Commission’s Medical Device Coordination Group (MDCG) has published a position paper clarifying the timelines for manufacturers to comply with master unique device identifiers (UDI-DI) for contact lenses, spectacle frames, and reading glasses. The paper was prompted by the amendments to the Medical Device Regulations (MDR), which were announced on 20 October 2023. These amendments introduced a new category known as the master UDI-DIs for highly indiv...

Date: 15/07/2025

**Title:** [FDA warns wearable tech firm, Korean drugmaker, and sellers of Kratom-derived compound](https://www.raps.org/news-and-articles/news-articles/2025/7/fda-warns-wearable-tech-firm,-korean-drugmaker,-an)

Summary: The US Food and Drug Administration (FDA) has issued a slew of warning letters to companies for marketing products unapproved or adulterated products, failing to meet current good manufacturing practice (CGMP) requirements, and over clinical trial protocol issues. On 15 July, FDA published more than a dozen warning letters, including one to the Boston-based wearable health technology company Whoop. The company was cited for marketing its Blood Pressure Insights (BPI)...

Date: 15/07/2025

**Title:** [Recon: FDA reviewers flag eye risks with GSK’s blood cancer therapy; FDA ends import screening exemption for low-value goods](https://www.raps.org/news-and-articles/news-articles/2025/7/recon-fda-reviewers-flag-eye-risks-with-gsk-s-bloo)

Summary: Welcome to Regulatory Reconnaissance, your regulatory news and intelligence briefing. In Focus: US FDA staff flags eye safety risks for GSK's blood cancer drug ( Reuters ) The end of animal testing? Transitioning to models is promising — but no silver bullet ( STAT ) Weight-loss drug use in kids surged after doctors' recommendation ( Axios ) The Trump administration disbanded a newborn screening panel. Advocates now face a harder path ( Endpoints ) FDA employees l...

Date: 15/07/2025

**Title:** [Study: Most nononcology accelerated approval pivotal trials use surrogate endpoints](https://www.raps.org/news-and-articles/news-articles/2025/7/study-most-nononcology-accelerated-approval-pivota)

Summary: Most pivotal clinical trials supporting the accelerated approval of nononcology products reported surrogate measures as primary endpoints, according to a recent research letter published in JAMA . Ian T. T. Liu, of the Program on Regulation, Therapeutics, And Law (PORTAL) research group at Harvard Medical School and Brigham & Women’s Hospital, and colleagues evaluated the characteristics of pivotal and confirmatory trials for 50 nononcology products granted accelera...

Date: 15/07/2025

**Title:** [RIF separation letters go out to HHS employees after Supreme Court order](https://www.raps.org/news-and-articles/news-articles/2025/7/rif-separation-letters-go-out-to-hhs-employees-aft)

Summary: Many Department of Health and Human Services (HHS) employees who were placed on administrative leave as part of the Trump administration’s reduction-in-force (RIF) actions earlier this year were officially laid off on 14 July. The RIF has been challenged in the courts, but a Supreme Court (SCOTUS) ruling last week lifted an injunction that cleared a path for the administration to proceed with the firings, according to an HHS email obtained by Focus . At around...

Date: 14/07/2025

**Title:** [Makary suggests lower PDUFA fees as reauthorization process begins](https://www.raps.org/news-and-articles/news-articles/2025/7/makary-suggests-lower-pdufa-fees-as-reauthorizatio)

Summary: The US Food and Drug Administration (FDA) kicked off the reauthorization process for the eighth iteration the Prescription Drug User Fee Act (PDUFA VIII) on Monday, with FDA Commissioner Marty Makary saying he’d like to see lower fees paid by industry this time around. “I’d like to see lower user fees. It’d be a reduced barrier for small companies and individual inventors and people in academics that may be trying to understand this process, including the capital r...

Date: 14/07/2025

**Title:** [MHRA plans to align with EU common specifications for high-risk IVDs](https://www.raps.org/news-and-articles/news-articles/2025/7/mhra-plans-to-align-with-eu-common-specifications)

Summary: The UK’s Medicines and Healthcare products Regulatory Agency (MHRA) plans to update its Medical Devices Regulations 2002 for Great Britain to align with the EU Common Specifications for high-risk in vitro diagnostic (IVD) devices. The move is another step in the agency's series of measures to reduce administrative burdens by aligning itself with trusted international regulators. Last year, MHRA proposed three major changes to update its regulation of high-risk IVDs a...

Date: 14/07/2025

**Title:** [Recon: Zimmer to acquire robotics firm Monogram for $177M; WHO adds Gilead’s biannual HIV shot to PrEP guidelines](https://www.raps.org/news-and-articles/news-articles/2025/7/recon-zimmer-to-acquire-robotics-firm-monogram-for)

Summary: Welcome to Regulatory Reconnaissance, your regulatory news and intelligence briefing. In Focus: US Zimmer to acquire Monogram Technologies for $177 million, boosting robotics portfolio ( Reuters ) Trump's spending bill will likely boost costs for insurers, shrink Medicaid coverage ( Reuters ) Federal Hiring Shake-Up (Again): What the Latest Executive Action and Supreme Court Decision Mean for Industry ( FDA Law Blog ) Trump Says 200% Pharma Tariffs Are Coming. Wall ...

Date: 14/07/2025

**Title:** [Asia-Pacific Roundup: Korean Pharmacopoeia selected to participate in Pharmacopeial Discussion Group](https://www.raps.org/news-and-articles/news-articles/2025/7/asia-pacific-roundup-korean-pharmacopoeia-selected)

Summary: The Korean Pharmacopoeia has been chosen as the next organization to start the process of joining the Pharmacopeial Discussion Group (PDG). PDG, a group formed by American, European, and Japanese organizations in 1989, has expanded in recent years to further its attempts to harmonize pharmacopeial topics. The group began its initial expansion phase in 2022 and, after a successful pilot, named the Indian Pharmacopoeia Commission (IPC) its first new member in 2023. ...

Date: 14/07/2025

**Title:** [This Week at FDA: Makary celebrates first 100 days, Senate committee passes FDA budget bill, and more](https://www.raps.org/news-and-articles/news-articles/2025/7/this-week-at-fda-makary-celebrates-first-100-days)

Summary: Welcome to another installment of This Week at FDA, your weekly source for updates—big and small—on FDA, drug, and medical device regulation and what we’re reading from around the web. This week FDA Commissioner Marty Makary touted his first 100-day record at the agency, the Senate Appropriations Committee advanced an FDA budget bill, and the agency has scheduled several important meetings. FDA Commissioner Marty Makary issued a statement commemorating his first on...

Date: 11/07/2025

**Title:** [Makary lauds user fees as FDA begins GDUFA IV reauthorization process](https://www.raps.org/news-and-articles/news-articles/2025/7/makary-lauds-user-fees-as-fda-begins-gdufa-iv-reau)

Summary: The US Food and Drug Administration (FDA) on Friday began the reauthorization process for the next iteration of the Generic Drug User Fee Amendments (GDUFA IV) with a public meeting to gather input from stakeholders ahead of negotiations with industry. Most of FDA’s user fee programs, including those for prescription and generic drugs, medical devices, and biosimilars, are set to expire on 30 September 2027. The agency is required to engage in lengthy negotiations wi...

Date: 11/07/2025

**Title:** [Sources: FDA won’t pay bonuses to RIFed, similar employees](https://www.raps.org/news-and-articles/news-articles/2025/7/sources-fda-won-t-pay-bonuses-to-rifed,-similar-em)

Summary: The US Food and Drug Administration (FDA) will not pay performance-based bonuses to employees who are part of several Trump Administration efforts to reduce the federal workforce. The lead federal union said it will challenge the decision. Like other federal employees, FDA staff are evaluated annually as part of the Performance Management Appraisal Program (PMAP), which allows them to receive a bonus in the form of cash, time-off, or a combination of the two based on...

Date: 10/07/2025

**Title:** [FDA publishes 200 complete response letters in transparency effort](https://www.raps.org/news-and-articles/news-articles/2025/7/fda-publishes-200-complete-response-letters-in-tra)

Summary: The US Food and Drug Administration (FDA) on Thursday published more than 200 complete response letters (CRLs) sent to drugmakers outlining the reasons for their products’ rejections in a centralized database. All of the letters pertain to products that were later approved, and most of the letters were previously published by FDA as part of each respective drug’s approval package. The letters are now available on the agency’s openFDA resource; previously, the publish...

Date: 10/07/2025

**Title:** [Recon: FDA approves Moderna's COVID shot for at risk children; Merck to buy Verona for $10B](https://www.raps.org/news-and-articles/news-articles/2025/7/recon-fda-approves-modernas-covid-shot-for-at-risk)

Summary: Welcome to Regulatory Reconnaissance, your regulatory news and intelligence briefing. In Focus: US Moderna gets full US approval for COVID shot in at-risk children 6 months and older ( Reuters ) US FDA publishes 200 complete response letters from archive in transparency drive ( Reuters ) ( STAT ) J&J defeats generic drugmakers in US appeal over schizophrenia treatment ( Reuters ) Merck to buy lung-disease biotech Verona Pharma for $10 billion ( STAT ) ( FT ) US ...

Date: 10/07/2025

**Title:** [Euro Roundup: EMA survey shows SMEs want simplification, streamlining to ease regulatory burdens](https://www.raps.org/news-and-articles/news-articles/2025/7/euro-roundup-ema-survey-shows-smes-want-simplifica)

Summary: Small and medium-sized enterprises (SMEs) have asked the European Medicines Agency (EMA) to simplify and streamline regulations to ease some of the burdens on their operations. EMA collected the views of SMEs in an online survey that garnered 266 unique and valid responses. The survey showed “strong satisfaction with EMA’s support, especially regulatory assistance services, fee incentives, the SME qualification process and training,” the agency said. Respondents prai...

