VIEIRA DE ALMEIDA

LIFE SCIENCES

NEW REGULATIONS | EXCEPTIONAL USE AUTHORISATIONS AND MARKETING AUTHORISATIONS

VdA EXPERTISE

September 2023

On August 31, Decision no. 840/2023, of 31 August, was published.

It approves two separate regulations, one on exceptional use authorisations ("EUA Regulation") and another on marketing authorisations for medicines without valid authorisation or registration in Portugal ("SAR Regulation"), revoking the previous rules in this regard.

These two new regulations come into force on 15 September 2023 and only do not apply to authorisations granted under the previous regulation or to applications pending on this date.

The overhaul of the previous regime aims to ensure greater "simplification and clarity", starting with the separation of the procedure for SARs, now established in a different regulation. In addition, there is greater correspondence between the new regime and the rules of the Medicines Statute dedicated to the same subject.

We highlight below some key aspects of the EUA Regulation:

a) The possibility of requesting EUAs for medicines with and without a MA is maintained;

b) However, EUAs are now categorised into two main groups, those relating to population groups and those relating to specific patients, with separate procedures for both;

c) With regard to EUAs for specific patients, it is clarified that these can be requested by entities with authorisation for direct purchase of medicines, such as NHS hospitals, or by street pharmacies, with different requirements applicable in both cases;

d) Reference is now made to Early Access Programmes ("EAP"), a topic that was not addressed in the previous regime, in the context of EUAs for specific patients requested by entities with authorisation for direct purchase of medicines, in an attempt to reconcile SiNATS, the EAP Regulation and the EUA Regulation;

e) EUAs for population groups now include EUAs for the use of batches to overcome supply shortages, which were previously regulated as a separate category.

The SAR Regulation, on the other hand, has undergone fewer changes, even though it has been separated from the EUA Regulation.

It provides, among other things, that MA holders, along with wholesale distributors and holders of manufacturing authorisations for medicines, can also apply for SARs. It is also established that the maximum validity of a SAR is three years, instead of the two years previously established.

Contacts

FRANCISCA PAULOURO
FP@VDA.PT