FMD workshop – 4 December 2019

Last week, I attended the latest FMD workshop for industry organised by EFPIA and MfE. The meeting was a good opportunity to speak with the associations and better understand progress on FMD implementation. The main points of interest were:

- EMVO informed me that they are planning two training sessions on reports for NCAs (Arvato and SolidSoft).
- EFPIA told me that they are not happy with NMVO’s alert management and are considering legal action.
- EMVO has started an alert quality management project that will look at different ways of improving the alerts. They will look at whitelisting of some product codes and batches, decommissioning intermarket, expiry date checks. I intervened saying that I was worried about the risk of whitelisting certain PCs and batches. There was very strong push-back from MfE, who said that there are still a large volume of generic medicines with Indian codes on the market that have not been uploaded in the system.
- The NMVOs are working on an alert management system that will be consulted with NCAs in February. One industry representative questioned the guidance since they don’t want to report suspected falsification twice to authorities.
- There was a lot of concern from industry about the end of stabilisation periods in some MS and the need to handle a high level of returns, especially if they are caused by end-user problems. On the one hand, there are still batches being released that trigger alerts. On the other hand, there are still many alerts caused by end-users. There were also concerns about liability if a patient doesn’t receive their medicines.
- At the request of EFPIA, EMVO has proposed a new country readiness overview report that would include details on: connected end-users, end-users scanning daily, active MAHs, alert rates and number of SKUs uploaded. NMVOs were not happy with the proposed indicators and will discuss with NMVOs on the type of data that can be communicated. Many NMVOs said that they were in regular contact with their NCAs and provided them with data on implementation.
- The NMVO fees for 2020 were presented. There is a flat fee in 15 countries and a ‘adjusted’ flat-fee in the rest.
- EMVO will take over the FMD workshops in 2020 and they will invite end-users to participate as well. The workshops will look at: alert management, the end of stabilisation, Brexit, end-user connections and aggregation.
- There was a final question on aggregation where I explained our willingness to discuss with the European Associations once the system is working well. Some of the EFPIA companies are starting work to implement aggregation. The position of MfE remains unchanged.
- In the margins of the meeting, informed me that EMA has been in touch with EMVO directly to request information on market launch of CAPs (in relation to the sunset clause).
also informed me that it would be possible for EMVO to provide EMA with information if product master data has been uploaded to the system prior to the first market launch.