Date: 10/07/2025

**Title:** [EU expert group established for pediatric and rare disease devices](https://www.raps.org/news-and-articles/news-articles/2025/7/eu-expert-group-established-for-pediatric-and-rare)

Summary: The European Commission on Monday published a regulation that establishes a new expert panel on medical devices focused on pediatrics and rare diseases. The measure was supported by many organizations and patient groups in the EU, who expressed hope that the panels would encourage the development of more devices to treat the pediatric population. The panel will provide scientific, technical, and clinical opinions to support the development of medical devices intended...

Date: 09/07/2025

**Title:** [EMA - Clinical Trials Highlights July 2025](https://www.therqa.com/news/ema-clinical-trials-highlights-july-2025/)

Summary: 23rd July 2025 EMA - Clinical Trials Highlights July 2025 Featuring: ACT EU News, CTIS Training, CTIS Events and more. View Now Share your experience on trustpilot.com

Date: 23/07/2025

**Title:** [MHRA - Digital mental health technology webinar](https://www.therqa.com/news/mhra-digital-mental-health-technology-webinar/)

Summary: 2nd June 2025 MHRA - Digital mental health technology The Wellcome Trust has funded a 3-year project focusing on effective regulation and evaluation of digital mental health technology. Review the recording of our webinar from Thursday 15 May 2025.

Date: 02/06/2025

**Title:** [EMA - Veterinary Medicines Highlights](https://www.therqa.com/news/ema-veterinary-medicines-highlights/)

Summary: 2nd June 2025 EMA - Veterinary Medicines Highlights Quarterly news, activities and interviews from EMA Veterinary Medicines Division May edition out now. View here Share your experience on trustpilot.com

Date: 02/06/2025

**Title:** [FDA - FDA Launches Agency-Wide AI Tool to Optimise Performance for the American People](https://www.therqa.com/news/fda-fda-launches-agency-wide-ai-tool-optimise-perf/)

Summary: 3rd June 2025 FDA - FDA Launches Agency-Wide AI Tool to Optimise Performance for the American People The U.S. Food and Drug Administration (FDA) today launched Elsa, a generative Artificial Intelligence (AI) tool designed to help employees—from scientific reviewers to...

Date: 03/06/2025

**Title:** [MHRA Blog - A Voyage in Good Distribution Practice (GDP): The Aviation and Marine Sectors](https://www.therqa.com/news/mhra-blog-voyage-good-distribution-practice-gdp-av/)

Summary: 4th June 2025 MHRA Blog - A Voyage in Good Distribution Practice (GDP): The Aviation and Marine Sectors View now Share your experience on trustpilot.com

Date: 04/06/2025

**Title:** [MHRA - RegulatoryConnect Webinar Added](https://www.therqa.com/news/mhra-regulatoryconnect-webinar-added/)

Summary: 5th June 2025 MHRA - RegulatoryConnect Webinar Added View Now Share your experience on trustpilot.com

Date: 05/06/2025

**Title:** [MHRA - MHRA launches new digital hub in Leeds to drive innovation and regional growth](https://www.therqa.com/news/mhra-mhra-launches-new-digital-hub-leeds-drive-inn/)

Summary: 6th June 2025 MHRA - MHRA launches new digital hub in Leeds to drive innovation and regional growth A new digital hub in Leeds is being launched by the Medicines and Healthcare products Regulatory Agency (MHRA), marking a significant step...

Date: 06/06/2025

**Title:** [MHRA - Documentation for implementation of data requirements under the new Post-Market Surveillance regulations](https://www.therqa.com/news/mhra-documentation-implementation-data-requirement/)

Summary: 10th June 2025 MHRA - Documentation for implementation of data requirements under the new Post-Market Surveillance regulations Documentation to support changes made to reporting Manufacturer Incident Reports (MIRs) and Field Safety Corrective Action Reports (FSCAs) to the MHRA following implementation...

Date: 10/06/2025

**Title:** [MHRA - Human medicines Modular Manufacture and Point of Care regulations 2025: Overview](https://www.therqa.com/news/mhra-human-medicines-modular-manufacture-and-point/)

Summary: 11th June 2025 MHRA - Human medicines Modular Manufacture and Point of Care regulations 2025: Overview Information to help you understand and prepare for the main regulatory changes that The Human Medicines (Amendment) Modular Manufacture and Point of Care regulations...

Date: 11/06/2025

**Title:** [MHRA - Decentralised Manufacture Guidance Documents](https://www.therqa.com/news/mhra-decentralised-manufacture-guidance-documents/)

Summary: 11th June 2025 MHRA - Decentralised Manufacture Guidance Documents now available: Decentralised manufacture: Clinical Trial Authorisation (CTA) and Good Clinical Practice (GCP) Decentralised manufacture: UK Guideline on Good Manufacturing Practice (GMP) Decentralised Manufacture: Labelling Decentralised Manufacture: UK Guideline of Good...

Date: 11/06/2025

**Title:** [Pharmacovigilance News - March 2025 to May 2025](https://www.therqa.com/news/pharmacovigilance-news-march-2025-may-2025/)

Summary: 12th June 2025 Pharmacovigilance News - March 2025 to May 2025 View Now Share your experience on trustpilot.com

Date: 12/06/2025

**Title:** [EMA - Overview of comments received on ICH M11 Technical Specification Updated Step 2b](https://www.therqa.com/news/ema-overview-comments-received-ich-m11-technical-s/)

Summary: 12th June 2025 EMA - Overview of comments received on ICH M11 Technical Specification Updated Step 2b The ICH M11 draft guidelines covers the clinical study protocol template and technical specifications. Following the end of public consultation on 22 April...

Date: 12/06/2025

**Title:** [MHRA - Unprecedented boost for clinical trials under 10 Year Health Plan](https://www.therqa.com/news/mhra-unprecedented-boost-clinical-trials-under-10-/)

Summary: 16th June 2025 MHRA - Unprecedented boost for clinical trials under 10 Year Health Plan Patients will receive the most cutting-edge treatments years earlier than planned under the government’s 10 Year Health Plan, which will speed-up clinical trials so the...

Date: 16/06/2025

**Title:** [MHRA - Human Medicines Highlights June 2025](https://www.therqa.com/news/mhra-human-medicines-highlights-june-2025/)

Summary: 16th June 2025 MHRA - Human Medicines Highlights June 2025 June 2025 Edition out now. Share your experience on trustpilot.com

Date: 16/06/2025

**Title:** [MHRA - First major overhaul of medical device regulation comes into force across Great Britain](https://www.therqa.com/news/mhra-first-major-overhaul-medical-device-regulatio/)

Summary: 16th June 2025 MHRA - First major overhaul of medical device regulation comes into force across Great Britain From today (16 June 2025), a landmark reform of how medical devices are regulated in Great Britain takes effect, as part of...

Date: 16/06/2025

**Title:** [MHRA - Electronic Common Technical Document (eCTD) submissions update](https://www.therqa.com/news/mhra-electronic-common-technical-document-ectd-sub/)

Summary: 18th June 2025 MHRA - Electronic Common Technical Document (eCTD) submissions update To improve the quality of submissions, the MHRA now requires stricter adherence to eCTD specifications. In accordance with the ICH (International Conference on Harmonisation of Technical Requirements of...

Date: 18/06/2025

**Title:** [MHRA - Fast, Expert and Open – how the MHRA is poised to become a global leader in risk-proportionate regulation](https://www.therqa.com/news/mhra-fast-expert-and-open-how-mhra-poised-become-g/)

Summary: 19th June 2025 MHRA - Fast, Expert and Open – how the MHRA is poised to become a global leader in risk-proportionate regulation New MHRA CEO and other senior leaders from the UK Medicines and Healthcare products Regulatory Agency (MHRA)...

Date: 19/06/2025

**Title:** [MHRA - AI breakthroughs drive expansion of ‘Airlock’ testing programme](https://www.therqa.com/news/mhra-ai-breakthroughs-drive-expansion-airlock-test/)

Summary: 24th June 2025 MHRA - AI breakthroughs drive expansion of ‘Airlock’ testing programme MHRA opens second round of applications to test cutting-edge AI medical technologies following successful pilot phase. Read More Share your experience on trustpilot.com

Date: 24/06/2025

**Title:** [MHRA - AI Airlock Phase 2 application](https://www.therqa.com/news/mhra-ai-airlock-phase-2-application/)

Summary: 24th June 2025 MHRA - AI Airlock Phase 2 application The call for application for phase 2 of the AI Airlock is now open. This page contains information on eligibility and how to apply:  https://www.gov.uk/government/publications/ai-airlock-phase-2-application Share your experience on trustpilot.com

Date: 24/06/2025

**Title:** [EMA - CTIS Newsflash Replaced with Clinical Trials Highlights Newsletter](https://www.therqa.com/news/ema-ctis-newsflash-replaced-clinical-trials-highli/)

Summary: 24th June 2025 EMA - Important Update: Changes to the CTIS Newsflash From July 2025, the biweekly CTIS Newsflash will be replaced by the Clinical Trials Highlights Newsletter. This newsletter will now be released monthly, offering a more comprehensive overview...

Date: 24/06/2025

**Title:** [NHS HRA - New CT Guideline and Survey](https://www.therqa.com/news/nhs-hra-new-ct-guideline-and-survey/)

Summary: 1st July 2025 HRA have  published new guidance  to accompany the updated clinical trials regulations which come into force on 28 April 2026. The guidance explains what will change in terms of processes, legal requirements, and expectations for anyone involved...

Date: 01/07/2025

**Title:** [MHRA - AI Airlock, CERSIs and a new global AI network for health regulators](https://www.therqa.com/news/mhra-ai-airlock-cersis-and-new-global-ai-network-h/)

Summary: 1st July 2025 MHRA - AI Airlock, CERSIs and a new global AI network for health regulators Marinos Ioannides, Head of Software and AI Medical Devices talks on AI Airlock, CERSIs and a new global AI network for health regulators...

