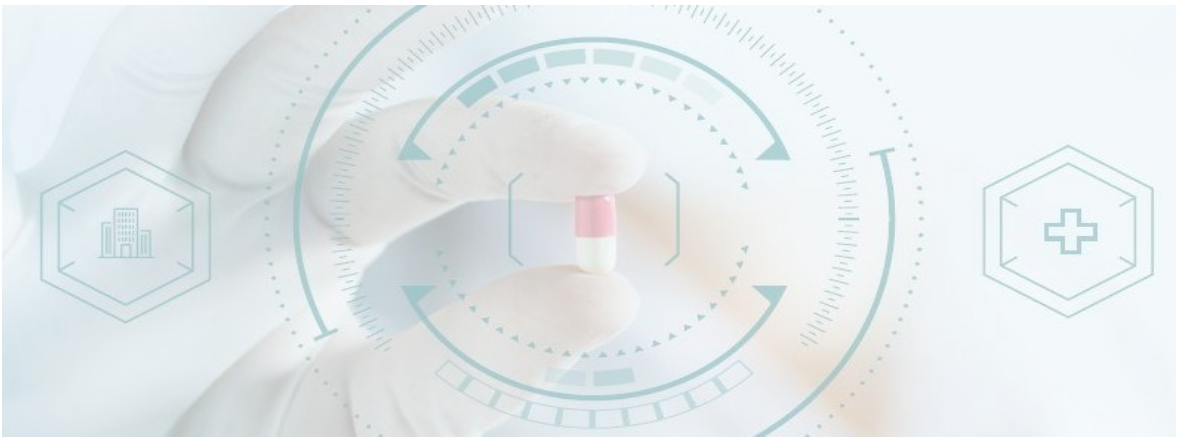
OSMR
Organizația de Serializare a Medicamentelor din România

