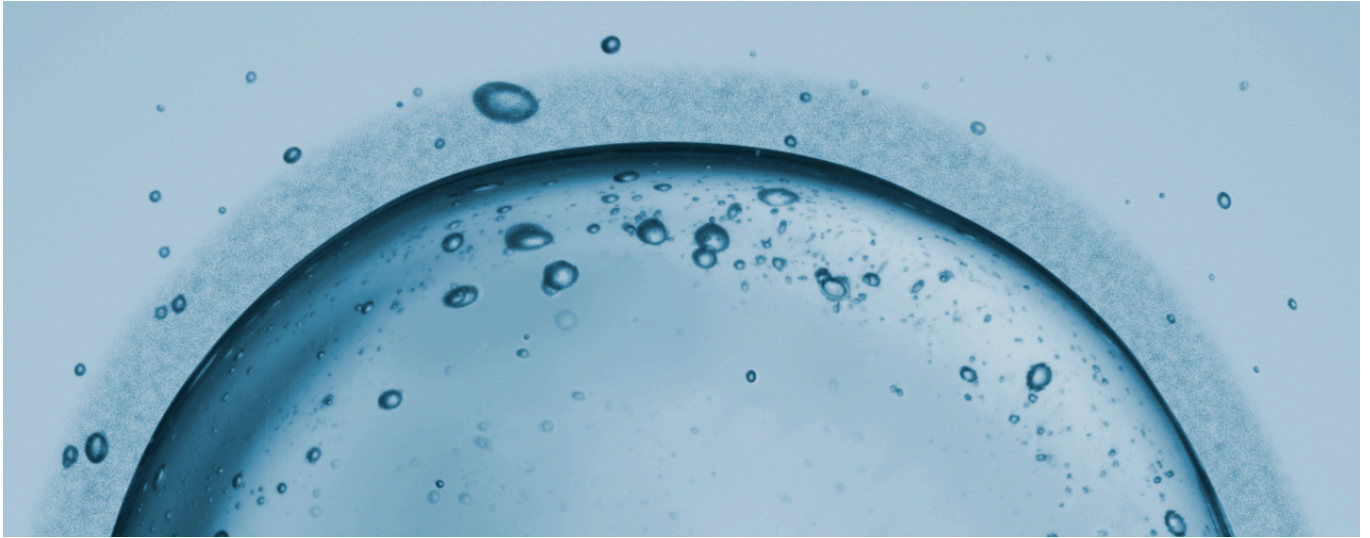


# Newsletter

by SRS LEGAL

● LIFE SCIENCES & HEALTHCARE



## ● RELEVANT LEGISLATION (AUGUST THROUGH SETEMBER) 2024

### DRE Publications

#### [Deliberation no. 1132/2024](#)

Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.  
Updating the list of critical medicines.

#### [Order no. 10110/2024](#)

Health - Office of the Secretary of State for Health

Approves the list of medicines that can be part of the proximity dispensing scheme and establishes some rules to be applied to the dispensing of these medicines under the aforementioned scheme.

#### [Order no. 201/2024/1](#)

HEALTH

Establishes the operating model for the 2024-2025 Autumn-Winter Seasonal Vaccination Campaign against influenza and COVID-19 in workshop pharmacies.

FINANCE AND HEALTH

Defines the terms and conditions for the provision of public health intervention services by workshop pharmacies in the Autumn-Winter 2024-2025 Seasonal Vaccination Campaign, as well as the respective remuneration.

## INFARMED - Circulars and Notices

### [Suspension of activity of wholesale distributor \[Auxilto Healthcare s.r.o.\]](#)

"Information Circular no.  
051/CD/550.20.001 of 22/07/2024"  
07/08/2024

### [Reference Price System - 3rd Quarter 2024 \(September\)](#)

"Information Circular No.  
56/CD/100.20.200 Date: 05/08/2024"  
13/08/2024

### [Updating of the list currently in force provided for in the Regulation on prior notification of drug transactions abroad - August 2024](#)

"Information Circular no.  
058/CD/100.20.200 of 13/08/2024"  
14/08/2024

### [Atazanavir Generis 150 mg and 300 mg Capsule MA Suspension Withdrawal](#)

"Information Circular No.  
059/CD/550.20.001 of 13/08/2024"  
14/08/2024

### [Tadalafil Ciclum 5, 10 and 20 mg Film-coated tablet MA Suspension Withdrawal](#)

"Information Circular No.  
060/CD/550.20.001 of 13/08/2024"  
14/08/2024

### [Vipam 50 mg Tablet MA Suspension Withdrawal](#)

"Information Circular No.  
061/CD/550.20.001 of 13/08/2024"  
14/08/2024

### [Pramipexole, 1.05 mg, prolonged release tablet - Authorisation to use batches labelled in a foreign language](#)

"Information Circular no.  
063/CD/100.20.200 of 21/08/2024"  
22/08/2024

### [Bydureon, exenatide, prolonged-release suspension for injection - withdrawal from the market](#)

"Information Circular no.  
064/CD/100.20.200 of 23/08/2024"  
26/08/2024

### [Update of the list of medicines whose export is temporarily suspended - September 2024](#)

"Information Circular no.  
068/CD/100.20.200 of 29/08/2024"  
30/08/2024

### [Olanzapine Aurobindo 2.5, 5, 7.5, 10, 15 and 20 mg Tablet Withdrawals suspension MA](#)

"Lifting MA suspension"  
05/09/2024

### [Olanzapine Aurovitas 2.5, 5, 7.5, 10, 15 and 20 mg Tablet MA Suspension Withdrawal](#)

"Lifting of MA Suspension"  
05/09/2024

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## [Vipmin 850 mg + 50 mg and Vipmin 1000 mg + 50 mg Lifting MA suspension](#)

"MA suspension survey"

05/09/2024

## [Information Circular - Metamizol - 071 of 09-09-2024](#)

"Medicines containing metamizole - Update of the SmPC/FI to raise awareness of the risk of agranulocytosis and facilitate its early detection and diagnosis"

09/09/2024

## [Recommendation not to purchase or use the cosmetic product TDC Clinik - Salipure Peeling Chemical Peel](#)

"Information circular No. 072/CD/100.20.200 of 13/09/2024"

16/09/2024

## [Reference Price System - 4th Quarter 2024 \(October\)](#)

"Information Circular No. 69/CD/100.20.200 Date: 04/09/2024"

16/09/2024

## Life Sciences Department



Ana Menéres  
Partner, SRS Legal



José Doroana de Almeida  
Associate, SRS Legal

## EMA

### [New pilot programme to support orphan medical devices](#)

Free advice and guidance available for manufacturers and notified bodies

2 August 2024

### [Meeting highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 2-5 September 2024](#)

EMA recommends measures to minimise serious outcomes of known side effect with painkiller metamizole

6 September 2024

### [EMA recommends measures to minimise serious outcomes of known side effect with painkiller metamizole](#)

Product information to be updated to raise awareness of known risk of agranulocytosis and facilitate its early detection and diagnosis

6 September 2024

### [Meeting highlights from the Committee for Veterinary Medicinal Products \(CVMP\) 10-12 September 2024](#)

Outcomes of the Committee for Veterinary Medicinal Products (CVMP) meeting.

13 September 2024

### [New chair elected for EMA's Orphan Medicinal Products Committee](#)

Tim Leest begins his three-year mandate on 16 September.

16 September 2024