23 September 2015
EMA/625931/2015
Corporate Stakeholders Department

Report of meeting held with GIRP - European Association of Pharmaceutical Full-line Wholesalers

10 September 2015, at the EMA

Participants:

EMA: B. Cuddy (Chair), A. Luis De Lima Marcal, M. Carr, P. Costello, N. Kriz, M-H. Pinheiro, L. Weingartz

MHRA: G. Heddell, B. Sinclair-Jenkins

GIRP: M. Derecque- Pois, M. FitzGerald, M. Rotaru, D. Gouveia, B. Grabner, C. Hajnal, I. Markaki, M. Sawer, L. Schenatz, G. Scrofina, B. Sickendiek, T. Torgo, M. Valdés, E. Van Nueten, A. Vatanen, T. Votruba

Objectives of the meeting:

- To provide a general introduction for GIRP members on the role and responsibilities of the EMA.
- To enhance EMA understanding of this stakeholder association, its activities and key areas of interest.

Topics addressed with agreed actions, if any:

Introduction to EMA

- A general introduction to the EMA and the European Medicines Regulatory Network was provided, with detailed focus on the role and responsibilities of the EMA's Compliance & Inspections Department and Manufacturing & Quality Compliance service.
- The important role of the GMDP Inspectors Working Group in co-ordinating input on GDP issues, where they arise, was highlighted. Changes are being driven through the increasing complexity and globalisation of the medicines supply chain.
- EMA is working closely with the European Commission and EU Member States to implement the Falsified Medicines Directive. EudraGMDP has recently been extended to include, in addition to MIAs and GMP certificates, WDAs, GDP certificates, and API manufacturers, importers and distributors registrations. Updated guidance on GDP has been issued, and written confirmation

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

requirements for APIs have been implemented. A website has been established explaining the EU logo for on-line pharmacies with a link to National Authorities websites.

- GIRP were asked to raise awareness of its members to the non-compliance reports published through EudraGMDP since December 2013. It was also recommended to refer to the documentation related to GDP published by the EU inspectorates on their quality systems.
- The importance of ensuring supply chain integrity and continuity of supply and preventing entry of falsified or defective medicines was emphasised.
- EMA is committed to improving mitigation of the causes and impact of shortages of human medicines caused by GMP non-compliance and quality defects. A reflection paper on medicinal product supply shortages was published by the EMA in November 2012. EMA is keen to understand from relevant stakeholders what more can be done in terms of better business practices, to support solutions. To this end, an EMA meeting with stakeholders is being organised on 9 October 2015.

  Action: GIRP to be invited to the upcoming meeting on medicines shortages and will forward their reflection paper in advance of that meeting.

Presentation of the European Association of Pharmaceutical Full-line Wholesalers (GIRP)

- An introduction to GIRP (Groupement International de la Reparticition Pharmaceutique) was provided. GIRP is the umbrella organization of pharmaceutical full-line wholesalers in Europe, and represents the national associations of over 750 pharmaceutical full-line wholesalers serving 33 European countries.
- The core activity of pharmaceutical full-line wholesaling consists of: purchase and sale; warehousing storage; order preparation; and delivery of medicines. An overview of Public Service Obligations for wholesalers in Europe was presented.
- With regard to the GDP guidelines the key areas which will impact on wholesalers were highlighted. Issues were noted with Chapter 9, regarding 'Transportation' and the need for risk assessment of delivery routes to identify when temperature control is needed. Harmonised guidance on how this should be implemented at national level is needed.

  Action: GIRP to forward summary of issue and an example of national guidance in this area.
- Regarding implementation of the FMD, a group of stakeholders including GIRP have come together to form the European Medicines Verification Organisation (EMVO). Established in February 2015, EMVO aims to set up a stakeholder governed model to secure the legal supply chain that is functioning, harmonised, cost-effective and inter-operable.
- GIRP's interest in participating in future GMDP Inspectors Working Group interested party meetings was noted.