Date: 01/07/2025

**Title:** [HRA Blog - Information governance in research](https://www.therqa.com/news/hra-blog-information-governance-research/)

Summary: 1st July 2025 HRA Blog - Information governance in research "The world of information governance (IG) in health and care research can often feel murky, shrouded in nuance and clouded by uncertainty. This is especially true for those who are...

Date: 01/07/2025

**Title:** [MHRA - Decentralised Manufacturing Regulations Update Webinar](https://www.therqa.com/news/mhra-decentralised-manufacturing-regulations-video/)

Summary: 3rd July 2025 MHRA - Decentralised Manufacturing Regulations Update Webinar Watch the video recording of the Decentralised Manufacturing Regulations Update Webinar, which took place on Tuesday 17 June 2025 View Now Share your experience on trustpilot.com

Date: 03/07/2025

**Title:** [MHRA - Decentralised Manufacturing Regulations Update Webinar](https://www.therqa.com/news/mhra-decentralised-manufacturing-regulations-updat/)

Summary: 3rd July 2025 MHRA - Decentralised Manufacturing Regulations Update Webinar Watch the video recording of the Decentralised Manufacturing Regulations Update Webinar, which took place on Tuesday 17 June 2025 View Now Share your experience on trustpilot.com

Date: 03/07/2025

**Title:** [ICH - ICH E20 Draft Guideline Available](https://www.therqa.com/news/ich-ich-e20-draft-guideline-available/)

Summary: 3rd July 2025 ICH - ICH E20 Draft Guideline Available ICH E20 Draft Guideline is Available Now on the ICH Website, 25th June 2025 The ICH E20 draft Guideline on “Adaptive Design for Clinical Trials” has reached Step 2b of...

Date: 03/07/2025

**Title:** [EDQM - 182nd session](https://www.therqa.com/news/edqm-182nd-session/)

Summary: 3rd July 2025 EDQM - 182nd session Highlights include: View More Share your experience on trustpilot.com

Date: 03/07/2025

**Title:** [MHRA - Medical devices: Standardised format for the periodic safety update report](https://www.therqa.com/news/mhra-medical-devices-standardised-format-periodic-/)

Summary: 4th July 2025 MHRA - Medical devices: Standardised format for the periodic safety update report Information and recommendations for manufacturers on the preparation and presentation of a periodic safety update report (PSUR). Read Now Share your experience on trustpilot.com

Date: 04/07/2025

**Title:** [EC - Stakeholders’ Consultation on EudraLex Volume 4](https://www.therqa.com/news/ec-stakeholders-consultation-eudralex-volume-4/)

Summary: 8th July 2025 EC - Stakeholders’ Consultation on EudraLex Volume 4 Good Manufacturing Practice Guidelines: Chapter 4, Annex 11 and New Annex 22 In light of the rapid advancement of digital technologies and the implementation of AI systems in pharmaceutical...

Date: 08/07/2025

**Title:** [MHRA - Medicines and Medical Devices Act 2021 – Stakeholder survey - Open Call for Evidence](https://www.therqa.com/news/mhra-medicines-and-medical-devices-act-2021-stakeh/)

Summary: 23rd July 2025 MHRA - Medicines and Medical Devices Act 2021 – Stakeholder survey - Open Call for Evidence The Medicines and Healthcare products Regulatory Agency (MHRA), in collaboration with the Department of Health and Social Care (DHSC), is conducting...

Date: 23/07/2025

**Title:** [Now the decision is made - Swetrial will become a reality!](https://www.lakemedelsverket.se/sv/nyheter/nu-ar-beslutet-fattat---swetrial-ska-bli-verklighet)

Summary: Swetrial is a new national partnership for clinical trials.

Date: 31/07/2025

**Title:** [New injection to prevent HIV infection in the EU and globally](https://www.lakemedelsverket.se/sv/nyheter/ny-injektion-for-att-forebygga-hiv-infektion-i-eu-och-globalt)

Summary: Lenacapavir, which is marketed under the name YEYTUO, is a drug that binds to the proteins in the HIV virus's outer shell and prevents the virus's ability to reproduce.

Date: 28/07/2025

**Title:** [Measures to secure access to anti-D immunoglobulins](https://www.lakemedelsverket.se/sv/nyheter/atgarder-for-att-sakra-tillgangen-till-anti-d-immunoglobuliner)

Summary: Anti-D immunoglobulins are today the only available treatment to prevent RHD immunization during pregnancy.

Date: 07/07/2025

**Title:** [The Swedish Medicines Agency offers generative AI to pharmaceutical authorities in the EU](https://www.lakemedelsverket.se/sv/nyheter/lakemedelsverket-erbjuder-generativ-ai-till-lakemedelsmyndigheter-i-eu)

Summary: Since March 2025, Regulus (Regulatory Universal Support), which is the Swedish Medicines Agency's own developed system for generative AI, has been used internally.

Date: 07/07/2025

**Title:** [Five new substances become drugs](https://www.lakemedelsverket.se/sv/nyheter/fem-nya-amnen-blir-narkotika)

Summary: On a proposal from the Public Health Authority, the government has decided that the following five substances should be classified as drugs from 15 July 2025 (SFS 2025: 662):  
3-methyl-alpha-piHP (3'hor-Mey-alpha-rant)  
Pyrofenidone  
2-chloromethcatinone (2br-CMC)  
ADB-4en-5BR-Pinaca (ADMBA-4ENAP-5BRA-PINACA)  
Spirochlorine (RAD-6890).

Date: 02/07/2025

**Title:** [Incorrect mammography response identified - the error fixed](https://www.lakemedelsverket.se/sv/nyheter/felaktiga-mammografisvar-identifierade--felet-atgardat)

Summary: Sectra Workstation IDS7 is an image processing system from manufacturer Sectra AB.

Date: 01/07/2025

**Title:** [First treatment for liver damage caused by fatty liver is recommended for approval in the EU](https://www.lakemedelsverket.se/sv/nyheter/forsta-behandlingen-mot-leverskador-orsakade-av-fettlever-rekommenderas-for-godkannande-i-eu)

Summary: MASH (Metabolic Dysfunction-Associated Steatohepatitis) is a serious form of fatty liver where fat accumulation leads to inflammation and liver damage.

Date: 23/06/2025

**Title:** [The Swedish Medicines Agency shall investigate the division of responsibilities for human biological material](https://www.lakemedelsverket.se/sv/nyheter/lakemedelsverket-ska-utreda-ansvarsfordelningen-for-humanbiologiskt-material)

Summary: On behalf of the government, the authorities will develop a new national scheme for permits and supervision in terms of human materials (soho system).

Date: 19/06/2025

**Title:** [The Dost Service for Medicines must work even in crises and war](https://www.lakemedelsverket.se/sv/nyheter/dostjansten-for-lakemedel-maste-fungera-aven-vid-kriser-och-krig)

Summary: At the end of March, a meeting was held within the national drug strategy where authorities, companies, organizations and regions gathered to discuss the current situation and the desired location for the dost service.

Date: 18/06/2025

**Title:** [Important treatment advice for care at Covid-19-Continued risk for the elderly and people in risk group](https://www.lakemedelsverket.se/sv/nyheter/viktiga-behandlingsrad-till-varden-vid-covid-19--fortsatt-risk-for-aldre-och-personer-i-riskgrupp)

Summary: The risk of becoming seriously ill or dying from Covid Väslas at high age-whether the person is vaccinated or has other illnesses.

Date: 12/06/2025

**Title:** [Swetrial sharpen Sweden's competitiveness within clinical trials](https://www.lakemedelsverket.se/sv/nyheter/swetrial-vassar-sveriges-konkurrenskraft-inom-kliniska-provningar)

Summary: Clinical trials are crucial for better health, for Sweden's future competitiveness and for prosperity in healthcare.

Date: 10/06/2025

**Title:** [Sweden needs a national strategy for collection of plasma for drug manufacturing](https://www.lakemedelsverket.se/sv/nyheter/sverige-behover-en-nationell-strategi-for-insamling-av-plasma-for-lakemedelstillverkning)

Summary: There is currently no national target image and actor with formal responsibility for ensuring the availability of plasma as raw material for drug manufacturing in Sweden.

Date: 09/06/2025

**Title:** [The Swedish Medicines Agency is working to strengthen the implementation of the regulations for medical technology products](https://www.lakemedelsverket.se/sv/nyheter/lakemedelsverket-arbetar-med-att-starka-implementering-av-regelverken-for-medicintekniska-produkter)

Summary: In its review of the supervision of medical technology products (the Government's letter 2024/25: 149), the OAG states that the low knowledge of the regulations for medical technology products among companies, health care and social services makes compliance with the EU MDR and IVDR.

Date: 03/06/2025

**Title:** [The Swedish Medicines Agency proposes improved requirements for parallel traded drugs](https://www.lakemedelsverket.se/sv/nyheter/lakemedelsverket-foreslar-forbattrade-krav-pa-parallellhandlade-lakemedel)

Summary: For parallel medicines, there is no requirement to report whether they are available or not.

Date: 03/06/2025

**Title:** [Knowledge of ADHD drugs must increase](https://www.lakemedelsverket.se/sv/nyheter/kunskapen-om-adhd-lakemedel-maste-oka)

Summary: During the 2000s, mental illness has increased, that is, from self-esteemed mental mental disorders to diagnosed psychiatric conditions.

