To:
Swiss authorised representatives and importers

Bern, 18.09.2024

Request to review devices that comply with the old legislation / legacy devices

Dear Sir/Madam

Important deadlines for legacy medical devices, i.e. medical devices that comply with the old legislation, and for the validity of certificates issued under the old legislation are going to expire on **September 26th 2024**. However, provided the regulatory requirements are met, legacy devices may continue to be placed on the market until 2027 or 2028. As part of its market surveillance activities, Swissmedic[1] makes you aware of **the transitional provisions and your obligations in this regard**. In vitro diagnostic medical devices are excluded from this information letter.
This information letter is sent to all authorised representatives and importers registered with Swissmedic and published on our website[2].

- **To which devices do the transitional provisions apply?**

  The transitional provisions apply to all devices that comply with the old legislation[3] for which the manufacturer is seeking certification in accordance with EU-MDR[4] and for which the relevant legal requirements[5] are met.
  You cannot assume that all legacy devices that you place on the market (importer) or for which you assume responsibility (authorised representative) fulfil the requirements. This must be evaluated individually for each device.

- **How can you perform this review?**

  As part of your verification and due diligence obligations[6], it is your responsibility to check and **document the plausibility of the conformity of the devices and the correct application of the transitional provisions**. This can be done on the basis of the following evidence:
  - A self-declaration by the manufacturer confirming that the conditions for placing devices that comply with the old legislation on the market are met (see template from the EU industry association)[7];
  - A confirmation letter issued by the designated/notified body stating that a written agreement has been signed before September 26th 2024 (see Team-NB template)[8].

[1] For further information, see: www.swissmedic.ch > Medical devices > Market surveillance
[2] www.swissmedic.ch
[3] Art. 101 para. 1 let. a and b MedDO Devices for which a declaration of conformity and, if applicable, certification according to Directive 93/42/EEC concerning medical devices or Directive 90/385/EEC on active implantable medical devices has been issued and for which the conformity assessment procedure according to MedDO requires the involvement of a designated body.
[4] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
[5] Art. 101 para. 1bis MedDO
[6] Art. 3 TPA
[7] www.medtecheurope.org > resources & data > resource library > Manufacturer's Declaration in relation to Regulation (EU) 2023/607
[8] European Association for Medical devices of Notified Bodies. www.team-nb.org > Team-NB Documents > Team-NB Position papers > Team-NB PositionPaper NB-ConfirmationLetterEU2023-607 V2

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products
Swissmedic | Hallerstrasse 7 | 3012 Bern | Switzerland | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12

- **What should you do if the conditions for application of the transitional provisions are not met?**

  Devices that do not fulfil the requirements for application of the transitional provisions may not be placed on the market.
  Where you as an **importer** consider or have reason to believe that a device is not in conformity with the requirements, you may **not** place the device on the market until conformity is ensured[9].
  As an **authorised representative** you are required to take the necessary measures as part of your responsibility for the formal and safety-related aspects of placing devices on the market[10] (e.g., change or termination of mandates with the manufacturer, prevention of placement on the market).

- **Do you have to provide feedback to Swissmedic regarding this review?**

  No, this is not necessary. It is part of your responsibility and due diligence of care as an economic operator to take the necessary measures to ensure that only compliant devices are placed on the market in Switzerland. As the competent authority, Swissmedic can inspect devices on the market at any time[11].

- **Where can you find further information?**

  The Swissmedic Information sheet Obligations for economic operators[12] provides detailed information as well as a flow chart on the transitional provisions.
  Swissmedic also relies on European practice when interpretating the applicable provisions. Further information can be found in the European Commission's Q&A[13].

Thank you for your support in ensuring a safe medical device market in Switzerland.

Kind regards

Swissmedic, Swiss Agency for Therapeutic Products
Division Medical Device Surveillance (MDS)
Hallerstrasse 7
3012 Bern
Switzerland
medical.devices@swissmedic.ch
www.swissmedic.ch

[9] Art. 53 MedDO
[10] Art. 51 para. 2 MedDO
[11] Chapter 9 MedDO
[12] www.swissmedic.ch > Medical devices > Market access > Obligations for authorised representatives, importers and distributors
[13] health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en > Other topics > Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Extension of the MDR transitional period and removal of the “sell off” periods