SRS ADVOGADOS
NEWS LETTER
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HIGHLIGHT

Legislation and Regulation on Health Law

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HEALTH AND LIFE SCIENCES

HIGHLIGHT

I. European Commission

Amendment to European pharmaceutical legislation - Public consultation

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en

European pharmaceutical legislation is in the process of evaluation and revision, taking into account, in particular, the lessons learned from the COVID-19 pandemic. The public consultation period started on 28 September and ends on 22 December 2021 (24 hours - Brussels time)

With this review, the Commission intends to ensure "a regulatory framework for pharmaceutical products that is crisis-resistant and future-proof".

This review process specifically aims to:

- ensure access to affordable medicines
- promote innovation, particularly in areas with unmet medical needs
- improve security of supply
- adapting to new scientific and technological developments
- cutting red tape

Anyone can submit their contribution. Contributions will be summarized in a synthesis report, which will describe how they have been taken into account. Contributions received will be published on the website of the European Commission, and therefore they must comply with the applicable rules.

The public consultation process aims to gather the views of stakeholders and the general public in order to support the assessment of the general pharmaceutical legislation in force on medicines for human use, as well as the impact assessment of its review in order to ensure a resilient and future-proof drug regulatory system. It is also based on the public consultation carried out with a view to drawing up the Pharmaceutical Strategy for Europe, dated November 2020. General pharmaceutical legislation sets out the main definitions, regulatory incentives and authorization procedures, as well as the

manufacturing, authorization and post-authorization requirements for medicines.

Anyone can participate in this public consultation by answering the online questionnaire. Contributions will be summarized in a synthesis report, which will describe how they have been taken into account. Contributions received will be published on the website of the European Commission, and therefore they must comply with the applicable rules.

II. Portuguese Medicines Agency - INFARMED – Amendment to the Regulation of Authorizations for Exceptional Use

https://www.infarmed.pt/documents/15786/4854518/Delibera%C3%A7%C3%A3o+086_2021/cda4990a-0bdf-62b4-5d4c-40aa30a42eb7

On 9 September, Infarmed published an amendment to the regulation of authorizations for exceptional use (AEU) and marketing authorizations for medicines without authorization or registration valid in Portugal (SAR) - Deliberation No. 086/CD/2021, of 9 September.

Medicines for human use to be marketed in the EU must have a marketing authorization (MA) following a strict and therefore usually time-consuming procedure, in order to verify the safety, quality and efficacy of the medicines, thus validating their use by patients for their intended purpose.

Exceptionally, the purchase of medications that do not have an AIM or that have a batch rupture may be authorized. For this purpose, Infarmed issues three types of marketing authorizations:

(i) the authorization of medicines for exceptional use (AEU),

(ii) the authorization to use batches of drugs in supply disruption and without therapeutic alternative (batch AEU) and

(iii) authorization to market medicines without authorization or valid registration in Portugal or that have not been the subject of a valid authorization or registration request (SAR).

These authorizations allow patients to have access to medicines that are not authorized in Portugal, preventing administrative barriers from hindering patients' access to the medicines they need.

As for the amendment now introduced, it is worth mentioning the following:

- The change aims to simplify and streamline the current procedure for submitting AUE applications by entities that hold an authorization for the direct purchase of medicines (such as hospitals, clinics, etc.).

- The following changes are highlighted:

  - Submission of AEU applications can take place at any time;

  - The request for an AEU is made by the health institution, which is responsible for identifying the person(s) responsible for submitting this type of request. The need for the signature of the Clinical Director is waived, not exempting the health institution from the responsibility of gathering internal authorizations for the process;

  - The SAR granted under this new wording are valid as long as the authorized quantities are not exhausted and the conditions for which they were granted are maintained;

- Previous addendums must be submitted as new SAR requests;

  - The AEUs in force until 31 December 2021 remain valid as long as the authorized quantities are not exhausted and the conditions for which they were granted are maintained.

  - Submission of requests under this wording of the regulation must be made using the new forms available in the "Management of drug availability" area.

III. General Directorate for Food and Veterinary Products – DGAV

Regulation (EU) 2019/6 Veterinary Medicines - Public consultation CMDv documents

https://www.dgav.pt/destaques/noticias/regulamento-ue-2019-6-medicamentos-veterinarios-consulta-publica-documentos-cmdv-2/It

On the CMDv website (HMA – Heads of Medicines Agencies), information is available on the public consultation of documents created by the CMDv related to the Regulation on Veterinary Medicines (Regulation (EU) 2019/6).

An electronic page dedicated to the implementation of the aforementioned Regulation was created and will be updated regularly.

This page can be consulted regularly as more documents will be added to the current list.

The address of this dedicated page is: https://www.hma.eu/631.html

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