Date: 02/06/2025

**Title:** [The Swedish Medicines Agency wants pharmacies to have extended opportunities to act in case of drug shortages](https://www.lakemedelsverket.se/sv/nyheter/lakemedelsverket-vill-att-apotek-ska-fa-utokade-mojligheter-att-agera-vid-lakemedelsbrist)

Summary: The Swedish Medicines Agency is working on an investigation into opportunities for pharmacists to change medicines in deficiency situations. In an initial analysis, the Swedish Medicines Agency sees that it should be possible for pharmacists at pharmacies to replace medicines in deficiency situations in certain circumstances. It requires a careful assessment of which drugs can be replaced and under what conditions. Works for the possibility of replacing medicines and breaking packaging the Swedish Medicines Agency also works with the conditions to be able to break drug packaging at pharmacies to distribute drugs to several patients in deficiency situations. Such handling also requires a careful assessment of which drugs can be broken ...

Date: 02/06/2025

**Title:** [Positively that reports of suspected side effects of drugs to animals are greatly increasing](https://www.lakemedelsverket.se/sv/nyheter/positivt-att-rapporter-om-misstankta-biverkningar-av-lakemedel-till-djur-okar-kraftigt)

Summary: A total of 1,281 reports on animal medicines were received in 2024, compared with 664 apports in 2020.

Date: 02/06/2025

**Title:** [Cosmic 3.12, 4.0 including 4.1.1 - Cambio Healthcare Systems](https://www.lakemedelsverket.se/sv/nyheter/cosmic-3.12-4.0-samt-4.1.1--cambio-healthcare-systems-ab)

Summary: Product: Cosmic 3.12, 4.0 and 4.1.1 Manufacturer: Cambio Healthcare Systems AB Manufacturer's reference number: VIG-557 The Swedish Medicines Agency's reference number: 6.6.2-2025-061115 Summary: Information on use risk. Modification of software. Manufacturer's documentation 2025-061115 - Cambio Healthcare Systems AB - FSN

Date: 16/07/2025

**Title:** [Cosmic 3.12 – Cambio Healthcare Systems AB](https://www.lakemedelsverket.se/sv/nyheter/cosmic-3.12--cambio-healthcare-systems-ab)

Summary: Product: Cosmic 3.12 Manufacturer: Cambio Healthcare Systems AB Manufacturer's reference number: VIG-578 The Swedish Medicines Agency's reference number: 6.6.2-2025-061161 Summary: Information on use risk. Modification of software. Manufacturer's documentation 2025-061161 - Cambio Healthcare Systems AB - FSN

Date: 16/07/2025

**Title:** [BIOFIRE FILMARRAY TORCH-system - BioFire Diagnosticss, LLC](https://www.lakemedelsverket.se/sv/nyheter/biofire-filmarray-torch-system---biofire-diagnosticss-llc2)

Summary: Product: Biofire Filmarray Torch system Manufacturer: Biofire Diagnostics, LLC Manufacturer's reference number: FSCA 5761-3 The Swedish Medicines Agency's reference number: 6.6.2-2025-060455 Summary: Information on use risk. Modification of products. Temporary action. Manufacturer's Documentation 2025-060455 - Biofire Diagnostics LLC - FSN

Date: 16/07/2025

**Title:** [Gripo - Hepro AS](https://www.lakemedelsverket.se/sv/nyheter/gripo---hepro-as)

Summary: Product: Gripo Manufacturer: HEPRO AS Manufacturer's reference number: 20250513 The Swedish Medicines Agency's reference number: 6.6.2-2025-040594 Summary: Information on use risk. Modification of operating instructions. Manufacturer's documentation 2025-040594 - Hepro AS - FSN

Date: 16/07/2025

**Title:** [Instrument carriers at DA Vinci X and XI systems- intuitive surgical, Inc.](https://www.lakemedelsverket.se/sv/nyheter/instrumentbarare-pa-da-vinci-x--och-xi-system---intuitive-surgical-inc)

Summary: Product: Instrument carriers on Da Vinci X and XI systems  
Manufacturer: Intuitive Surgical, Inc.

Date: 15/07/2025

**Title:** [SOLUSCOPE SERIE 4 - Soluscope SAS](https://www.lakemedelsverket.se/sv/nyheter/soluscope-serie-4---soluscope-sas3)

Summary: Product: Soluscope Series 4 Manufacturers: Soluscope SAS Manufacturer's reference number: SLC-FSCA-003 The Swedish Medicines Agency's reference number: 6.6.2-2025-060263 Summary: Information on use risk. Modification of operating instructions. Manufacturer's documentation 2025-060263 - Soluscope SAS - FSN

Date: 15/07/2025

**Title:** [Cardiosave Hybrid och Cardiosave Rescue aortaballongpump (IABP) - Datascope Corp](https://www.lakemedelsverket.se/sv/nyheter/cardiosave-hybrid-och-cardiosave-rescue-aortaballongpump-iabp---datascope-corp)

Summary: Product: Cardiosave Hybrid and Cardiosave Rescue aortic balloon pump (IABP) Manufacturer: DataScope Corp. Manufacturer's reference number: 2249723-06/02/2023-013-C Medicines Agency's reference number: 6.6.2-2023-66444 Summary: Information on use risk. Modification of products. Temporary action. Follow -up security notice. Manufacturer's documentation 2023-66444 - Datascope Corp - May 2025 FSN Related Information This Security Message Has New/Updated Information and is a complement to the message published September 15, 2023. Previous Security Message - Cardiosave Hybrid and Cardiosave Rescue Aortic Pump (IABP) -

Date: 15/07/2025

**Title:** [CROSS Hemi Shoulder - Camp Scandianvia AB](https://www.lakemedelsverket.se/sv/nyheter/cross-hemi-shoulder---camp-scandianvia-ab)

Summary: Product: Cross Hemi Shoulder Manufacturer: Camp Scandianvia AB Manufacturer's reference number: QS#1124FSCA Medicines Agency's reference number: 6.6.2-2025-057963 Summary: Information on use risk. Modification of operating instructions. Follow -up security notice. Manufacturer's documentation 2025-057963 - Camp Scandianvia AB - July 2025 Replacement FSN Related Information This security message replaces a previous security message on this product. Previous Security Message - Cross Hemi Shoulder - Camp Scandianvia AB

Date: 15/07/2025

**Title:** [Sectra RIS – Sectra AB](https://www.lakemedelsverket.se/sv/nyheter/sectra-ris--sectra-ab)

Summary: Product: Sectra Ris Manufacturer: Sectra AB Manufacturer's reference number: DOC-Lhen-DJ5JK3 Medicines Agency's reference number: 6.6.2-2025-058262 Summary: Information on use risk. Modification of software. Manufacturer's documentation 2025-058262 - Sectra AB - FSN

Date: 15/07/2025

**Title:** [Ambu Spur II - Ambu A / s](https://www.lakemedelsverket.se/sv/nyheter/ambu-spur-ii---ambu-as)

Summary: Product: Ambu Spur II Manufacturer: Ambu A/S Manufacturer's reference number: Ambu2025FA00002 Medicines Agency's reference number: 6.6.2-2025-056506 Summary: Products shall be taken out of use Manufacturer's documentation 2025-056506-Ambu AS-FSN

Date: 15/07/2025

**Title:** [Automated Impella control unit - Abiomed Inc.](https://www.lakemedelsverket.se/sv/nyheter/automatiserad-impella-styrenhet---abiomed-inc)

Summary: Product: Automated Impella controller (AIC) Manufacturer: Abiomed Inc. Manufacturer's reference number: 2025-FA-0000103 The Swedish Medicines Agency's reference number: 6.6.2-2025-053781 Summary: Information on use risk. Manufacturer's documentation 2025-053781 - Abiomed Inc - FSN

Date: 15/07/2025

**Title:** [CATCHVIEW - BALT EXTRUSION SAS](https://www.lakemedelsverket.se/sv/nyheter/catchview---balt-extrusion-sas)

Summary: Product: CatchView (Catchvmini20, Tromboembolectomy Product) Manufacturer: Balt Extrusion SAS Manufacturer's reference number: HHHHE2025006 The Swedish Medicines Agency's reference number: 6.6.2-2025-055715 Summary: Products to be recalled. Manufacturer's documentation 2025-055715 - Balt Extrusion SAS - FSN

Date: 15/07/2025

**Title:** [MS -DC35, 3.5 mm x 5 "Drill with quick coupling - Acumed LLC](https://www.lakemedelsverket.se/sv/nyheter/ms-dc35-35-mm-x-5-borr-med-snabbkoppling---acumed-llc)

Summary: Product: MS-DC35, 3.5 mm x 5 "Drill with quick coupling Manufacturer: Acumed LLC Manufacturer's reference number: R25-003 The Swedish Medicines Agency's reference number: 6.6.2-2025-055284 Summary: Products shall be withdrawn. The manufacturer's documentation 2025-055284-Acumed LLC-

Date: 15/07/2025

**Title:** [Covidie Nellcor Bedside Monitor for Monitoring Patients Spo2 - Covidie LLC](https://www.lakemedelsverket.se/sv/nyheter/covidien-nellcor-bedside-monitor-for-overvakning-av-patients-spo2---covidien-llc)

Summary: Product: Covidien Nellcor Bedside Monitor for monitoring Patient's Spo2 Manufacturer: Covidien LLC Manufacturer's reference number: FA1489 The Swedish Medicines Agency's reference number: 6.6.2-2025-054712 Summary: Information on use risk. Modification of operating instructions. Temporary action. Manufacturer's documentation 2025-054712 - Covidia LLC - FSN

Date: 15/07/2025

**Title:** [SureTek Burr Hole Cover Kit - Boston Scientific Neuromodulation Corporation](https://www.lakemedelsverket.se/sv/nyheter/suretek-burr-hole-cover-kit---boston-scientific-neuromodulation-corporation)

Summary: Product: Suretek Burr Hole Cover Kit Manufacturer: Boston Scientific Neuromodulation Corporation Manufacturer's reference number: 97049464 The Swedish Medicines Agency's reference number: 6.6.2-2025-059631 Summary: Information on use risk. Modification of operating instructions. Manufacturer's documentation 2025-059631 - Boston Scientific Neuromodulation Corporation - FSN

