Pharmaceutical Strategy - Timely patient access to affordable medicines

Keys issues

1. Recognition of the role of healthcare distributors

1. GIRP calls on the EU institutions and policymakers to recognise the critical public service role and function full-service healthcare distributors (wholesale distribution authorization holders) provide. Acting as the 'Vital Link in Healthcare' between pharmaceutical manufacturers and pharmacies as well as hospitals and other dispensing points, full-service healthcare distributors ensure the safe, rapid, continuous, cost-effective and manufacturer independent supply of all medicinal products.

   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 ensure that even the most isolated patients can receive even the most specialist medicines via their pharmacist in a safe and timely manner.

   Pharmaceutical full-line wholesalers' commit to:
   - carry and distribute the complete assortment of products in range and depth within the frame set by the authorities and the market;
   - ensure product availability to patients within a matter of hours continuously;
   - create and maintain quality standards that ensure, above all, safety and integrity of the medicine when delivered to the retail pharmacists as well as other health care professionals
   - perform a public service function.

2. It is essential that the European Commission, in collaboration with the Member States, strengthens the well-established structures of full-service healthcare distributors, as well as community pharmacies, and make use of their logistic capacities such as for the distribution of Personal Protective Equipment (PPE), test-kits and later on vaccines. The COVID-19 crisis has shown the importance of primary care and products previously dispensed in hospitals can more easily and safely be made available to patients in pharmacies. Full-service healthcare distributors have the facilities to hold buffer and emergency stocks and can distribute these efficiently and equitably to the dispensing points. Indeed, unique features of the sector include the possibility of holding rotating emergency stocks, preventing products from expiring by applying FEFO (first expired first out) principles, by integrating emergency stocks in normal operations (thereby strictly respecting the agreed buffer quantities).

3. GIRP calls on the European Commission to encourage National Competent Authorities (NCAs) to allow stock optimisation measures introduced by full-service healthcare distributors or their customers to restrict deliveries or the number of products dispensed to ensure availability of products for other pharmacies, hospitals, clinics and ultimately patients who also need treatment. Government, physician and pharmacist driven communication towards patients should be in place to prevent over-stocking at patient level.

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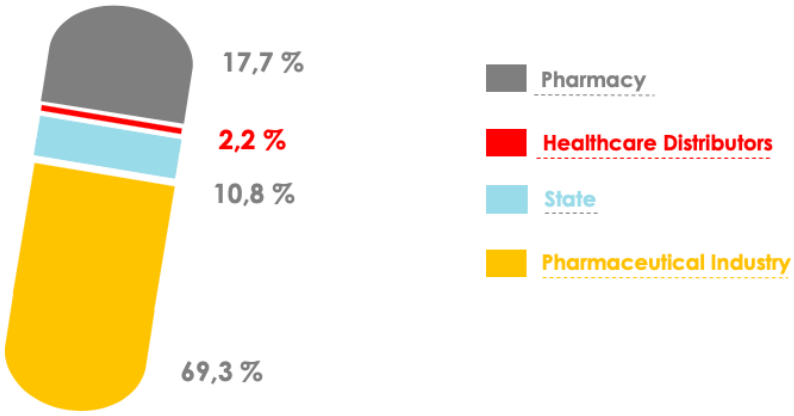
4. Given the essential role carried out by full-service healthcare distributors in medicines distribution, GIRP calls that they be recognised as part of the "critical infrastructure" or "essential services" in all EU Member States. The critical infrastructure status confers full-service healthcare distributors the means to ensure the stability needed to maintain the necessary activity levels for medicines distribution in times of crisis, which should include among others, special access and permits to carry out their public health duties and access to PPE for staff and drivers.

5. In order to improve safety and reliability while removing inequity from the supply chain, GIRP calls for a general revision of the wholesale distribution licensing systems, differentiating full-service healthcare distributors by law. Full-service healthcare distributors require a license to operate yet some operators are not required to hold such authorisations. The National Medicines Verification System could act as an indicator of active wholesaling licenses: healthcare distributors who do not connect to the national system could see their licenses revoked. Ultimately, a single European licensing system – as it is the case for the distribution of veterinary products - would simplify the supply chain and regulatory processes.

2. Sustainability of the sector

6. GIRP calls on the EU institutions to encourage and work with Member States to promote measures, such as the application of a sustainable remuneration for the sector, to support the financial viability of the full-service healthcare distribution sector which is a key factor for a healthcare system's overall resilience. The insufficient remuneration for medicines' distribution in several EU Member States endangers current service levels and the continuous availability of all medicines for patients.

Average price composition of reimbursed medicines sold in pharmacies FRANCE, 2018



7. GIRP calls on EU institutions to ensure that all new legislative and regulatory measures are subject to economic impact assessment reviews prior to their implementation. While the remuneration for full-service healthcare distributors is regulated at national level, EU institutions and policymakers should ensure the cost of compliance is made transparent in order to be properly covered by the different national remuneration systems for healthcare distributors.
8. GIRP calls on authorities to build new supply chain solutions based on the existing infrastructure and processes of full-service healthcare distributors.

