NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

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| **1.** | **Notifying Member:** SWITZERLAND  **If applicable, name of local government involved (Articles 3.2 and 7.2):** |
| **2.** | **Agency responsible:** *Office fédéral de la santé publique*, OFSP (Federal Office of Public Health)  **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**  *Secrétariat d'Etat à l'économie*, SECO (State Secretariat for Economic Affairs)  Holzikofenweg 36, 3003 Berne  [tbt@seco.admin.ch](mailto:tbt@seco.admin.ch), <http://www.seco.admin.ch/> |
| **3.** | **Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition where applicable):** (i) Medicines including products of chemical or biological origin which are intended to have a medical effect on human or animal organisms, or which are presented as such, and which serve namely to diagnose, prevent or treat diseases, injuries or disabilities; blood and blood products are considered as medicines (relevant tariff items: 3002, 3003, 3004).  (ii) Medical devices including products such as instruments, apparatus, equipment, in-vitro diagnostics, software, implants, reagents, material and other articles or substances which are intended for medical use, or which are presented as such, and which do not achieve their principal action through medicines (relevant tariff items: 3006, 9001.3000, 9001.4000, 9001.5000, 9003, 9004, 9018-9021). |
| **5.** | **Title, number of pages and language(s) of the notified document:** *Projet d'acte modificateur de la loi fédérale sur les médicaments et les dispositifs médicaux (Loi sur les produits thérapeutiques, LPTh)* (Draft Act amending the Federal Law on Medicinal Products and Medical Devices (Law on Therapeutic Products, LPTh)) (12 pages, available in French, German and Italian) |
| **6.** | **Description of content:** The European Union has adopted two new regulations: one on medical devices, and the other on in-vitro diagnostic devices. It aims to improve the quality and safety of medical devices, to harmonize the implementation of legislation in the EU, and thereby increase the safety of patients. In the context of the partial revision of the Law on Therapeutic Products, the legislation relating to the regulation of medical devices has been redrafted and adapted to the new EU legislation. The partially revised law establishes, inter alia, the obligations for economic operators and the adapted requirements for medical devices, the conformity assessment procedure, and the registration and identification of products that must be brought into line with the corresponding EU provisions (the regulation on medical devices and the regulation on in-vitro diagnostic devices). In parallel, the legislation in force regarding medical devices has been reviewed in terms of existing measures, and adapted where necessary. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The amendment of the Law on Therapeutic Products will improve the safety and quality of medical devices in Switzerland. Furthermore, it is essential to maintain equivalence between Swiss and European legislation to avoid technical barriers to trade between the two parties and to continue to guarantee supply, and ensure the safety of patients. Switzerland and the EU are working together to effectively and efficiently monitor the market for medical devices and ensure that patients benefit from greater security and increased transparency regarding information on medical devices. |
| **8.** | **Relevant documents:**  *Projet d'acte modificateur de la loi fédérale sur les médicaments et les dispositifs médicaux (Loi sur les produits thérapeutiques, LPTh)* (Draft Act amending the Federal Law on Medicinal Products and Medical Devices (Law on Therapeutic Products, LPTh)):   * German: <https://www.admin.ch/ch/d/gg/pc/documents/2941/HMG_de.pdf> * French: <https://www.admin.ch/ch/f/gg/pc/documents/2941/LPTh_fr.pdf> * Italian: <https://www.admin.ch/ch/i/gg/pc/documents/2941/LATer_it.pdf>   *La loi fédérale sur les médicaments et les dispositifs médicaux actuellement en vigueur (Loi sur les produits thérapeutiques, LPTh)* (Federal Law on Medicinal Products and Medical Devices currently in force (Law on Therapeutic Products, LPTh)):   * German: <https://www.admin.ch/opc/de/classified-compilation/20002716/index.html> * French: <https://www.admin.ch/opc/fr/classified-compilation/20002716/index.html> * Italian: <https://www.admin.ch/opc/it/classified-compilation/20002716/index.html> |
| **9.** | **Proposed date of adoption:** 21 November 2018  **Proposed date of entry into force:** 27 May 2020 |
| **10.** | **Final date for comments:** 60 days from the date of notification. |
| **11.** | **Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** |