Date: 15/07/2025

**Title:** [Vercise Genus implanterbar pulsgenerator (IPG) - Boston Scientific Neuromodulation Corporation](https://www.lakemedelsverket.se/sv/nyheter/vercise-genus-implanterbar-pulsgenerator-ipg---boston-scientific-neuromodulation-corporation2)

Summary: Manufacturer: Boston Scientific Neuromodulation Corporation Manufacturer's reference number: 97222956-FA Medicines Agency's reference number: 6.6.2-2024-068678 Summary: Information on use risk. Modification of operating instructions. Follow -up security notice. Manufacturer's documentation 2024-068678 - Boston Scientific Neuromodulation Corporation - FSN July 2025 Related Information This Security Message has new/updated information and is a complement to the message published on August 12, 2024. Previous Security Message - Vercise Genus Implantable Core Generator (IPG) - Boston Scenos

Date: 15/07/2025

**Title:** [PRAC's review of rare, known risk with chickenpox vaccines completed](https://www.lakemedelsverket.se/sv/nyheter/pracs-granskning-av-sallsynt-kand-risk-med-vattkoppsvaccciner-avslutad)

Summary: This also applies to combination vaccine containing vaccines against chickenpox. Those who receive the vaccine should seek medical help if they experience signs of infection or brain inflammation. Further information The vaccines are not suitable for people with impaired immune systems. The updated product information will provide more information about the known side effect of brain inflammation, which has been observed in conjunction with live weakened chickenpox vaccines, in some cases with fatal outcome. Related Information Highlights from the PRAC meeting 7–10 July 2025 (English) Prac Reviews known, very rare risk with chickenpox vaccines

Date: 14/07/2025

**Title:** [The restriction of vaccination with ixchiq to people who are 65 years and older repealed](https://www.lakemedelsverket.se/sv/nyheter/begransningen-av-vaccinering-med-ixchiq-till-personer-som-ar-65-ar-och-aldre-upphavd)

Summary: The previously temporary restriction on vaccination of persons 65 years and older has now been lifted.

Date: 14/07/2025

**Title:** [Svalgtuber - IntersurgicaL Ltd.](https://www.lakemedelsverket.se/sv/nyheter/svalgtuber---intersurgical-ltd)

Summary: Product: Svalgt tuber Manufacturer: Intersurgical Ltd. Manufacturer's reference number: CAR196 The Swedish Medicines Agency's reference number: 6.6.2-2025-051114 Summary: Products must be taken out of use. Manufacturer's documentation 2025-051114 - Intersurgical Ltd - FSN

Date: 11/07/2025

**Title:** [Cosmic 3.12, 4.0 and 4.1 - Cambio Healthcare Systems AB](https://www.lakemedelsverket.se/sv/nyheter/cosmic-3.12-4.0-och-42.1--cambio-healthcare-systems-ab)

Summary: Product: Cosmic 3.12, 4.0 and 4.1 Manufacturers: Cambio Healthcare Systems AB Manufacturer's reference number: VIG-556 Medicines Agency's reference number: 6.6.2-2025-058825 Summary: Information on use risk. Modification of software. Manufacturer's documentation 2025-058825 - Cambio Healthcare Systems AB - FSN

Date: 11/07/2025

**Title:** [Carotid WALLSTENT Monorail Endoprotes - Boston Scientific Corporation](https://www.lakemedelsverket.se/sv/nyheter/carotid-wallstent-monorail-endoprotes---boston-scientific-corporation)

Summary: Product: Carotid Wallstent Monorail Endoprotes Manufacturer: Boston Scientific Corporation Manufacturer's reference number: 97434080 The Swedish Medicines Agency's reference number: 6.6.2-2025-05879 Summary: Products must be revoked. Manufacturer's documentation 2025-058879 - Boston Scientific Corporation - FSN

Date: 11/07/2025

**Title:** [Philips Allura R8.2.x-system - Philips Medical Systems Nederland BV](https://www.lakemedelsverket.se/sv/nyheter/philips-allura-r8.2.x-system---philips-medical-systems-nederland-bv)

Summary: Product: Allura R8.2.X, which is equipped with a Certeray X-ray generator Manufacturer: Philips Medical Systems Nederland BV Manufacturer's reference number: 2025-BST-002 Medicines Agency's reference number: 6.6.2-2025-058644: Information on use risk information. Modification of software. Temporary action. Manufacturer's documentation 2025-058644 - Philips Medical Systems Nederland BV - FSN

Date: 11/07/2025

**Title:** [MR system with 60 cm wide opening (Intera, Achieva, Ingenia CX, SmartPath to Dstream) - Philips Healthcare](https://www.lakemedelsverket.se/sv/nyheter/mr-system-med-60-cm-bred-oppning-intera-achieva-ingenia-cx-smartpath-to-dstream---philips-healthcare2)

Summary: Product: MR system with 60 cm wide opening (Intera, Achieva, Ingenia CX, SmartPath To Dream) Manufacturer: Philips Healthcare Manufacturer's reference number: 2023-PD-MR-013 The Swedish Medicines Agency's reference number: 6.6.2-2024-2291 Summary: Information on usage risk. Modification of products. Temporary action. Follow -up security notice. Manufacturer's documentation 2024-2291 - Philips Healthcare - July 2025 FSN Related Information This Security Message has new/updated information and is a complement to the message published February 6, 2024. Previous security message - MR system with 60 cm wide opening (Intera, Achieva, Ingenia C, SmartPateh) - Phili

Date: 11/07/2025

**Title:** [Deficiency situation for zypadhera](https://www.lakemedelsverket.se/sv/nyheter/bristsituation-for-zypadhera)

Summary: In the spring, the Swedish Medicines Agency received information that there could be a temporary shortage of Zypadhera, which we published a news on April 11. According to the initial forecasts from the company, the situation would stabilize during the summer, but the problems with the asset have continued. The drug is used for maintenance treatment of adult patients with schizophrenia stabilized during urgent treatment with oral olanzapine. In general, deficiency situations can usually be solved with dispensation or licensed drugs. For Zypadhera, the lack is global, which limits those opportunities. Advice to prescribers Avoid new deposits of Zypadhera. Avoid drugs to waste, for example, when preparing the syringe. For patients with good compliance ...

Date: 08/07/2025

**Title:** [Cosmic 3.12, 4.0 including 4.1 - Cambio Healthcare Systems](https://www.lakemedelsverket.se/sv/nyheter/cosmic-3.12-4.0-samt-4.1--cambio-healthcare-systems-ab)

Summary: Product: Cosmic 3.12, 4.0 and 4.1 Manufacturer: Cambio Healthcare Systems AB Manufacturer's reference number: VIG-555 The Swedish Medicines Agency's reference number: 6.6.2-2025-058297 Summary: Information on use risk. Modification of software. Manufacturer's documentation 2025-058297 - Cambio Healthcare Systems AB - FSN

Date: 08/07/2025

**Title:** [Now the decision is made - Swetrial will become a reality!](https://www.lakemedelsverket.se/sv/nyheter/nu-ar-beslutet-fattat---swetrial-ska-bli-verklighet)

Summary: Swetrial is a new national partnership for clinical trials.

Date: 31/07/2025

**Title:** [New injection to prevent HIV infection in the EU and globally](https://www.lakemedelsverket.se/sv/nyheter/ny-injektion-for-att-forebygga-hiv-infektion-i-eu-och-globalt)

Summary: Lenacapavir, which is marketed under the name YEYTUO, is a drug that binds to the proteins in the HIV virus's outer shell and prevents the virus's ability to reproduce.

Date: 28/07/2025

**Title:** [Cosmic 3.12, 4.0 including 4.1.1 - Cambio Healthcare Systems](https://www.lakemedelsverket.se/sv/nyheter/cosmic-3.12-4.0-samt-4.1.1--cambio-healthcare-systems-ab)

Summary: Product: Cosmic 3.12, 4.0 and 4.1.1 Manufacturer: Cambio Healthcare Systems AB Manufacturer's reference number: VIG-557 The Swedish Medicines Agency's reference number: 6.6.2-2025-061115 Summary: Information on use risk. Modification of software. Manufacturer's documentation 2025-061115 - Cambio Healthcare Systems AB - FSN

Date: 16/07/2025

**Title:** [Cosmic 3.12 – Cambio Healthcare Systems AB](https://www.lakemedelsverket.se/sv/nyheter/cosmic-3.12--cambio-healthcare-systems-ab)

Summary: Product: Cosmic 3.12 Manufacturer: Cambio Healthcare Systems AB Manufacturer's reference number: VIG-578 The Swedish Medicines Agency's reference number: 6.6.2-2025-061161 Summary: Information on use risk. Modification of software. Manufacturer's documentation 2025-061161 - Cambio Healthcare Systems AB - FSN

Date: 16/07/2025

**Title:** [BIOFIRE FILMARRAY TORCH-system - BioFire Diagnosticss, LLC](https://www.lakemedelsverket.se/sv/nyheter/biofire-filmarray-torch-system---biofire-diagnosticss-llc2)

Summary: Product: Biofire Filmarray Torch system Manufacturer: Biofire Diagnostics, LLC Manufacturer's reference number: FSCA 5761-3 The Swedish Medicines Agency's reference number: 6.6.2-2025-060455 Summary: Information on use risk. Modification of products. Temporary action. Manufacturer's Documentation 2025-060455 - Biofire Diagnostics LLC - FSN

Date: 16/07/2025

**Title:** [Gripo - Hepro AS](https://www.lakemedelsverket.se/sv/nyheter/gripo---hepro-as)

Summary: Product: Gripo Manufacturer: HEPRO AS Manufacturer's reference number: 20250513 The Swedish Medicines Agency's reference number: 6.6.2-2025-040594 Summary: Information on use risk. Modification of operating instructions. Manufacturer's documentation 2025-040594 - Hepro AS - FSN

Date: 16/07/2025

**Title:** [Instrument carriers at DA Vinci X and XI systems- intuitive surgical, Inc.](https://www.lakemedelsverket.se/sv/nyheter/instrumentbarare-pa-da-vinci-x--och-xi-system---intuitive-surgical-inc)

Summary: Product: Instrument carriers on Da Vinci X and XI systems  
Manufacturer: Intuitive Surgical, Inc.

