
*June 2022*

# EMVS Community Newsletter

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## Introduction: Welcome to the June edition

Welcome to this new edition of the EMVS (*European Medicines Verification System*) Community Newsletter! In this issue, you will find an overview of the latest developments and activities in our community, starting with a deep dive into the end of the stabilisation period in Ireland and finishing off with a summary of the best practices on Product Code Unknown (A1). We hope you will enjoy reading our newsletter! If you have any comments or feedback which you would like to share, reach out to us on communications@emvo-medicines.eu.

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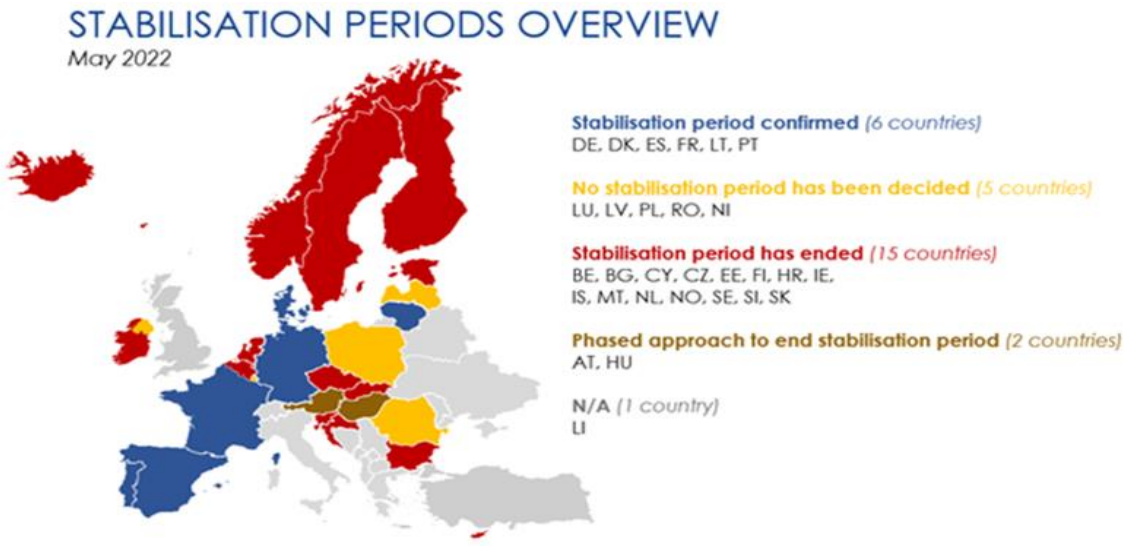
# Stabilisation Period & Alerts Overview

## Introduction & Overview

To allow for a smooth FMD implementation, some countries had opted to enter a "stabilisation" period, during which, packs triggering alerts could still be dispensed to patients, at the discretion of the pharmacist.
The diagram below outlines the current situation on the stabilisation periods in each country up to the end of May 2022.



Currently, for most of the countries (20) either the stabilisation period has ended (15) or one was not implemented (5). Austria and Hungary are currently in a phased or "stepped" approach to end their stabilisation period, meaning that the transition out of stabilisation period has been divided in several phases (for example by End-User category). For these two countries, the end date is under discussion with their NMVO Board and NCA, respectively.

For the six (6) countries still in a stabilisation period, the timeframes are as follows:

- Germany, Portugal, Spain: under discussion with the NCA
- Denmark: until packs released prior to 9th Feb. 2019 expire;
- France: the stabilisation period will persist until the alert rate comes closer to 0,01% and is manageable by all parties;
- Lithuania: an end date currently under preparation by the NCA.

Since the "go-live" of the EMVS took place three years ago, the 20 countries with no stabilisation period in place indicate that with cooperation and coordination amongst all parties it is possible to maintain a stable situation. Ireland, the latest country to end their stabilisation period on 30th May 2022, shared with us their phased approach, or their 'use and learn' experience, below. EMVO will continue to encourage the remaining countries to move towards ending their stabilisation periods soon.

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## Case study: FMD 'use and learn' ends in Ireland

*From Leonie Clarke, IMVO Chief Executive*

The 'use and learn' period of FMD ended in Ireland on Monday 30th May 2022. A phased approach was taken to ending 'use and learn', starting with primary wholesalers voluntarily scanning packs at goods inwards since September 2021. 'Use and learn' ended for wholesalers on 9th May 2022 and the final phase applies to pharmacies and hospitals who are now required to investigate alerts and ensure packs are not falsified before they are supplied.

Progress with FMD implementation in Ireland is overseen by the Safety Features Oversight Group, comprising IMVO, the Department of Health, the two Irish NCAs and health service organisations. When FMD came into effect in February 2019, the

Safety Features Oversight Group opted for a 'use and learn' phase to ensure the continuity of supply of medicines while all parties gained a better understanding of the new system. Plans to exit 'use and learn' were delayed several times, due in part to Brexit and COVID.

