Newsletter

Life Sciences & Healthcare

Health Law Legislation and Regulations

SRS LEGAL

About Law.
Around People.

SEPTEMBER TO DECEMBER 2023

I. The Life Sciences 2023 Highlights.

In 2023, there are two milestones that must be highlighted as leading to major changes in European pharmaceutical legislation:

The reform of the European Union legislation proposed by the European Commission published on 26 April 2023.

https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_pt.

On the other hand, the political agreement between the European Parliament and the Council on Artificial Intelligence - reached on 9 December 2023.

- ***The Reform of the European Pharma Legislation***

The proposal for **a new Directive and a New Regulation, which revises and replaces the EU pharmaceutical legislation,** is the largest reform of the pharmaceutical legislation in over 20 years.

The aim of this reform is to create a single market for medicines that guarantees to all EU patients a timely and equitable access to safe medicines.
https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_pt.

The reform is based on four pillars:

i. To ensure **patients access to affordable medicines** and responding to **unmet medical needs** (in the fields

of antimicrobial resistance and rare diseases, for example);

ii. To support the **competitiveness, innovation and sustainability** of the EU pharmaceutical industry and the development of high quality, safe, effective and more environmentally friendly medicines;

iii. To strengthen **crisis preparedness and response mechanisms, diversified and secure supply chains,** dealing with shortages of medicines; The list of critical medicines has already been published (as mentioned in II. below);

iv. To ensure a **strong EU presence in the world** by promoting a high level of quality, efficacy and safety standards.

- ***AI and Health - Agreement of the Council and the European Parliament on Artificial Intelligence (AI)***

Negotiators from the Council and the European Parliament have reached a provisional agreement on the harmonisation of the rules on AI through the Artificial Intelligence Act.

The proposed legal framework aims to ensure that AI systems placed on the European market and used in the EU are safe and respect fundamental rights and EU values.

The main points of this interim Agreement are:

i. To put in place rules on the impact of the purpose of AI models that could cause a systemic risk in the future and the revision of the governance system with the granting of powers at EU level and the drawing up of a list of prohibitions but enabling the remote use of biometric identification for law enforcement in public spaces, subject to safeguards for the protection of rights;

ii. The new legal framework will not be applied outside the scope of the European Union legislation, and should in no way affect the competences of member states with regard to national security;

iii. The new legal framework will also not be applied to AI systems that are exclusively intended to be used for research and innovation purposes or to people who use AI for non-professional purposes;

iv. The agreement reached provides for four horizontal layers of protection, ranging from **unacceptable risk** (all AI systems deemed to pose a risk to the safety, livelihood and rights of individuals, will be banned, such as toys that use voice to encourage dangerous behaviour), **high risk** (covering critical infrastructure that could jeopardise people's lives and health, **covers the safety of product components, such as the application of AI in robots used in surgeries,** uses that are subject to a risk assessment and

compliance regime to be implemented by the competent authorities), **limited risk** (covers AI systems that are subject to specific transparency obligations - people using, for example, chatbots must be informed that they are talking to a machine and that they must make properly informed decisions or stop using), **minimal or no risk** (the proposal authorises the free use of, for example, video games or spam filters, covering most of the AI currently used in the EU).

AI is and will undoubtedly be the most powerful tool for health, in all areas but particularly in advancing clinical research, obtaining more accurate and efficient diagnoses, improving the quality and speed of information. It has an important role to play in health equity by improving results and discoveries at a global level.

II. Highlights of December 2023.

A. The European Commission, the HMA and the EMA have published the first version of the Union's list of critical medicines.

https://www.ema.europa.eu/en/news/first-version-union-list-critical-medicines-agreed-help-avoid-potential-shortages-eu

On the 12th December 2023, a list was published of more than **200 active substances** in medicines for human use that are considered critical for the European Union's national health systems.

This concern that the Member States have shown aims to prioritise critical medicines for action at EU level in order to strengthen the supply chain, thus guaranteeing its safety but also making it more robust.

