

**From:** [REDACTED] (SANTE) on behalf of [REDACTED]  
(SANTE)  
**Sent:** jeudi 29 octobre 2020 15:52  
**To:** [REDACTED] (SANTE)  
**Subject:** BTO - GIRP 28 09 2020

**Attendees:**

**Meeting participants**

**GIRP**

[REDACTED], GIRP  
[REDACTED], GIRP  
[REDACTED], Alliance Healthcare DE  
[REDACTED], McKesson EU

**SANTE :** Commissioner Kyriakides, Karolina Herbout-Borczak (Member of the Cabinet), [REDACTED]  
[REDACTED] Unit B4)

Commissioner briefed the association about the situation on the COVID-19. EC is concerned about the steady increase of COVID-19 cases in the EU and rely on the Member States to put into place the necessary measures to avoid a generalized lockdown. Commissioner referred to the forthcoming adoption of the pharmaceutical strategy to address affordability and access of medicines, innovation, strategic autonomy of the EU and reinforcing the manufacturing capacity of the EU. The pharmaceutical strategy is to be adopted at the end of November and will be patent centered. Commissioner also referred to the vaccines strategy, the agreements with AZ and Sanofi-GSK and the negotiations concluded with four other companies.

GIRP presented the association, namely the association representing full line wholesalers in 33 countries. They ensure full supply without interruption of a wide range of medicines and other healthcare products such as gloves and masks, lifesaving vaccines, emergency products and individual patients packaging . They supply pharmacies in 2.5 hours, 16 times per week even during the crisis and perform public service obligations in some Member States. They also contributed to help implementing the legislation GDP, falsified medicines and shortages of medicines.

GIRP invited Commissioner to open their annual conference planned at the end of November.

**Core issues raised by GIRP**

- **Shortages of medicines:** GIRP made its own survey on shortages of medicines. The shortage of medicines in rich countries is due to the production problems while small price countries suffer from medicines withdrawals. It is not the same medicines in shortages across the EU. Moreover, parallel trade is not a reason for shortages of medicines. GIRD called for an harmonized notification system as well as a coordination of shortages at EU level. Some national IT systems are promising such as in Spain and in DE (for COVID-19). EMA should compile the data and ensure full transparency. GIRP believes that the falsified medicines system is not suitable for monitoring shortages of medicines; GIRP also called for enforcing the Article 81 on the obligation of continuous supply. Nevertheless, GIRP called for making a clear distinction between the obligations to supply by the marketing authorization holder and by the distribution authorization holder. Distributors should have the right to be supplied by industry to fulfil the public service obligations. A study is ongoing to analyze the root causes and possible legislative options. EC confirmed that the Pharmaceutical strategy will cover proposals to tackle shortages of medicines as well as a review of the legislation.

- **Pharmaceutical strategy:** GIRP submitted their comments to the public consultation. GIRP called to recognize the key role of the full service healthcare distributors in the EU legislation. All Member States do not have full line wholesalers on their territory. GIRP also called for streamlining full licensing systems of the Member States across the EU. Moreover, financial sustainability is crucial as profit margin is very low. GIRP asked to eliminate any restriction to parallel exports and to encourage multimarket packs. This would facilitate the sales of medicines across the EU.
- **COVID-19 vaccines:** [REDACTED] worldwide supplier for healthcare distribution, offered to support the distribution of COVID-19 vaccines based on the long standing experience in distribution of healthcare products. The company Mc Kenson has invested in IT system to supply to industry and consumers, contingency plans and allow to deploy medicines in short notice and according to strict temperature controls. Mc Kenson will contribute to the distribution of vaccines in the US and would be very well prepared for the EU . It may cover vaccines, PPP gloves or syringes. GIRP would also like to contribute if ECDC is drafting a guideline on the distribution of vaccines in the EU;
- **COVID-19 crisis:** GIRP members ensured the supply of healthcare products during the entire crisis. Nevertheless, Member States restricted the distribution of medicines. They also had problems with the distribution of medicines in certain restricted areas during the lockdown. GIRP asked to be recognized in all Member States as a critical activity to ensure continuity of supply and have access to protective equipment. The green lines were enforced in some Member States. Wholesalers can also introduce emergency stocks at the request of the authority. GIRP asked to be invited in the weekly call with the Commissioner when discussing shortages.

EC confirmed that access and affordable medicines will be addressed in the pharmaceutical strategy and shortages of medicines will also be addressed in the package dealing with the crisis strategy and the lesson learned from the crisis with more coordination at EU level..

Commissioner confirmed her availability to do a video message for the annual conference and accepted to invite GIRP in the meeting with industry.