GIRP Statement at the online consultation with non-State actors on the Oslo Medicines Initiative: Better access to effective, novel, high-priced medicines - a new vision for collaboration between the public and private sectors 27 April 2021 (11:30-14:30 CEST)

GIRP welcomes the Oslo Medicines Initiative and the opportunity to share our ideas and input on the topic of better access to effective, novel, high-priced medicines with the World Health Organisation, the Norwegian authorities and with all other relevant participants, including national authorities and supply chain partners.

GIRP and its members fully applaud the effort by WHO and the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency to bring together supply chain stakeholders and national competent authorities in a discussion on ensuring safe and fair access to novel therapies and high-priced medicines to all patients across Europe.

In the context of this initiative, GIRP would like to outline the core function of full-service healthcare distributors (also referred to as pharmaceutical full-line wholesalers), being the vital link for the fair, efficient, timely and safe distribution of all medicinal products, including medical devices and other medical supplies, to patients across Europe. Full-service healthcare distributors, through their stockkeeping and financing function, their extensive web of distributions centers and warehouses, as well as, through their logistic excellence are able to deliver any medicine in Europe within a very short time span to even the most remote location (average delivery time in Europe is 2.5h).

The continuity of supply and guaranteed availability of medicines are key necessities and therefore unique dynamics are required within the pharmaceutical market. Full-service healthcare distributors are committed to ensuring that even the most isolated patients can receive even the most specialised medicines via their pharmacist in a safe and timely manner.

In doing so, full-service healthcare distributors also ensure the integrity of the medicinal products upon dispensation through full compliance to a comprehensive set of national, EU and international level regulations, including but not limited to the WHO and EU Good Distribution Practice guidelines as well as all relevant EU and national legislative frameworks.

Full-service healthcare distributors continually adapt their infrastructure and their practices to fulfil requirements of new specialty products as they enter the market. GIRP members are acutely aware that systems of specialty distribution have become increasingly complex and require a much higher amount of agility, flexibility and innovation from the supply chain. Supply chain actors need to analyse their levels of mobility to be able to cater to the specific patients' needs. As such, full-service healthcare distributors leverage their unique position in the supply chain to be able to provide tailored services.

That said, this new model requires a high-functioning level of communication between all partners of the supply chain. Digitalisation of the supply chain and use of data in a safe and up-to-date regulatory framework are key to develop the structure for safe, fair and sustainable specialty distribution. From the pharmaceutical industry down to the payor, supply chain networks need to build platforms to discuss the specific needs of patient groups and tailor solutions to their individual needs. The WHO could support discussions and progress on the development of such structures to ensure all elements of access to high-priced medicines be considered including refitting of the downstream supply chain from distribution to dispensation.

GIRP calls on the instigators of the discussion to ensure that the downstream supply chain and the challenges brought by new specialised, high-priced medicines are not overlooked and that the existing supply chain mechanisms are not bypassed.

GIRP also calls for the sustainability of the healthcare supply chain to be considered when addressing the issue of medicines pricing. The remuneration models of full-service healthcare distributors vary across Member



States, although in most countries they highly depend on an extremely slim percentage of products' prices with a maximum cap placed on the delivery of high-priced medicines. Unfortunately, in some countries, full-service healthcare distributors are reaching breaking point in the sustainability of the distribution sector where the remuneration is insufficient to cover the costs of pre-financing, risk assumption, storage, picking and delivery. A key factor for a healthcare system's overall resilience and its capacity to adapt to new healthcare models is based on ensuring full-service healthcare distributors' financial sustainability.

Full-service healthcare distributors are the only ones to assume a financing function towards manufacturers and pharmacies. They finance the quasi-entire medicinal product market (on average EUR 11.6 bn over a period of 45 days¹) and thus support the development of novel therapies without distinction between smaller or larger players. In doing so, full-service healthcare distributors enable SMEs which do not have the infrastructure or the resources to organise the complete supply chain of their innovative products themselves.

Conclusion

Safe and fair access to high-priced medicines to all patients across can only be guaranteed through considering the specificities of the requirements for such products and the impact of the transformation throughout the supply chain and through ensuring a seamless-communication and cooperation between supply chain stakeholders and with the competent authorities.