It's important to clarify that although a substance is on the list, it doesn't mean that there will be a shortage in the near future. The intention is to warn of possible shortages that could have a significant impact on patients.

A medicine is considered "critical" if it is used for serious illnesses and cannot be easily replaced by other medicines, for example in the event of a shortage. Note that it is included on the EU list of critical medicines if it fulfils certain criteria, including being critical in more than a third of EU/EEA countries. This degree of criticality was assigned on the basis of an agreed methodology developed in consultation with key stakeholder groups, including patient and healthcare professional organisations and industry associations.

Additional notification requirements for marketing authorisation holders and national competent authorities will be established for these medicines and will enter into force as soon as the proposed pharmaceutical legislation becomes applicable.

To finalise, it's important to give two points:

(i) The medicines on the list **can continue to be prescribed and used as normal by patients and healthcare professionals;** and

(ii) The publication of the **EU list will have no impact on** existing or future **national lists** of critical medicines. However, it will support the network's efforts to draw up national lists, if they do not already exist. It will also support and accelerate the EC's analysis of the supply chain for critical medicines to determine potential vulnerabilities.

B. Amendment of the rules on the retail sale of veterinary medicinal products - several years later.

https://diariodarepublica.pt/dr/detalhe/despacho/7551-2023-215919334

The Directorate-General for Food and Veterinary Products issued Order no. 7551/2023 of 20 July, which "*Amends the supplementary rules on retail establishments selling veterinary medicines*".

With the aim of transposing Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 and the respective control over the entire distribution chain of veterinary medicines, from manufacture or import into the Union to supply to the end user.

The changes are as follows:

(i) MVSRMV can only be sold in pharmacies and duly authorised sales outlets;

(ii) MVNSRMV can only be sold in pharmacies, points of sale, MNSRM sales points, MVNSRMV sales points and Veterinary Medical Care Centres (CAMV).

For these MVNSRMV sales outlets there are new rules not only regarding premises, personnel and the obligations of authorisation holders, but also with regard to the authorisation applications they have to submit in order to continue operating in this sector.

Furthermore, the Order points to the new rules regarding the responsibilities and incompatibilities inherent in holding the position of technical director of a retail outlet selling veterinary medicines and technical manager of a retail outlet selling veterinary medicines not subject to veterinary prescription - based on the defence and preservation of public health, animal health and a correct policy for the rational use of veterinary medicines, including those containing antimicrobials.

III. Official Journal - Relevant Legislation.

(September to December)

Decree-Law no. 102/2023 - Official Gazette no. 215/2023, Series I of 2023-11-07
Presidency of the Council of Ministers

Creates local health units as public business entities

Decree-Law no. 89/2023 - Official Gazette no. 197/2023, Series I of 2023-10-11
Presidency of the Council of Ministers

Creates the Institute for Addictive Behaviours and Dependencies, I. P.

Council of Ministers Resolution no. 115/2023 - Official Gazette no. 187/2023, Series I of 2023-09-26
Presidency of the Council of Ministers

Approves the National Plan for the Reduction of Addictive Behaviours and Dependencies 2030 and the Action Plan for the Reduction of Addictive Behaviours and Dependencies - Horizon 2024

Council of Ministers Resolution no. 113/2023 - Official Gazette no. 185/2023, Series I of 2023-09-22
Presidency of the Council of Ministers

Authorises expenditure and the assumption of multiannual charges for the years 2023 to 2026 for the purchase of COVID-19 vaccines under the centralised European procedure

Presidency of the Council of Ministers

Council of Ministers Resolution no. 139/2023 - Official Gazette no. 216/2023, Series I of 2023-11-08
Presidency of the Council of Ministers

Determines the exceptional and temporary increase in the operational activity of the National Institute of Medical Emergency, I. P.

Decree-Law no. 82/2023 - Official Gazette no. 185/2023, Series I of 2023-09-22
Presidency of the Council of Ministers

Updates the regime regulating the non-professional use of plant protection products in the domestic environment

Order no. 9981/2023 - Official Gazette no. 188/2023, Series II of 2023-09-27
Health - Minister's Office

Determines the creation of the National Health Service Awards, whose regulations and model must be approved by the Executive Directorate of the National Health Service, I. P.

