## NOTIFICATION

The following notification is provided in accordance with Article 10.6.

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| **1.** | **Notifying Member:** SWISS<br><br>**Where applicable, local public authorities concerned (Articles 3.2 and 7.2):** |
| **2.** | **Responsible body:** Federal Office of Public Health (FOPH)<br><br>**The name and address (including telephone and fax numbers and e-mail and website addresses, if any) of the body or authority designated to deal with the comments concerning the notification must be indicated if this body or authority is different from the above-mentioned body:**<br><br>Secretary of State E for Economic Affairs SECO<br>Holzikofenweg 36, 3003 Bern<br>tbt@seco.admin.ch , www.seco.admin.ch |
| **3.** | **Notification under Article 2.9.2 [ X ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], others:** |
| **4.** | **Products covered (if applicable, HS or CCCN position, otherwise national tariff heading, ICS numbers may be provided in addition, where applicable):** (i) Medicinal products that include or are represented as being of a chemical or biological nature intended to act or be shown to be medically effective in the human or animal body, including the diagnosis, prevention or treatment of diseases, injuries and diseases. disabilities; Blood and blood products are considered drugs (the relevant tariff numbers: 3002, 3003, 3004).<br><br>(ii) medical devices that include products, including instruments, apparatus, equipment, in vitro diagnostics, software, implants, reagents, materials and other articles or substances intended for medical use, or presented as such, whose main action is not obtained by a drug (the relevant tariff numbers: 3006, 9001.3000, 9001.4000, 9001.5000, 9003, 9004, 9018-9021). |
| **5.** | **Title, number of pages and language (s) of the notified text:** Draft Act amending the Federal Law on Medicines and Medical Devices (Therapeutic Products Act, LPTh) ( 12 pages, available in French, German and Italian) ) |
| **6.** | **Content:** The European Union (EU) has adopted two new regulations, one on medical devices (RDM) and the other on in vitro diagnostic medical devices (IVDM). It aims to improve the quality and safety of medical devices, harmonize enforcement in the EU and thus increase patient safety. As part of the partial revision of the LPTh, the legal bases for the regulation of medical devices are reworked and adapted to the new EU law. The partially revised law describes, inter alia, the obligations of economic operators as well as the appropriate requirements for medical devices, the conformity assessment procedure, the registration and the identification of products which must thus be harmonized with the relevant provisions. EU (RDM and RDIV). At the same time, the existing legal bases for medical devices have been checked for existing and, where appropriate, adapted measures. |
| **7.** | **Objective and rationale, including the nature of urgent problems, if any:** The amendment of the Therapeutic Products Act will improve the safety and quality of medical devices in Switzerland. In addition, maintaining the equivalence of the Swiss and European legal bases is essential to avoid technical barriers to trade between the two parties and to continue to guarantee the supply and safety of patients. Switzerland and the EU are collaborating to effectively and efficiently monitor the medical device market and provide patients with enhanced patient safety as well as new transparency in medical device information. |

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| **. 8** | **Relevant documents:**<br>Draft Act amending the Federal Law on Medicines and Medical Devices (Therapeutic Products Act, HTL):<br>• German: https://www.admin.ch/ch/d/gg/pc/documents/2941/HMG_de.pdf<br>• French: https://www.admin.ch/ch/f/gg/pc/documents/2941/LPTh_en.pdf<br>• Italian: https://www.admin.ch/ch/i/gg/pc/documents/2941/LATer_it.pdf<br>The current Federal Law on Medicines and Medical Devices (Therapeutic Products Act, HTL):<br>• German: https://www.admin.ch/opc/de/classified-compilation/20002716/index.html<br>• French: https://www.admin.ch/opc/en/classified-compilation/20002716/index.html<br>• Italian: https://www.admin.ch/opc/it/classified-compilation/20002716/index.html |
| **9.** | **Proposed date of adoption:** November 21, 2018<br>**Proposed date of entry into force:** May 27, 2020 |
| **10.** | **Final date for comments:** 60 days from the date of notification |
| **11.** | **Texts available from: National Inquiry Point [ X ] or address, telephone and fax numbers and e-mail and Web site addresses, if available, of another organization:** |