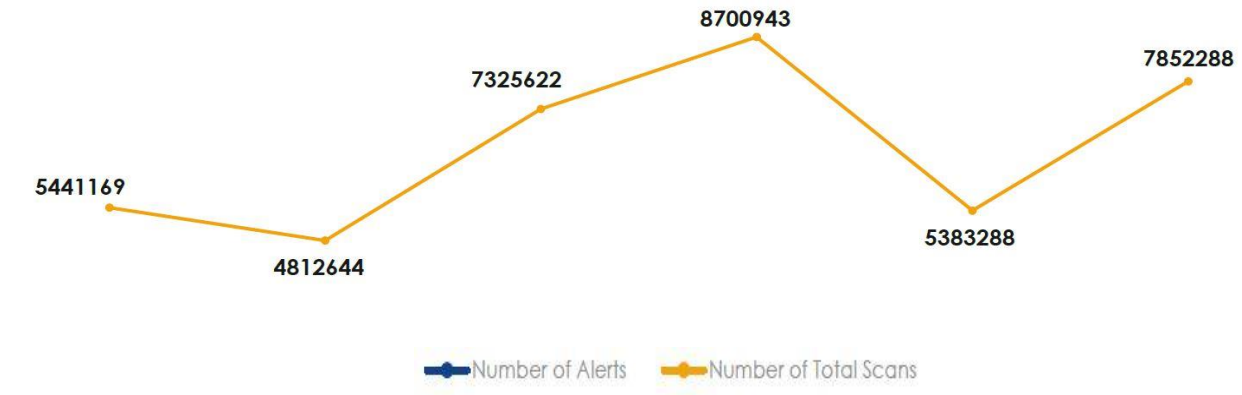
NEWSLETTER



ALERTS GENERATED BY NMVS

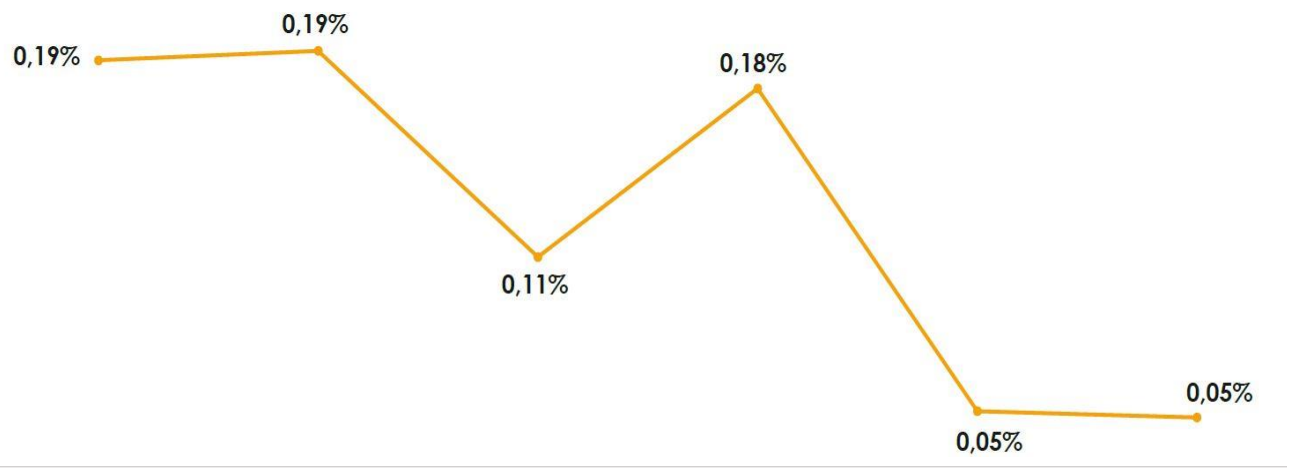
2021 followed the trend that has been established last year, meaning maintaining an alert percentage of 0,05 out of the total transactions operated in the National Medicines Verification System.
The graphs below illustrate the decreasing path of the alerts' number.

OVERVIEW OF TOTAL OF ALERTS AND SCANS



2019 Week 11 | 2020 Week 20 | 2020 Week 48 | 2020 Week 50 | 2020 Week 52 | 2021 Week 1

TOTAL NUMBER OF ALERTS IN RELATION WITH THE TOTAL NUMBER OF SCANS



2019 Week 11 | 2020 Week 20 | 2020 Week 48 | 2020 Week 50 | 2020 Week 52 | 2021 Week 1

INTER-MARKET TRANSACTIONS (IMT) – ALERT INVESTIGATION OVERVIEW

As IMTs have become a hot topic over the last few months, EMVO has prepared a guidance document which clarifies some basic aspects of the overall process.
We would like to share with you a few details so as to acquire a general understanding of the IMT investigation.

On one hand there is **the Initiating market, meaning the country in which the alert was raised** and on the other hand there is **the Fulfilling market, the country for which the product data was uploaded.**

Therefore, **the medicine pack which initiated the alert is in possession of an End-User from the Initiating market.**
The respective End-User is connected to the National Medicines Verification System (NMVS) after having signed the Terms & Conditions with the National Medicines Verification Organization (NMVO) in the Initiating country.
Moreover, the End-User can be inspected or sanctioned only by the National Competent Authorities (NCA) from the Initiating country.

The Initiating NMVO, meaning the authorised NMVO in the Initiating country which registered the End-User from the above-mentioned example to the NMVS, **does not have access to a full Audit trail**. Also, it might not have the MAH to which the data belongs to onboarded.

The Fulfilling NMVO, meaning the organization that is authorised for managing the NMVS in the country for which the product data was uploaded, **has access to pack audit trail report and the MAH to which the data belongs to is onboarded**.

As per EMVO's recommendations, we highlight the following:

- ❖ All stakeholders in the Initiating market have to follow national legislation and cooperate for ensuring patient safety in the concerned country.
- ❖ Fulfilling NMVO should provide support to initiating NMVO if needed for purpose of:
  - Disclosing OBP/MAH information;
  - Providing the Audit trail details, for those alerts where this information is needed for root cause determination.

COVID-VACCINES

EMVO, together with the NMVOs, formed a COVID-19 Task Force with the purpose of ensuring that the European Medicines Verification System (EMVS) is ready to receive the vaccines' serialised data.

However, at this point, at European level the decision has been taken to allow the first batches of vaccines to enter the market without serialisation as the number one priority world-wide is to stop the ongoing pandemic.

As EMVO has communicated, this is a temporary measure and **starting with the beginning of Q2 2021, the unique identifiers will be uploaded to the EMVS, according to the FMD regulations.**

office@osmr.ro www.osmr.ro +40 371 400 348