Deliberation no. 899/2023 - Official Gazette no. 177/2023, Series II of 2023-09-12
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Approves the Code of Ethics and Conduct of INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Deliberation no. 926/2023 - Official Gazette no. 184/2023, Series II of 2023-09-21
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Sub-delegation of powers of the board of INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P., to its members

Order no. 11593/2023 - Official Gazette no. 221/2023, Series II of 2023-11-15
Health - Minister's Office

Determines that the start-up of the Sintra Proximity Hospital is ensured by the Professor Doutor Fernando Fonseca Hospital, E. P. E

Order no. 11043/2023 - Official Gazette no. 209/2023, Series II of 2023-10-27
Health - Minister's Office

Appoints and removes from office members of the Commission for the Evaluation of Medicinal Products (CAM)

Order no. 10735/2023 - Official Gazette no. 204/2023, Series II of 2023-10-20
Health - Minister's Office

Authorises the Centro Hospitalar Universitário de Santo António, E. P. E., to set up a Culture Cornea Bank, in accordance with the applicable legal and regulatory provisions

Notice no. 17681/2023 - Official Gazette no. 178/2023, Series II of 2023-09-13
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Conclusion of indefinite public service contracts with several employees

Notice no. 21928/2023 - Official Gazette no. 221/2023, Series II of 2023-11-15
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Revokes authorisation to DIAVERUM - Investimentos e Serviços, Lda. for the direct acquisition of narcotic and psychotropic substances and their preparations

Notice no. 21122/2023 - Official Gazette no. 212/2023, Series II of 2023-11-02
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Revokes authorisations to Clever Leaves Portugal, Unipessoal, Lda. for the cultivation, manufacture, import and export of the cannabis plant for medicinal purposes

Notice no. 21120/2023 - Official Gazette no. 212/2023, Series II of 2023-11-02
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorises Yotto Green, Lda. to supply narcotic and psychotropic substances and their preparations for specific purposes involving the cannabis plant and its derivatives.

Notice no. 21007/2023 - Official Gazette no. 211/2023, Series II of 2023-10-31
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorises Xpharma, Lda. to wholesale narcotic and psychotropic substances and their preparations

Notice no. 21006/2023 - Official Gazette no. 211/2023, Series II of 2023-10-31
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorises Medbeat, Lda. to export narcotic and psychotropic substances and their preparations

Notice no. 21005/2023 - Official Gazette no. 211/2023, Series II of 2023-10-31
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorisation for the cultivation, import and export of the cannabis plant for medicinal purposes granted to GBE Pharma, Unipessoal, Lda.

Notice no. 21004/2023 - Official Gazette no. 211/2023, Series II of 2023-10-31
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorisation for the manufacture, import and export of the cannabis plant for medicinal purposes granted to Blossom Genetics Unipessoal, Lda.

Notice (extract) no. 19446/2023 - Official Gazette no. 196/2023, Series II of 2023-10-10
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Homologation of the unitary list of final order for the common competition procedure to fill three posts in the career/category of senior technician

Notice no. 18702/2023 - Official Gazette no. 189/2023, Series II of 2023-09-28
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Revokes SPD - Sociedade Portuguesa de Diálise, S. A.'s authorisation for the direct acquisition of narcotic and psychotropic substances and their preparations

Notice no. 18701/2023 - Official Gazette no. 189/2023, Series II of 2023-09-28
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Revokes from Societé Française de Bienfaisance - Hospital Saint Louis the authorisation for the direct purchase of narcotic and psychotropic substances and their preparations

Notice no. 18700/2023 - Official Gazette no. 189/2023, Series II of 2023-09-28

Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorises Krka Farmacêutica, Sociedade Unipessoal, Lda. to import narcotic and psychotropic substances and their preparations

Notice no. 18699/2023 - Official Gazette no. 189/2023, Series II of 2023-09-28
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Revokes Empifarma - Produtos Farmacêuticos, S. A.'s authorisation to export narcotic and psychotropic substances and their preparations