Date: 15/07/2025

**Title:** [SOLUSCOPE SERIE 4 - Soluscope SAS](https://www.lakemedelsverket.se/sv/nyheter/soluscope-serie-4---soluscope-sas3)

Summary: Product: Soluscope Series 4 Manufacturers: Soluscope SAS Manufacturer's reference number: SLC-FSCA-003 The Swedish Medicines Agency's reference number: 6.6.2-2025-060263 Summary: Information on use risk. Modification of operating instructions. Manufacturer's documentation 2025-060263 - Soluscope SAS - FSN

Date: 15/07/2025

**Title:** [Cardiosave Hybrid och Cardiosave Rescue aortaballongpump (IABP) - Datascope Corp](https://www.lakemedelsverket.se/sv/nyheter/cardiosave-hybrid-och-cardiosave-rescue-aortaballongpump-iabp---datascope-corp)

Summary: Product: Cardiosave Hybrid and Cardiosave Rescue aortic balloon pump (IABP) Manufacturer: DataScope Corp. Manufacturer's reference number: 2249723-06/02/2023-013-C Medicines Agency's reference number: 6.6.2-2023-66444 Summary: Information on use risk. Modification of products. Temporary action. Follow -up security notice. Manufacturer's documentation 2023-66444 - Datascope Corp - May 2025 FSN Related Information This Security Message Has New/Updated Information and is a complement to the message published September 15, 2023. Previous Security Message - Cardiosave Hybrid and Cardiosave Rescue Aortic Pump (IABP) -

Date: 15/07/2025

**Title:** [CROSS Hemi Shoulder - Camp Scandianvia AB](https://www.lakemedelsverket.se/sv/nyheter/cross-hemi-shoulder---camp-scandianvia-ab)

Summary: Product: Cross Hemi Shoulder Manufacturer: Camp Scandianvia AB Manufacturer's reference number: QS#1124FSCA Medicines Agency's reference number: 6.6.2-2025-057963 Summary: Information on use risk. Modification of operating instructions. Follow -up security notice. Manufacturer's documentation 2025-057963 - Camp Scandianvia AB - July 2025 Replacement FSN Related Information This security message replaces a previous security message on this product. Previous Security Message - Cross Hemi Shoulder - Camp Scandianvia AB

Date: 15/07/2025

**Title:** [Sectra RIS – Sectra AB](https://www.lakemedelsverket.se/sv/nyheter/sectra-ris--sectra-ab)

Summary: Product: Sectra Ris Manufacturer: Sectra AB Manufacturer's reference number: DOC-Lhen-DJ5JK3 Medicines Agency's reference number: 6.6.2-2025-058262 Summary: Information on use risk. Modification of software. Manufacturer's documentation 2025-058262 - Sectra AB - FSN

Date: 15/07/2025

**Title:** [Ambu Spur II - Ambu A / s](https://www.lakemedelsverket.se/sv/nyheter/ambu-spur-ii---ambu-as)

Summary: Product: Ambu Spur II Manufacturer: Ambu A/S Manufacturer's reference number: Ambu2025FA00002 Medicines Agency's reference number: 6.6.2-2025-056506 Summary: Products shall be taken out of use Manufacturer's documentation 2025-056506-Ambu AS-FSN

Date: 15/07/2025

**Title:** [Automated Impella control unit - Abiomed Inc.](https://www.lakemedelsverket.se/sv/nyheter/automatiserad-impella-styrenhet---abiomed-inc)

Summary: Product: Automated Impella controller (AIC) Manufacturer: Abiomed Inc. Manufacturer's reference number: 2025-FA-0000103 The Swedish Medicines Agency's reference number: 6.6.2-2025-053781 Summary: Information on use risk. Manufacturer's documentation 2025-053781 - Abiomed Inc - FSN

Date: 15/07/2025

**Title:** [CATCHVIEW - BALT EXTRUSION SAS](https://www.lakemedelsverket.se/sv/nyheter/catchview---balt-extrusion-sas)

Summary: Product: CatchView (Catchvmini20, Tromboembolectomy Product) Manufacturer: Balt Extrusion SAS Manufacturer's reference number: HHHHE2025006 The Swedish Medicines Agency's reference number: 6.6.2-2025-055715 Summary: Products to be recalled. Manufacturer's documentation 2025-055715 - Balt Extrusion SAS - FSN

Date: 15/07/2025

**Title:** [MS -DC35, 3.5 mm x 5 "Drill with quick coupling - Acumed LLC](https://www.lakemedelsverket.se/sv/nyheter/ms-dc35-35-mm-x-5-borr-med-snabbkoppling---acumed-llc)

Summary: Product: MS-DC35, 3.5 mm x 5 "Drill with quick coupling Manufacturer: Acumed LLC Manufacturer's reference number: R25-003 The Swedish Medicines Agency's reference number: 6.6.2-2025-055284 Summary: Products shall be withdrawn. The manufacturer's documentation 2025-055284-Acumed LLC-

Date: 15/07/2025

**Title:** [Covidie Nellcor Bedside Monitor for Monitoring Patients Spo2 - Covidie LLC](https://www.lakemedelsverket.se/sv/nyheter/covidien-nellcor-bedside-monitor-for-overvakning-av-patients-spo2---covidien-llc)

Summary: Product: Covidien Nellcor Bedside Monitor for monitoring Patient's Spo2 Manufacturer: Covidien LLC Manufacturer's reference number: FA1489 The Swedish Medicines Agency's reference number: 6.6.2-2025-054712 Summary: Information on use risk. Modification of operating instructions. Temporary action. Manufacturer's documentation 2025-054712 - Covidia LLC - FSN

Date: 15/07/2025

**Title:** [SureTek Burr Hole Cover Kit - Boston Scientific Neuromodulation Corporation](https://www.lakemedelsverket.se/sv/nyheter/suretek-burr-hole-cover-kit---boston-scientific-neuromodulation-corporation)

Summary: Product: Suretek Burr Hole Cover Kit Manufacturer: Boston Scientific Neuromodulation Corporation Manufacturer's reference number: 97049464 The Swedish Medicines Agency's reference number: 6.6.2-2025-059631 Summary: Information on use risk. Modification of operating instructions. Manufacturer's documentation 2025-059631 - Boston Scientific Neuromodulation Corporation - FSN

Date: 15/07/2025

**Title:** [Vercise Genus implanterbar pulsgenerator (IPG) - Boston Scientific Neuromodulation Corporation](https://www.lakemedelsverket.se/sv/nyheter/vercise-genus-implanterbar-pulsgenerator-ipg---boston-scientific-neuromodulation-corporation2)

Summary: Manufacturer: Boston Scientific Neuromodulation Corporation Manufacturer's reference number: 97222956-FA Medicines Agency's reference number: 6.6.2-2024-068678 Summary: Information on use risk. Modification of operating instructions. Follow -up security notice. Manufacturer's documentation 2024-068678 - Boston Scientific Neuromodulation Corporation - FSN July 2025 Related Information This Security Message has new/updated information and is a complement to the message published on August 12, 2024. Previous Security Message - Vercise Genus Implantable Core Generator (IPG) - Boston Scenos

Date: 15/07/2025

**Title:** [PRAC's review of rare, known risk with chickenpox vaccines completed](https://www.lakemedelsverket.se/sv/nyheter/pracs-granskning-av-sallsynt-kand-risk-med-vattkoppsvaccciner-avslutad)

Summary: This also applies to combination vaccine containing vaccines against chickenpox. Those who receive the vaccine should seek medical help if they experience signs of infection or brain inflammation. Further information The vaccines are not suitable for people with impaired immune systems. The updated product information will provide more information about the known side effect of brain inflammation, which has been observed in conjunction with live weakened chickenpox vaccines, in some cases with fatal outcome. Related Information Highlights from the PRAC meeting 7–10 July 2025 (English) Prac Reviews known, very rare risk with chickenpox vaccines

Date: 14/07/2025

**Title:** [The restriction of vaccination with ixchiq to people who are 65 years and older repealed](https://www.lakemedelsverket.se/sv/nyheter/begransningen-av-vaccinering-med-ixchiq-till-personer-som-ar-65-ar-och-aldre-upphavd)

Summary: The previously temporary restriction on vaccination of persons 65 years and older has now been lifted.

