

## Press release

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# Department of Health media statement on Medicines Shortages

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The Department of Health would like to assure members of the public concerned by medicines shortages that there are numerous alternatives available to ensure continuity of care.

With respect to the various commonly-used medications listed in today's press coverage that have been notified to the Health Products Regulatory Authority (HPRA), where a patient has any disruption to their routine branded supply, continuity of treatment can be assured through the use of alternative products.

Individual brands or strengths of a medication may be temporarily unavailable, but for the vast majority of medicines there are appropriate substitutions such as different strengths, brands or similar classes of medicines.

The Medicines Shortages Framework, operated by the HPRA on behalf of the Department of Health, aims to prevent, where possible, and mitigate the impact of medicines shortages through close collaboration with the department, the Health Service Executive (HSE), industry and healthcare professionals.

The HSE takes continuity of supply into account when making decisions in relation to pricing, with the listed price of new medicines set at the average price paid by 14 European states. Suppliers who find that it is uneconomic to continue supplying a medicine under current Framework Agreements can apply to the HSE for a price increase. Currently 36 medicines are the subject of a price increase application, less than 0.01% of all reimbursed items.

# Notes

Recent public health emergencies and international geopolitical situations have highlighted many global challenges in ensuring the supply of medicines. It is a global health problem, not unique to Ireland, and increases in demand for medications and medicines shortages have been observed in the UK, throughout the EU and across the world in recent months. These challenges have been recognised across the EU and more globally, and additional steps are being taken to tackle shortages. There are several work programmes at European level, in which Ireland is heavily involved, aimed at addressing and preventing shortages.

In Ireland, based on an analysis of the data reported by the pharmaceutical industry to the Health Products Regulatory Authority (HPRA) over several years, the majority (> 50%) of shortages are caused by manufacturing delays, which aligns with what is observed across the EU where quality and manufacturing issues were found to cause 51% of shortages.

Substitution and reference pricing for groups of interchangeable medicinal products was introduced in 2013. This gives authority to a pharmacist to change a named product to a generic interchangeable version, provided it is therapeutically appropriate. Certain medicines available from a single source may have multiple pharmaceutical forms and strengths available. Where there is a shortage of a particular strength, other available strengths may be used to make up a dosage for the period of the short-term shortage where there is no suitable therapeutic alternative option available.

When making decisions in relation to pricing of medicines, the HSE takes into account pricing in other Member States as well as continuity of supply. The listed price of new medicines in Ireland is set at the average price paid by 14 European States (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK).

It is determined under the Framework Agreements on Pricing and Supply of Medicines 2021-2025 (FASPM), multi-annual agreements with the manufacturers of originator and generic medicines. Generics, biosimilar and hybrids are priced at a percentage reduction (45-60%) of the average prices for new on-patent medicines.

Under the current Framework Agreements where it becomes uneconomic for a Supplier to supply a particular medicine under the terms of the Agreements, direct representations may be made by the Supplier to the HSE for variation of any term of the

Agreement, in relation to that medicine, including its price terms in the interest of continuity of supply. Generally, a very low volume of applications are under consideration by the HSE at any given time, with 36 applications as of June 2023.

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