Notice no. 18698/2023 - Official Gazette no. 189/2023, Series II of 2023-09-28
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorises Bluepharma - Indústria Farmacêutica, S. A., to manufacture and import narcotic and psychotropic substances and their preparations

Notice no. 18697/2023 - Official Gazette no. 189/2023, Series II of 2023-09-28
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorises Bluepharma - Indústria Farmacêutica, S. A., to export narcotic and psychotropic substances and their preparations

Notice no. 18696/2023 - Official Gazette no. 189/2023, Series II of 2023-09-28
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorises Eurodial - Centro de Nefrologia e Diálise de Leiria, S. A., to directly purchase narcotic and psychotropic substances and their preparations for the exclusive use of its inpatients

Notice no. 18695/2023 - Official Gazette no. 189/2023, Series II of 2023-09-28
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorisation for the cultivation, import and export of the cannabis plant for medicinal purposes granted to Canneurox Portugal, Unipessoal, Lda.

Notice no. 18694/2023 - Official Gazette no. 189/2023, Series II of 2023-09-28
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorises the Societé Française de Bienfaisance - Hospital Saint Louis to directly purchase narcotic and psychotropic substances and their preparations for the exclusive use of its inpatients

Notice no. 18692/2023 - Official Gazette no. 189/2023, Series II of 2023-09-28
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorisation to carry out manufacturing, import and export activities relating to the cannabis plant for medicinal purposes granted to Somaí Pharmaceuticals, Unipessoal, Lda.

Notice no. 18691/2023 - Official Gazette no. 189/2023, Series II of 2023-09-28
Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.

Authorisation for the cultivation, import and export of cannabis plants for medicinal purposes granted to BELVEDERE PHARMA, S. A.

IV. INFARMED

- **Rimactán - Authorisation to use batches labelled in a foreign language**

"Information Circular no. 119/CD/100.20.200 of 30/11/2023"

30/11/2023

- **Reference Price System - 4th Quarter 2023 (December)**

"Information Circular No. 114/CD/100.20.200 Date: 14/11/2023"

16/11/2023

- **Xeplion - Authorisation to use batches labelled in a foreign language**

"Information Circular no. 116/CD/100.20.200 of 14/11/2023"

15/11/2023

- **Edronax - Authorisation to use batches labelled in a foreign language**

"Information Circular no. 117/CD/100.20.200 of 14/11/2023"

15/11/2023

- **Updating the list of medicines whose export is temporarily suspended - November 2023**

"Information Circular no. 115/CD/100.20.200 of 14/11/2023"

15/11/2023

- **Immediate suspension of marketing and recall of the device Sterile TNT compress, brand DivisionCare, manufacturer SHAOXING GANGFENG HOSPITAL PRODUCTS Co Ltd**

"Information Circular No. 113/CD/550.20.001 of 02/11/2023"

09/11/2023

- **Voluntary recall of batch 323, expiry date 05 2026 of the medicine Dexamytrex 0.3 mg g + 3 mg g, ophthalmic ointment (Bausch & Lomb, S.A)**

"Information Circular No. 112/CD/550.20.001 of 31/10/2023"

02/11/2023

- **Latanoprost + Timolol - Authorisation to use batches labelled in a foreign language**

"Information Circular no. 110/CD/100.20.200 of 24/10/2023"

24/10/2023

- **Withdrawal of authorisation from wholesale distributor Az-Naturemed GmbH**

"Information Circular No. 107/CD/550.20.001 of 18/10/2023"

20/10/2023

- **Revocation of the decision to suspend the activity of the wholesale distributor Alliance Healthcare Espana SA**

"Information Circular No. 108/CD/550.20.001 of 18/10/2023"

19/10/2023

- **Reintroduction to the market of the type IIR surgical mask from the manufacturer Alliande - Cosméticos e Suplementos Alimentares Lda**

"Information Circular No. 106/CD/550.20.001 of 16/10/2023"