Date: 14/07/2025

**Title:** [Svalgtuber - IntersurgicaL Ltd.](https://www.lakemedelsverket.se/sv/nyheter/svalgtuber---intersurgical-ltd)

Summary: Product: Svalgt tuber Manufacturer: Intersurgical Ltd. Manufacturer's reference number: CAR196 The Swedish Medicines Agency's reference number: 6.6.2-2025-051114 Summary: Products must be taken out of use. Manufacturer's documentation 2025-051114 - Intersurgical Ltd - FSN

Date: 11/07/2025

**Title:** [Cosmic 3.12, 4.0 and 4.1 - Cambio Healthcare Systems AB](https://www.lakemedelsverket.se/sv/nyheter/cosmic-3.12-4.0-och-42.1--cambio-healthcare-systems-ab)

Summary: Product: Cosmic 3.12, 4.0 and 4.1 Manufacturers: Cambio Healthcare Systems AB Manufacturer's reference number: VIG-556 Medicines Agency's reference number: 6.6.2-2025-058825 Summary: Information on use risk. Modification of software. Manufacturer's documentation 2025-058825 - Cambio Healthcare Systems AB - FSN

Date: 11/07/2025

**Title:** [Carotid WALLSTENT Monorail Endoprotes - Boston Scientific Corporation](https://www.lakemedelsverket.se/sv/nyheter/carotid-wallstent-monorail-endoprotes---boston-scientific-corporation)

Summary: Product: Carotid Wallstent Monorail Endoprotes Manufacturer: Boston Scientific Corporation Manufacturer's reference number: 97434080 The Swedish Medicines Agency's reference number: 6.6.2-2025-05879 Summary: Products must be revoked. Manufacturer's documentation 2025-058879 - Boston Scientific Corporation - FSN

Date: 11/07/2025

**Title:** [Philips Allura R8.2.x-system - Philips Medical Systems Nederland BV](https://www.lakemedelsverket.se/sv/nyheter/philips-allura-r8.2.x-system---philips-medical-systems-nederland-bv)

Summary: Product: Allura R8.2.X, which is equipped with a Certeray X-ray generator Manufacturer: Philips Medical Systems Nederland BV Manufacturer's reference number: 2025-BST-002 Medicines Agency's reference number: 6.6.2-2025-058644: Information on use risk information. Modification of software. Temporary action. Manufacturer's documentation 2025-058644 - Philips Medical Systems Nederland BV - FSN

Date: 11/07/2025

**Title:** [MR system with 60 cm wide opening (Intera, Achieva, Ingenia CX, SmartPath to Dstream) - Philips Healthcare](https://www.lakemedelsverket.se/sv/nyheter/mr-system-med-60-cm-bred-oppning-intera-achieva-ingenia-cx-smartpath-to-dstream---philips-healthcare2)

Summary: Product: MR system with 60 cm wide opening (Intera, Achieva, Ingenia CX, SmartPath To Dream) Manufacturer: Philips Healthcare Manufacturer's reference number: 2023-PD-MR-013 The Swedish Medicines Agency's reference number: 6.6.2-2024-2291 Summary: Information on usage risk. Modification of products. Temporary action. Follow -up security notice. Manufacturer's documentation 2024-2291 - Philips Healthcare - July 2025 FSN Related Information This Security Message has new/updated information and is a complement to the message published February 6, 2024. Previous security message - MR system with 60 cm wide opening (Intera, Achieva, Ingenia C, SmartPateh) - Phili

Date: 11/07/2025

**Title:** [Deficiency situation for zypadhera](https://www.lakemedelsverket.se/sv/nyheter/bristsituation-for-zypadhera)

Summary: In the spring, the Swedish Medicines Agency received information that there could be a temporary shortage of Zypadhera, which we published a news on April 11. According to the initial forecasts from the company, the situation would stabilize during the summer, but the problems with the asset have continued. The drug is used for maintenance treatment of adult patients with schizophrenia stabilized during urgent treatment with oral olanzapine. In general, deficiency situations can usually be solved with dispensation or licensed drugs. For Zypadhera, the lack is global, which limits those opportunities. Advice to prescribers Avoid new deposits of Zypadhera. Avoid drugs to waste, for example, when preparing the syringe. For patients with good compliance ...

Date: 08/07/2025

**Title:** [Cosmic 3.12, 4.0 including 4.1 - Cambio Healthcare Systems](https://www.lakemedelsverket.se/sv/nyheter/cosmic-3.12-4.0-samt-4.1--cambio-healthcare-systems-ab)

Summary: Product: Cosmic 3.12, 4.0 and 4.1 Manufacturer: Cambio Healthcare Systems AB Manufacturer's reference number: VIG-555 The Swedish Medicines Agency's reference number: 6.6.2-2025-058297 Summary: Information on use risk. Modification of software. Manufacturer's documentation 2025-058297 - Cambio Healthcare Systems AB - FSN

Date: 08/07/2025

**Title:** [Heartsine Samaritan PAD 350P/360P/450P/500P – Medical (Heartsine Technologies Ltd.)](https://www.lakemedelsverket.se/sv/nyheter/heartsine-samaritan-pad-350p360p450p500p--medical-heartsine-technologies-ltd)

Summary: Product: HeartSine Samaritan Pad 350p/360p/450p/500p Manufacturer: Medical (Heartsine Technologies Ltd.) Manufacturer's reference number: RA2025-3977961 FA318 The Swedish Medicines Agency's reference number: 6.6.2-2025-05226977977979797961 Modification of products. Manufacturer's documentation 2025-052697 - Medical Heartsine Technologies Ltd - FSN

Date: 08/07/2025

**Title:** [Codman disposable perforator 14 mm - integra lifesciences mansfield](https://www.lakemedelsverket.se/sv/nyheter/codman-engangsperforator-14-mm--integra-lifesciences-mansfield)

Summary: Product: Codman disposable perforator 14 mm Manufacturer: integra lifesciences Mansfield Manufacturer's reference number: 2024-HHHE-022B Medicines Agency's reference number: 6.6.2-2025-032327 Summary: Products are recalled. Manufacturer's documentation 2025-032327 - Integra Lifesciences Mansfield - FSN

Date: 08/07/2025

**Title:** [3mensio Workstation (Vascular – Fenestrated) - Pie Medical Imaging B.V.](https://www.lakemedelsverket.se/sv/nyheter/3mensio-workstation-vascular--fenestrated---pie-medical-imaging-b.v)

Summary: Product: 3mensio Workstation (Vascular - Fenestrated) Manufacturer: Pie Medical Imaging B.V. Manufacturer's reference number: FSN HDC-2545 The Swedish Medicines Agency's reference number: 6.6.2-2025-056164 Summary: Information on use risk. Modification of software. Temporary action. Manufacturer's documentation 2025-056164 - PIE Medical Imaging B V - FSN

Date: 08/07/2025

**Title:** [TOPRA IN Benelux Steering Group event in partnership with FAMHP](https://www.topra.org/TOPRA/TOPRA_Member/News_Folder/2025/TOPRA_IN_Benelux_FAMHP.aspx)

Summary: On 12 June, Belgium’s Federal Agency for Medicines and Health Products (FAMHP) warmly welcomed members of the TOPRA IN Benelux Steering Group, alongside TOPRA members, non-members and UK-based TOPRA staff to their offices in Brussels.

Date: 30/07/2025

**Title:** [TOPRA announces new Chief Executive](https://www.topra.org/TOPRA/TOPRA_Member/News_Folder/2025/TOPRA_announces_new_Chief_Executive.aspx)

Summary: TOPRA’s Board of Directors has appointed Dr Samantha Atkinson as its new Chief Executive. Sam succeeds interim Chief Executive John Wilkinson OBE and is now in post.

Date: 09/06/2025

**Title:** [TOPRA and RAPS partner to host two London conferences this November](https://www.topra.org/TOPRA/TOPRA_Member/News_Folder/2025/TOPRA_RAPS.aspx)

Summary: The Organisation for Professionals in Regulatory Affairs (TOPRA) and the Regulatory Affairs Professionals Society (RAPS) have announced that they will jointly host two new conferences for November 2025 at the Hilton London Wembley, UK.

Date: 07/07/2025

**Title:** [Breastfeeding in Indonesia on the rise, but mothers need more support](https://www.who.int/news/item/01-08-2025-breastfeeding-in-indonesia-on-the-rise--but-mothers-need-more-support)

Summary: Jakarta, 1 August 2025 – As Indonesia commemorates World Breastfeeding Week 2025, UNICEF and the World Health Organization (WHO) are highlighting the importance of strengthening support systems for breastfeeding mothers across the country.

Date: 01/08/2025

**Title:** [IPC Gaza Strip Food Insecurity and Malnutrition Alert](https://www.who.int/news/item/29-07-2025-ipc-gaza-strip-food-insecurity-and-malnutrition-alert)

Summary: The Integrated Food Security Phase Classification (IPC), of which WHO is a member, today issued a Food Insecurity and Malnutrition Alert for the Gaza Strip.

Date: 29/07/2025

**Title:** [Statement of the Forty-second meeting of the Polio IHR Emergency Committee](https://www.who.int/news/item/28-07-2025-statement-of-the-forty-second-meeting-of-the-polio-ihr-emergency-committee)

Summary: The Forty-second meeting of the Emergency Committee under the International Health Regulations (2005) (IHR) on the international spread of poliovirus was convened by the WHO Director-General on 18 June 2025 with committee members and advisers meeting via video conference with affected countries, supported by the WHO Secretariat.

Date: 28/07/2025

**Title:** [Global hunger declines, but rises in Africa and western Asia: UN report](https://www.who.int/news/item/28-07-2025-global-hunger-declines-but-rises-in-africa-and-western-asia-un-report)

Summary: An estimated 8.2 percent of the global population, or about 673 million people, experienced hunger in 2024, down from 8.5 percent in 2023 and 8.7 percent in 2022.

Date: 28/07/2025

**Title:** [WHO urges action on hepatitis, announcing hepatitis D as carcinogenic](https://www.who.int/news/item/28-07-2025-who-urges-action-on-hepatitis-announcing-hepatitis-d-as-carcinogenic)

Summary: As we mark World Hepatitis Day, WHO calls on governments and partners to urgently accelerate efforts to eliminate viral hepatitis as a public health threat and reduce liver cancer deaths.

Date: 28/07/2025

**Title:** [Malnutrition rates reach alarming levels in Gaza, WHO warns](https://www.who.int/news/item/27-07-2025-malnutrition-rates-reach-alarming-levels-in-gaza--who-warns)

Summary: Malnutrition is on a dangerous trajectory in the Gaza Strip, marked by a spike in deaths in July.

Date: 27/07/2025

**Title:** [Timor-Leste certified malaria-free by WHO](https://www.who.int/news/item/24-07-2025-timor-leste-certified-malaria-free-by-who)

Summary: The World Health Organization (WHO) has certified Timor-Leste as malaria-free, a remarkable achievement for a country that prioritized the disease and embarked on a concerted, nation-wide response shortly after gaining independence in 2002.

Date: 24/07/2025

**Title:** [WHO operations compromised following attacks on warehouse and facility sheltering staff and families in Deir al Balah, Gaza](https://www.who.int/news/item/21-07-2025-who-operations-compromised-following-attacks-on-warehouse-and-facility-sheltering-staff-and-families-in-deir-al-balah)

Summary: WHO condemns in the strongest terms the attacks on a building housing WHO staff in Deir al Balah in Gaza, the mistreatment of those sheltering there, and the destruction of its main warehouse.

Date: 21/07/2025

**Title:** [Senegal joins growing list of countries that have eliminated trachoma](https://www.who.int/news/item/15-07-2025-senegal-joins-growing-list-of-countries-that-have-eliminated-trachoma)

Summary: The World Health Organization (WHO) has validated Senegal as having eliminated trachoma as a public health problem.

Date: 15/07/2025

**Title:** [Global childhood vaccination coverage holds steady, yet over 14 million infants remain unvaccinated – WHO, UNICEF](https://www.who.int/news/item/15-07-2025-global-childhood-vaccination-coverage-holds-steady-yet-over-14-million-infants-remain-unvaccinated-who-unicef)

Summary: In 2024, 89% of infants globally – about 115 million – received at least one dose of the diphtheria, tetanus and pertussis (DTP)-containing vaccine, and 85% – roughly 109 million – completed all three doses, according to new national immunization coverage data released today by the World Health Organization (WHO) and UNICEF. Compared to 2023, around 171 000 more children received at least one vaccine, and one million more completed the full three-dose DTP series. While the gains are modest, they signal continued progress by countries working to protect children, even amid growing challenges. Still, nearly 20 million infants missed...

Date: 15/07/2025

**Title:** [WHO recommends injectable lenacapavir for HIV prevention](https://www.who.int/news/item/14-07-2025-who-recommends-injectable-lenacapavir-for-hiv-prevention)

Summary: The World Health Organization (WHO) released today new guidelines recommending the use of injectable lenacapavir (LEN) twice a year as an additional pre-exposure prophylaxis (PrEP) option for HIV prevention, in a landmark policy action that could help reshape the global HIV response.

Date: 14/07/2025

**Title:** [Joint statement by OCHA, UNDP, UNFPA, UNOPS, UNRWA, WFP and WHO on fuel shortage in Gaza](https://www.who.int/news/item/12-07-2025-joint-statement-by-ocha--undp--unfpa--unops--unrwa--wfp-and-who-on-fuel-shortage-in-gaza)

Summary: The United Nations warns that the fuel shortage in Gaza has reached critical levels.

Date: 12/07/2025

**Title:** [World leaders recognized for championing the WHO Pandemic Agreement](https://www.who.int/news/item/11-07-2025-world-leaders-recognized-for-championing-the-who-pandemic-agreement)

Summary: The World Health Organization has formally recognized the pivotal role of a number of heads of state and government in securing the adoption of the WHO Pandemic Agreement by the Seventy-eighth World Health Assembly in May 2025.

Date: 11/07/2025

**Title:** [Burundi eliminates trachoma as a public health problem](https://www.who.int/news/item/11-07-2025-burundi-eliminates-trachoma-as-a-public-health-problem)

Summary: The World Health Organization (WHO) has validated Burundi as having eliminated trachoma as a public health problem, making it the eighth country in WHO’s African Region to reach this important milestone.

Date: 11/07/2025

**Title:** [WHO, ITU, WIPO showcase a new report on AI use in traditional medicine](https://www.who.int/news/item/11-07-2025-who--itu--wipo-showcase-a-new-report-on-ai-use-in-traditional-medicine)

Summary: Artificial intelligence (AI) is ushering in a transformative era for traditional medicine, one where centuries-old healing systems are enhanced by cutting-edge technologies to deliver more safe, personalized, effective, and accessible care.

Date: 11/07/2025

**Title:** [WHO Member States hold first meeting, agree on next steps to take forward key elements of the WHO Pandemic Agreement](https://www.who.int/news/item/10-07-2025-who-member-states-hold-first-meeting--agree-on-next-steps-to-take-forward-key-elements-of-the-who-pandemic-agreement)

Summary: WHO Member States have held their first meeting of the Intergovernmental Working Group (IGWG) on the WHO Pandemic Agreement, formalizing next steps on implementing key provisions of the historic legal instrument to make the world safer from future pandemics.

Date: 10/07/2025

**Title:** [Fourth meeting of the International Health Regulations (2005) Emergency Committee regarding the upsurge of mpox 2024](https://www.who.int/news/item/10-07-2025-fourth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-upsurge-of-mpox-2024)

Summary: The Director-General of the World Health Organization (WHO) is hereby transmitting the report of the fourth meeting of the International Health Regulations (2005) (IHR) Emergency Committee (Committee) regarding the upsurge of mpox 2024, held on Thursday, 5 June 2025, from 12:00 to 17:00 CEST.

Date: 10/07/2025

**Title:** [Readout on WHO participation in global nuclear emergency exercise](https://www.who.int/news/item/03-07-2025-readout-on-who-participation-in-global-nuclear-emergency-exercise)

Summary: On 25 June, the World Health Organization (WHO) concluded its participation in a 36-hour nuclear emergency exercise organized by the International Atomic Energy Agency (IAEA).

Date: 03/07/2025

**Title:** [WHO launches bold push to raise health taxes and save millions of lives](https://www.who.int/news/item/02-07-2025-who-launches-bold-push-to-raise-health-taxes-and-save-millions-of-lives)

Summary: The World Health Organization (WHO) today has launched a major new initiative urging countries to raise real prices on tobacco, alcohol, and sugary drinks by at least 50% by 2035 through health taxes in a move designed to curb chronic diseases and generate critical public revenue.

Date: 02/07/2025

**Title:** [Suriname certified malaria-free by WHO](https://www.who.int/news/item/30-06-2025-suriname-certified-malaria-free-by-who)

Summary: Today, Suriname became the first country in the Amazon region to receive malaria-free certification from the World Health Organization (WHO).

Date: 30/06/2025

**Title:** [Social connection linked to improved health and reduced risk of early death](https://www.who.int/news/item/30-06-2025-social-connection-linked-to-improved-heath-and-reduced-risk-of-early-death)

Summary: The World Health Organization (WHO) Commission on Social Connection has released its global report revealing that 1 in 6 people worldwide is affected by loneliness, with significant impacts on health and well-being.

Date: 30/06/2025

**Title:** [WHO Scientific advisory group issues report on origins of COVID-19](https://www.who.int/news/item/27-06-2025-who-scientific-advisory-group-issues-report-on-origins-of-covid-19)

Summary: The WHO Scientific Advisory Group for the Origins of Novel Pathogens (SAGO), a panel of 27 independent, international, multidisciplinary experts, today published its report on the origins of SARS-CoV-2, the virus responsible for the COVID-19 pandemic.

Date: 27/06/2025

**Title:** [The use of semaglutide medicines and risk of non-arteritic anterior ischemic optic neuropathy (NAION)](https://www.who.int/news/item/27-06-2025-27-06-2025-semaglutide-medicines-naion)

Summary: WHO is alerting health-care professionals and regulatory authorities to the risk of non-arteritic anterior ischemic optic neuropathy (NAION) associated with the use of semaglutide medicines—Ozempic®, Rybelsus®, and Wegovy®.

Date: 27/06/2025

**Title:** [Energy access has improved, yet international financial support still needed to boost progress and address disparities](https://www.who.int/news/item/25-06-2025-energy-access-has-improved--yet-international-financial-support-still-needed-to-boost-progress-and-address-disparities)

Summary: Tracking SDG 7: The Energy Progress Report 2025 finds that almost 92% of the world’s population now has basic access to electricity.

Date: 25/06/2025

**Title:** [Tobacco control efforts protect 6.1 billion people – WHO’s new report](https://www.who.int/news/item/23-06-2025-tobacco-control-efforts-protect-6.1-billion-people-who-s-new-report)

Summary: The World Health Organization (WHO) today released its report on the Global Tobacco Epidemic 2025 at the World Conference on Tobacco Control in Dublin, warning that action is needed to maintain and accelerate progress in tobacco control as rising industry interference challenges tobacco policies and control efforts.

Date: 23/06/2025

**Title:** [WHO issues first global guideline to improve pregnancy care for women with sickle cell disease](https://www.who.int/news/item/19-06-2025-who-issues-first-global-guideline-to-improve-pregnancy-care-for-women-with-sickle-cell-disease)

Summary: The World Health Organization (WHO) today released its first-ever global guideline on the management of sickle cell disease (SCD) during pregnancy, addressing a critical and growing health challenge that can have life-threatening consequences for both women and babies.

Date: 19/06/2025

**Title:** [WHO calls for global expansion of midwifery models of care](https://www.who.int/news/item/18-06-2025-who-calls-for-global-expansion-of-midwifery-models-of-care)

Summary: The World Health Organization (WHO) today released new guidance to help countries adopt and expand midwifery models of care - where midwives serve as the main care provider for women and babies throughout pregnancy, childbirth, and the postnatal period.

Date: 18/06/2025

**Title:** [The WHO Hub in Berlin: driving innovation to make the world safer from health threats](https://www.who.int/news/item/17-06-2025-the-who-hub-in-berlin-driving-innovation-to-make-the-world-safer-from-health-threats)

Summary: WHO is developing new tools and innovative partnerships to boost countries’ defenses against future pandemics, including real-time threat detection and genomic analysis of viruses.

Date: 17/06/2025