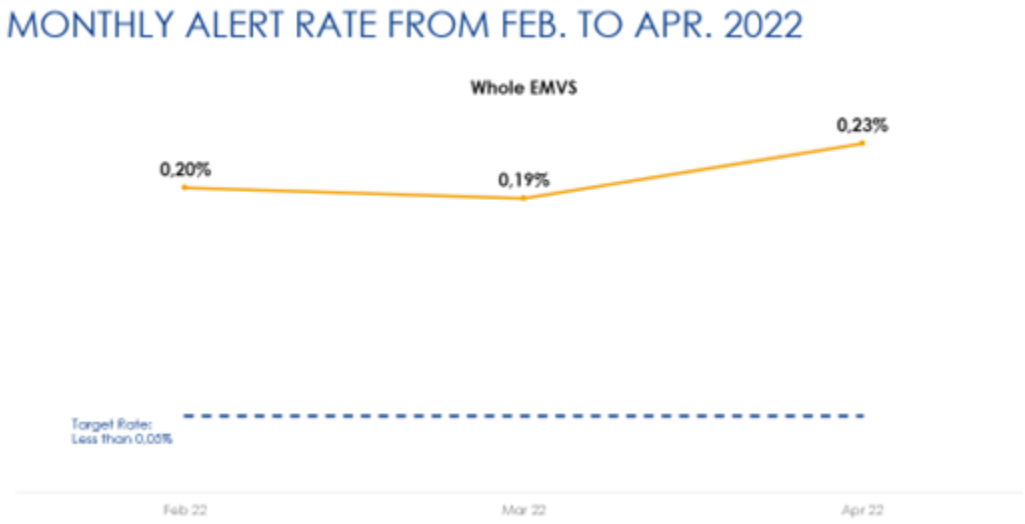
Significant activity has been undertaken to ensure everyone was ready for the end of 'use and learn' in Ireland:

- Alert management guidance, based on the EMVO Best Practice on Alert Handling, was drafted in consultation with stakeholders (including the two Irish NCAs).
- The alert management guidance strongly recommends the use of IMVO's alert management system, NMVS Alerts, for alert communications. End-Users and MAHs have been informed on how to access and use NMVS Alerts.
- FMD software now includes links from alert messages to 'Alert Help' pages on the IMVO website, which provide step-by-step guidance for End-Users, tailored to the relevant alert type.
- In IMVO, we have fine-tuned our internal procedures for alert handling in line with our obligations under the alert management guidance.
- The importance of alert prevention as the best way to reduce the burden of alert management for everyone has been widely messaged. Additionally, End-Users and MAHs with high numbers of alerts are identified by IMVO, and they and FMD software providers, are contacted to take action to reduce avoidable alerts. The alert rate has been falling since the start of 2022 and during April, 50% of pharmacies raised no alerts and 90% of them raised 4 or fewer alerts.
- Extensive communications have taken place with End-Users, MAHs and FMD software providers on how to prepare for the end of 'use and learn', via webinars, newsletters, articles, posting materials to pharmacies, additional resources on the IMVO website and social media posts. Communications activity and messaging was co-ordinated with the two NCAs.
- The pharmacy NCA continues to follow up with a small number of pharmacies who are not scanning as much as they should be. Scanning rates have improved in recent months.
- IMVO's service desk hours have been extended so that End-Users and MAHs can access level 1 support in the evenings, at weekends and on public holidays.

The feedback from other NMVOs whose stabilisation periods have ended is that the situation settles quickly, and IMVO looks forward to this being the case in Ireland.

## Alerts Overview

The monthly alert rate in the EMVS was higher in April than in the past months, reaching 0,23%, due mainly to an increase in Portugal in week 17 caused by an End-User software issue, as well as an increase in the Netherlands during the month, also caused by an end-user. Overall, most of the alerts were A68 alerts (Batch ID mismatch), and A24 & A7 alerts (Attempt to decommission an already decommissioned pack), generally caused by a single, or a few, users. Nevertheless, the overall alert rate remains steady. These cases are being addressed by the NMVOs with the concerned user directly, involving EMVO when necessary.




## Sub-working Group "Best Practice on Product Code Unknown (A1)"

*From Christoph Lendl and Rita Freitag, AMVS*

In September 2021, a subgroup of the working group on Best Practice on Alert Handling was formed under the lead of Christoph Lendl (AMVS) to create a document of best practices for handling of "product code unknown" (A1) exceptions.

Members from several different NMVOs - Rita Freitag (AT), Jean Pierre Engels (BE), Senne Machtelinckx (BE), Alexandra Theodoulou (CY), Ciaran Murphy (IE), Jonas Kreku (SE), Mitja Pirman (SI), Jerome Bertin (UKNI), David Croucher (UKNI) - contributed to several focused and productive sessions by sharing their local experiences and discussing common aspects on the investigation and monitoring activities of A1 exceptions.

In some NMVO countries, the number of A1 exceptions is very high. However, most of these exceptions can quickly be categorised into, amongst others, Indian barcodes, medical devices and OTC products; other less frequent cases require more investigation time. Typing errors/scanning failures, scanning of secondary/tertiary packaging and Anti-Virus Software scrambling product code numbers are further examples causing A1 exceptions.

Within the working group sessions, some main process steps were identified as a common ground to handle product code unknown exceptions and provide guidance on the investigation and monitoring approach to NMVOs. The outcome was presented in the AMS Steering Committee and the EMVO PM Community Meeting, as well as in a recent FMD Workshop, receiving appreciation from the various participants.

The results of this subgroup's discussions and NMVO collaboration are now documented in a Best Practice on Product Code Unknown guidance document which will be published on the EMVO SharePoint.

## Stay up to date with the EMVS!

Watch out for our Summer Holidays Bulletin, in August 2022, as we provide you with more information on the role of the IT, QA and IOT groups within the EMVS.

Stay tuned for the next EMVS newsletter and NCA workshop, both coming up next October!

If you have any questions, please do not hesitate to contact our Helpdesk.

Kind Regards,

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