17/10/2023

- **Dental whitener LyDenti EndoWhite Gel EXTRA 38 % from the manufacturer Zhengzhou Huaer Electro-Optics Technology Co, Ltd**

"Information Circular No. 105/CD/550.20.001 of 16/10/2023"

17/10/2023

- **Suspension of activity of wholesale distributor Alliance Healthcare Espana SA**

"Information Circular No. 097/CD/550.20.001 of 22/09/2023"

12/10/2023

- **Updating of the lists provided for in the Regulation on prior notification of drug transactions abroad - October 2023**

"Information Circular no. 103/CD/100.20.200 of 06/10/2023"

10/10/2023

- **Reference Price System - 4th Quarter 2023 (November)**

"Information Circular No. 102/CD/100.20.200 Date: 06/10/2023"

09/10/2023

Updating the SMUH-AIM and SMUH-ALTER platforms within the scope of Ordinance 235 2023 of 27 July

"Information Circular No. 101/CD/100.20.200 Date: 04/10/2023"

06/10/2023

- **Medicines containing levothyroxine- recommendations on the interference of biotin in laboratory tests of thyroid function**

"Medicines containing levothyroxine- recommendations on the interference of biotin in laboratory tests of thyroid function"

29/09/2023

- **Update - Immediate suspension of the marketing of tooth whiteners improperly qualified as medical devices**

"Information Circular No. 099/CD/550.20.001 of 25/09/2023"

29/09/2023

- **Immediate suspension of the marketing of the product NICECIAplus+ non-sterile nitrile gloves, from the manufacturer Jiangsu Maolin Medical Technology Co., Ltd.**

"Information Circular No. 100/CD/550.20.001 of 25/09/2023"

26/09/2023

- **Transition of clinical trials to the European regulation**

"Information Circular No. 098/CD/100.20.200 of 22/09/2023"

25/09/2023

- **Voluntary recall | Medicine Bglau (Brimonidine) 0.7 mg 0.35 ml, Eye drops, solution in single-dose container (batch no. 23A079)**

"Information Circular No. 096/CD/550.20.01 of 18/09/2023"

19/09/2023

- **Reference Price System - 4th Quarter 2023 (October)**

"Information circular No. 95/CD/100.20.200 Date: 18/09/2023"

19/09/2023

- **EUAA regulation - new version**

"EUAA regulation - new version"

14/09/2023

- **Reference Price System - Suspension of Tapentadol homogeneous group**

"Information Circular No. 93/CD/100.20.200 Date: 14/09/2023"

14/09/2023

- **Suspicion of falsification of the medicinal product - Testoviron Depot, Testosterone, 250 mg-1 ml, solution for injection, ampoule 1 unit-1ml, lot KT02S51, incorrect val 12-2026**

"Information Circular No. 086/CD/550.20.001 Date: 17/08/2023"

14/09/2023

- **Medicines containing Topiramate - New measures to prevent exposure during pregnancy: Additional restrictions on use and implementation of a pregnancy prevention programme**

"Information Circular No. 092/CD/550.20.001 Date: 12/09/2023"

13/09/2023

- **Suspension of marketing and withdrawal from the domestic market of all batches of Nuud Deodorant**

"Information Circular No. 091/CD/100.20.200 of 08/09/2023"

11/09/2023

- **Transition of clinical trials to the European Regulation**

"Information Circular No. 088/CD/100.20.200 of 04/09/2023"

06/09/2023

- **Suspension of marketing and recall of batch 622104 of the medical device intravenous catheter, reference BM0185-22G, from the manufacturer Bio-Med Healthcare Products Pvt. Ltd**

"Information Circular No. 090/CD/550.20.001 of 04/09/2023"

06/09/2023

- **Updating the list of medicines whose export is temporarily suspended - September 2023**

"Information Circular no. 089/CD/100.20.200 of 04/09/2023"

05/09/2023

V. EMA

Towards a permanent collaboration framework for EMA and Health Technology Assessment bodies
15 September 2023

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 11-14 September 2023
15 September 2023

