The Falsified Medicines Directive – overcoming the challenges of verification in the hospital arena

There has been much talk about the difficulties of implementing a robust process-driven verification system of prescription packs within the hospital settings across Europe. Depending on which hospital pharmacist you talk to, you will still get a rainbow of opinions. This in despite of the legal implication, that as of 9th February 2019 all pharmacists should be ready to fulfil the final stage of the Falsified Medicines Directive's (FMD) safety features that will help ensure the patient is protected from falsified medicines. Opinions range from "We have implemented the Directive and can see great halo benefits" to those that feel "It adds no value, only extra work and cost".

The EU Parliament meeting on 19th February titled "**Improving patient safety with the FMD in the hospital pharmacy, status of implementation – are we ready?**" was initiated by the European Alliance for Access to Safe Medicines (EAASM) in collaboration with MEP José Inácio Faria to support the final elements of the FMD. The programme was designed to dispel some of these myths and establish a firmer base for the sharing of best practices by bringing together a team of experts to offer their advice and expertise.

From the technical perspective, the head of the IT solution whose repository captures all of the bar-coding data, Andreas Walter (General Manager – European Medicines Verification Organisation) stated the system had been built in all 28 Member States and that there is the need for a period of stabilisation and inspection measures. This is the largest verification system initiative in the world which is further complicated by the commitment for each Member State to construct a compatible subsidiary nationally based IT architecture.

The example of a very successful implementation was presented by Maija Gohlke kokkonen, General Manager of the Finnish Medicines Verification Organisation. Despite 83% of transactions which have been successful, there are still challenges faced by hospital pharmacies and four in-country views by experts as well, as the European Association of Hospital Pharmacists (EAHP) presented their practical solutions to the implementation of the FMD.

Challenges such as procurement of new IT systems, volume of packs, complexity of distribution pathways within the hospital, slow decommissioning, staffing resource issues, planning procedures for in-bound stock, identifying who can perform the decommissioning and the need for a standing buffer were all cited.

Critical success factors were identified as:

- Support from national bodies to ensure alignment and financial support where possible across the national health system;
- Communication between stakeholders (from hospital to hospital and allied services; ambulance services etc.) to standardise the processes to ensure that the technology platforms are compatible and fully integrated into existing workflow;
- The relationship with third-party automation providers and their understanding and cooperation to work out the final optimal approach
- Definition and handling of false alerts
- A clear and understandable language within the system read outs

- The use of technology to overcome the manual burden placed on hospitals was required with robotics as a way to facilitate the implementation process.

The final presentation by Agnès Mathieu Mendes of the Directorate-General for Health and Food Safety of the European Commission forcefully reminded the audience that falsified medicines are a serious public health concern. They harm patients and affect every region in the world. Between 2013 and 2017, the Commission received 400 notifications of falsification in the EU and in 2017 around 7 million euros worth of counterfeit medicines were seized at the EU border.

10 days after the implementation date of the FMD, the European Hub functions properly and no major issues have been identified so far. All databases are connected and connection to end-users is in progress. The Commission is an observer who tries to facilitate the discussion between stakeholders as the level of awareness is still not sufficient and so there is a need for more outreach to actors. DG SANTE had set up a sub group of Member States to investigate possibilities of having a system of data files with suppliers instead of aggregation where they can ensure decommission under certain safety checks.

While it is clear there is a need for a period of stabilization, European policymakers will continue to help and dialogue with EU Member States; hence it will be critical to work together at a local, national and European level to overcome existing challenges and protect patient safety, ensuring a controlled application of the NMVS as well as an uninterrupted medicines supply.

More information on the event are available here.