NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** SWITZERLAND  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  Federal Office of Public Health (FOPH)  Therapeutic Products Law Section  Federal Office of Public Health FOPH  Schwarzenburgstrasse 157  3003 Berne  Switzerland  E-mail: [hmr@bag.admin.ch](mailto:hmr@bag.admin.ch)  **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:**  State Secretariat for Economic Affairs  Holzikofenweg 36  3003 Berne  [tbt@seco.admin.ch](mailto:tbt@seco.admin.ch)  www.seco.admin.ch |
| **3.** | **Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicinal products for human use |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Ordinance on unique identifiers and anti-tampering devices on the outer packaging of medicinal products for human use; (14 page(s), in French), (14 page(s), in German), (13 page(s), in Italian) |
| **6.** | **Description of content:** This Draft Ordinance on unique identifiers and anti-tampering devices establishes rules for the mandatory implementation of safety features to prevent falsified medicines from entering the legal supply chain in Switzerland.  A unique identifier in the form of a 2D Data Matrix code on the outer packaging ensures the identification of each individual package by uploading the relevant information into a database hosted by the Swiss Medicines Verfication Organisation (SMVO). Additionally, an anti-tampering device, such as a tamper-evident seal, indicates whether a package has been opened. These measures help verify the authenticity of medicines, ensuring that counterfeit products are identified before they reach patients.  The ordinance mandates the establishment of an "end-to-end" verification system for safety features, supplemented by risk-based checks at the wholesale level. In practice, the safety features placed on a medicine pack by the manufacturer or marketing authorization holder are systematically verified for authenticity at the end of the supply chain, before that pack is dispensed to a patient (e.g.: by pharmacies or hospitals).  Furthermore, the ordinance regulates the setting up, management and supervision of a repositories system where legitimate unique identifiers are stored. This system, managed by stakeholders under the supervision of the competent authorities, serves as a reference for verifying the authenticity of medicinal products. In Switzerland, the operation of the database system will be entrusted to a non-profit private organization, the SMVO, which has been founded by the manufacturers and marketing authorization holders of medicinal products labeled with unique identifiers. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**  Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA): [SR 812.21 - Federal Act of 15 December 2000 on M... | Fedlex](https://www.fedlex.admin.ch/eli/cc/2001/422/en)  Text of the Article 17a – Federal Decree of 29 September 2017 (Medicrime), available in German, French and Italian: [AS 2018 4771 - Bundesbeschluss über die Genehmig... | Fedlex](https://www.fedlex.admin.ch/eli/oc/2018/765/de)  [Combatting counterfeit therapeutic products](https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/heilmittel/heilmittelfaelschung-illegaler-handel.html) (available in German, French, Italian and English)  [Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use](https://eur-lex.europa.eu/eli/reg_del/2016/161/oj/eng) |
| **9.** | **Proposed date of adoption:** end of 2026  **Proposed date of entry into force:** end of 2026 |
| **10.** | **Final date for comments:** 60 days from 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:**  <https://members.wto.org/crnattachments/2025/TBT/CHE/25_03222_00_f.pdf> |