Spikevax: EMA recommends approval of adapted COVID-19 vaccine targeting Omicron XBB.1.5
14 September 2023

PRAC recommends new measures to avoid topiramate exposure in pregnancy
1 September 2023

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 28-31 August 2023
1 September 2023

New treatment option for heavily pre-treated multiple myeloma patients
13 October 2023

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 9-12 October 2023
13 October 2023

Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 5-7 September 2023
12 October 2023

Monitoring of products originating from Japan for the possibility of radioactivity
11 October 2023

Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 3-5 October 2023
6 October 2023

EMA Management Board: highlights of October 2023 meeting
6 October 2023

Revised transparency rules for the EU Clinical Trials Information System (CTIS)
6 October 2023

EMA recommends non-renewal of authorisation of Duchenne muscular dystrophy medicine Translarna
5 October 2023

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 25-28 September 2023
29 September 2023

EMA recommends non-renewal of authorisation of multiple myeloma medicine Blenrep
28 September 2023

Global regulators celebrate 10 years of strategic leadership and cooperation
9 November 2023

First electronic product information (ePI) published for selected human medicines
8 November 2023

EMA encourages companies to submit type I variations for 2023 in November 2023
3 November 2023

Call for expressions of interest for patients' organisations representatives to join Committee for Orphan Medicinal Products (COMP)
3 November 2023

Call for expression of interest for independent scientific experts to participate in the work of EMA's Safety Committee
3 November 2023

EMA recommends approval of adapted Nuvaxovid COVID-19 vaccine targeting Omicron XBB.1.5
31 October 2023

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 23-26 October 2023
27 October 2023

EMA takes further steps to address critical shortages of medicines in the EU
24 October 2023

EMA alerts EU patients and healthcare professionals to reports of falsified Ozempic pens

18 October 2023

EU medicines agencies reflect on lessons learnt from COVID-19
The report reviews the response to the pandemic and highlights the main learnings for the future.

1 December 2023

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 27-30 November 2023

1 December 2023

Consumption of antimicrobials in animals reaches lowest level ever in Europe
European countries have substantially reduced sales of veterinary antibiotics.

20 November 2023

Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 7-9 November 2023
10 November 2023

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 6-9 November 2023
EMA's human medicines committee (CHMP) recommended eight medicines.

10 November 2023

First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU
The first version of the Union list of critical medicines contains more than 200 active substances of medicines for human use considered critical for healthcare systems across the EU / EEA, for which continuity of supply is a priority and shortages should be avoided.

12 December 2023

Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 5-7 December 2023
CVMP opinions on veterinary medicinal products

8 December 2023

Global regulators strengthen efforts to ensure continuous availability of safe and high-quality medicines
Collaboration between medicines regulators is paving the way towards a global Pharmaceutical Quality Knowledge Management System (PQ KMS).

8 December 2023

VI. ERS

Supervisory alert no. 2/2023
23/10/2023

End of the validity of Directorate-General for Health (DGS) Guideline no. 18/2020, of 30 March 2020, on Pregnancy and Childbirth in the context of the response to the SARS-CoV-2 epidemic and COVID-19 disease.

Supervisory alert no. 3/2023
14/11/2023
Users' access to their medical records
Considering the legal and guiding framework regarding users' access to the elements of their medical records, as provided for in the law

Supervisory alert no. 4/2023
16/11/2023
Obligation to register and update the data of healthcare establishments operating in Mobile Units in the Health Regulator's Regulated Establishments Registration System
Whereas healthcare establishments that operate in motorised units and establishments that provide healthcare at home - jointly known as **Mobile Units**

Explanatory Note | SUPERVISORY ALERT No. 5/2023
The Health Regulatory Authority (ERS) published Supervisory Alert No. 5/2023 on Thursday, 30 November 2023.

Supervisory Alert no. 5/2023
Supervisory alert no. 5/2023
Compliance with the obligations relating to the processing of complaints and the updating of registration data with the Health Regulatory Authority within the scope of the restructuring provided for in Decree-Law no. 102/2023 of 7 November.

Meet Our Team: