10 September 2021
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Information Management

New legal basis and authorisation procedure values available in the Article 57 database

To support the **voluntary submissions** of medicinal product information for medicinal products supplied in the European Union (EU) or the European Economic Area (EEA) that fall out of scope of Article 57 requirements, new **'Legal basis'** (AP.12.13) values will be made available in the Article 57 database production environment from 13 September 2021:

- Authorisation according to Article 5(1) of Directive 2001/83/EC (12);
- Authorisation according to Article 5(2) of Directive 2001/83/EC (13);
- Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC (14);
- Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC (15);
- Available under Article 83(2) of Regulation (EC) No 726/2004 (16).

The above referenced legal basis should only be used in conjunction with a new '**Authorisation procedure' (AP.12.2)**:

- EU other approval/authorisation procedure (13).

The selection of any of the new legal basis values, whilst referencing authorisation procedure other than *'EU other approval/authorisation procedure (13)'* during a product submission in the eXtended EudraVigilance Medicinal Product Dictionary data-entry tool (EVWEB), will lead to an error message.

For Gateway users, a negative eXtended EudraVigilance Product Report Message (XEVPRM) Acknowledgement will be returned to the sender organisation if an XEVPRM contains product information referencing any of the new legal basis values with authorisation procedure other than *'EU other approval/authorisation procedure (13)'*.

The addition of the above listed legal basis and authorisation procedure will allow companies supplying products without a marketing authorisation in the EU/EEA, which are provided under emergency use, compassionate use or other national schemes, to correctly record and identify such products in the Article 57 database, on a voluntary basis.

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Companies are not required to perform a dedicated, immediate update of their product entities in the Article 57 database to reference the new legal basis/authorisation procedure values, where applicable, as this can be done as part of a regular maintenance.