Press Release

Only 255 days to go live for European Medicines Verification System

Sector wide impact for Europe's pharma sector

29th May 2018

Dublin, Ireland – The go live date for Medicines Verification Systems across Europe is front of mind for most delegates gathered in Dublin at the European Healthcare Distribution Associations' 59th Annual General Meeting and Conference.

On Saturday 9 February 2019, deadlines set by the EU Delegated Regulation on Safety Features, which is part of the so-called Falsified Medicines Directive (FMD), will kick-in and Medicines Verifications Systems will go live across Europe. On that date, the entire pharmaceutical sector will have to comply with the requirements established in the falsified medicines legislation.

"Across Europe, each healthcare distributor sees thousands upon thousands of medicines packs pass through their distribution centres daily", Monika Derecque-Pois, Director General, GIRP, explained. "Our picking, packing and shipping processes to our pharmacy and other healthcare professional clients would grind to a stand-still if pharmaceutical full-line wholesalers were required to verify each pack. Healthcare distributors will only verify medicines if they do not receive them directly from a manufacturer or their pre-wholesaler." While expressing high confidence in the readiness of GIRP members, Derecque-Pois emphasised "that there are still a number of important issues to address, some challenges to overcome and very, very little time to get it done, even more importantly tight deadlines left to get it done right."

The European Medicines Verification Organisation (EMVO), of which GIRP is a founding member, is missioned with establishing the central hub to which all Marketing Authorisation Holders (MAHs) and the repository system of the different National Medicines Verifications Systems (NMVSs) need to connect. All these connections are mandatory for the entire system to become fully functional, operational and interoperable. "While enormous efforts have been underway, and work currently reaches new highs, there is concern at the forefront of the minds of those responsible for getting the systems fully operational on time" Andreas Walter, EMVO General Manager stated during a discussion on the issue at the meeting. "To-date only close to 900 of the near 2,300 MAH on-boarding partners are in the process of connecting to the European hub and only 8 national systems have connected. While encouraging to see the numbers rising daily, we have a long way to go", he said.

GIRP is the European organisation representing over 750 healthcare distributors which as pharmaceutical full-line wholesalers hold not more than one tenth of the total number of wholesale distribution authorisations in Europe. GIRP conservatively estimates that there may be as many as over 10,000 wholesale distribution authorisation holders in the market place and all will need to establish a connection to their respective national system in order to discharge/fulfil their regulatory obligations as set out the FMD and DR.

GIRP is concerned about the status of the European Medicines Agency (EMA) EudraGMDP database which lacks data on wholesale distribution authorisation holders from some countries. "We urgently need to have a fully populated, fully updated database of all legitimate authorisation holders and call upon National Competent Authorities (NCAs) to ensure at a minimum that national data bases are fully operational. National system owner need a reliable primary data source to ensue only legitimate authorisation holders are granted connections to the NMVSs.", Monika Derecque-Pois stated. We absolutely need to have the active support of NCAs in reaching out and communicating with all MAHs, wholesale distributors and dispensing entities.

Monika Derecque-Pois also expressed some concern about the so-called Article 23 entities which are non-healthcare institutions, such as, care homes, opticians, army and prisons. Article 23 operators will not need to verify or decommission medicines if Member States legislate for wholesalers who supply the medicine to the institution to verify and decommission on their behalf. "The fine details of Article 23, however, are still subject

to Member States specific legislation and to date, we are not aware about wide spread discussion on this point", Derecque-Pois explained.

In closing a session dedicated to the subject matter, all discussants, recalled their dedication, commitment and high energy investment in supporting all system users' readiness ahead of the deadline.

For information please contact: Martin FitzGerald, Deputy Director General m.fitzgerald@girp.eu

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ABOUT GIRP

GIRP, the European Healthcare Distribution Association, is the umbrella organisation for pharmaceutical full-line wholesalers and distributors of healthcare products and services in Europe. It represents the national associations of over 750 pharmaceutical wholesalers serving 35 European countries, as well as major international and pan-European healthcare distribution companies. GIRP members employ over 140,000 people and distribute around 15 billion packs of medicines as well as a wide range of healthcare products per year. As the vital link in healthcare, they are committed to developing and providing innovative and efficient healthcare products and services to improve health and wellbeing of patients across Europe.