Feedback from: GIRP - European Healthcare Distribution Association

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GIRP - European Healthcare Distribution Association

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Pharmaceuticals – safe and affordable medicines (new EU strategy) (/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceuticals-safe-and-affordable-medicines-new-EU-strategy-)

GIRP considerations for the Pharmaceutical Strategy for Europe (PSE)

GIRP welcomes the European Commission's (EC) recognition of the pharmaceutical value chain in the Roadmap for a PSE. GIRP looks forward to working with the EU institutions, Member States (MS) and value chain stakeholders to develop concrete solutions for the future of healthcare. Medicines availability and accessibility, taking into consideration the EU single market, lessons learned from COVID-19, national approaches to healthcare, as well as future healthcare organisation are key factors. We need to have an assessment of the challenges and opportunities, to find solutions which incentivise rather than mandate through obligations.

Full-service healthcare distributors are the invisible, yet vital link between manufacturers and pharmacies and hospitals assuming the timely delivery of all medicines to patients. They are in a unique position to ensure that all health products (including vaccines) are distributed safely and fairly across national territories.

Keys considerations:

1. Recognition of the full-service healthcare distributors' role

GIRP calls for improved recognition of the full-service healthcare distributors' public service role as they ensure continuous supply, maintain buffer stocks, optimise stock allocation and pre-finance the supply chain. The EC should encourage MS to review their current licensing systems and progress towards a European distribution authorisation regime and the differentiation of full-service healthcare distributors by law. The EC should urge MS, who have not, to include full-service healthcare distributors in their national critical infrastructures.

2. Sustainability of the healthcare distribution sector

While the remuneration of healthcare distributors lie at national level, GIRP calls on the EC to work with MS to support the viability and sustainability of the full-service healthcare distribution sector as a pillar of EU healthcare systems.

3. Medicines shortages, accessibility and single market

a. Medicines shortages

GIRP calls on the EC and MS to agree on the adoption of a common definition of medicine shortage. GIRP calls on the EC and MS to ensure information sharing at EU level through a common medicines shortages database / early warning system involving all supply chain stakeholders. GIRP also calls for the harmonisation of national shortages databases, allowing cross-country root cause analysis and visibility. GIRP stresses that the European Medicines Verification System is not an appropriate tool for shortages monitoring as it does not contain accurate data of market supply and demand. Lastly, shortages monitoring is not within the direct scope of the legislation.

b. Medicines availability

System failures can be addressed through the full implementation, effective monitoring and enforcement of Article 81, paragraph 2 of the Directive 2001/83/EC in national legislations in a way that places separate obligations on both Marketing Authorisation Holders (MAHs) and healthcare distributors. The latter should have the “right to be adequately supplied” by MAHs to fulfil patients’ needs. Full implementation ensure that appropriate levels of buffer stock are maintained at national level.

c. Parallel trade

GIRP appreciates the EC guidance (ev_20180525_rd01_en) and encourages swift and determined action in case of disproportionate hurdles to the Single Market. Temporary export restrictions can only be justified in case of products in short apply following strict criteria proposed by the EC.

d. EU Single Market for Medicines

GIRP calls for the EC to progress with a dialogue on advancing the Single Market for medicines through a forum comprising all supply chain stakeholders and authorities.

4. Digitalisation

GIRP calls on the EC and MS to facilitate and incentivise digitalisation to improve healthcare and its distribution including a legislative basis for electronic data interchange amongst supply chain partners.

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