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3. Medicines shortages, access to medicines and supply chain

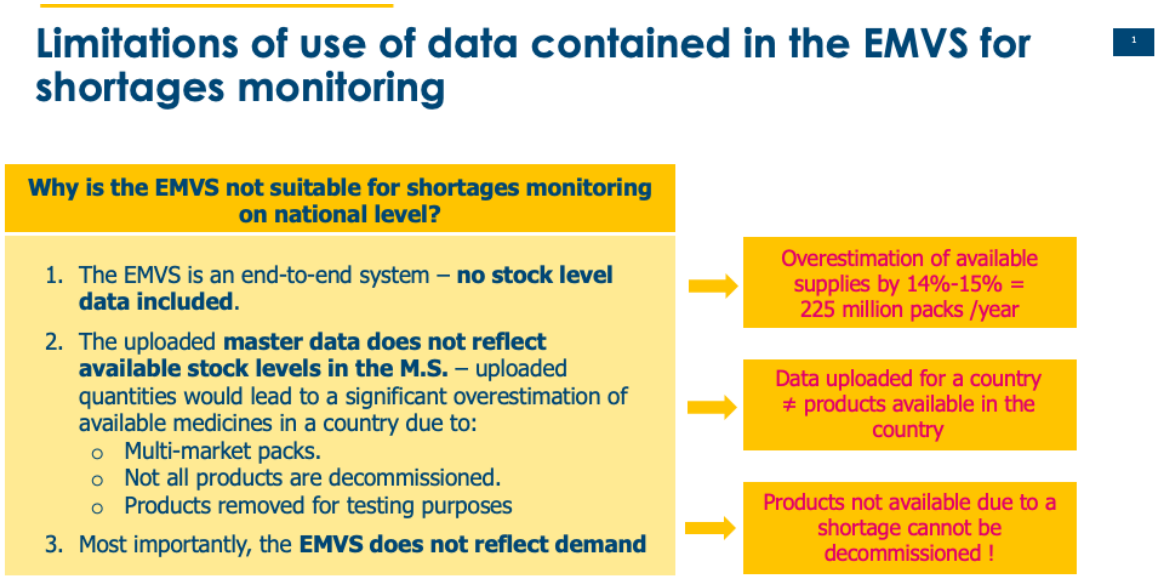
A. Medicines shortages and information sharing at European level

9. GIRP recommends an early warning system for anticipated and existing shortages, involving all supply chain stakeholders, from manufacturers, full-service healthcare distributors (wholesale distribution authorisation holders), pharmacists to prescribers and the national competent authorities.
Additionally, legislation should foresee the obligation of early notification of shortages by MAHs to full-service healthcare distributors (as well as to the National Competent Authorities), contributing to better stock management and supply.

10. GIRP recommends the harmonisation of root causes of shortages and the inclusion of tracking of shortages of APIs in national medicines' databases to improve transparency of unavailability of medicines at EU level. This would allow for solving, or at least mitigating, medicines shortages by importing from other Member States and a more efficient tackling of root causes. From the currently 27 EU Member States only 17 countries have published lists of medicines in shortage and only 11 countries include their root causes with very different degrees of granularity.

    See here the outcome of the GIRP analysis of national databases on root causes for shortages. (Link)

11. The European Medicines Verification System (EMVS) cannot provide a clear overview of national stock levels as the data contained therein will – due to multi-market packs among other reasons - always be significantly higher than the number of packs actually shipped to the national markets. Most importantly, data about products decommissioned from the system in no way shows the national demand - especially as in case of a shortage, these figures would be highly misleading and lead to wrong conclusions with a detrimental impact on patients' access to medicines.



12. The EMVS was built to protect patients from receiving falsified medicines through the legal supply chain and is therefore not suitable for the monitoring of shortages as it cannot provide accurate information on supply and demand.

* See here GIRP position on potential use of data contained in the EMVS for shortages monitoring

B. Ensuring medicines availability to European patients

13. The continuous availability of medicines for patients whenever and wherever they are needed is one of the primordial pillars of our healthcare systems. Full-service healthcare distributors – through their stock-keeping and financing function, their tight web of distributions centres and warehouses as well as through their logistic excellence are able to deliver any medicine in Europe within a very short time span to wherever the patient is (average European delivery time 2,4h). However, some hurdles such as shortages, too stringent supply quotas or selective distribution models, may prevent patients from having reliable access to their medicines.

14. Some supply chain system failures can be addressed through the full implementation, effective monitoring and enforcement of Article 81, paragraph 2 of the Directive 2001/83/EC. Article 81 paragraph 2 should be interpreted and appropriately set-out in national legislations in a way that places separate obligations on both Marketing Authorisation Holders (MAH) and full-service healthcare distributors, as most importantly provide the "right to be adequately and continuously supplied" for full-service healthcare distributors. GIRP therefore calls for the European Commission to work with Member States to ensure the accurate interpretation of this provision in national legislation (as it is the case in Belgium, France and Germany) which should provide for an auditable right for full-service healthcare distributors to be appropriately and continuously supplied by MAHs with the full range of products in order to fulfil the needs of patients in the Member States in an appropriate manner. Full effective implementation can ensure that appropriate levels of buffer stock are maintained at national levels to help mitigate medicines shortages and effectively prepare for health emergencies such as possible future waves of the COVID-19 pandemic.

15. If there is a justifiable need to impose supply quotas for medicinal products due to a national shortage, full-service healthcare distributors should be made aware of an existing or anticipated shortage and informed about their respective allocated quantities in advance (no "black-box" quotas with unknown amounts of products) to allow optimised allocation of the available quantities of medicines to the dispensing points across the national territory. Supply quotas in general are highly problematic and based on legal grounds should be abolished. The practice of supply quotas cannot be reconciled with Public Service Obligations (PSOs) or Public Service Functions, they can force full-service healthcare distributors in turn to apply quotas to pharmacies and are therefore rather contributing to the occurrence of shortages than avoiding them.

16. A distinction should be made between full-service healthcare distributors (pharmaceutical full-line wholesalers) who ensure the continuous availability of all medicines and healthcare products they can procure within the limitations of the legal framework and market conditions and other actors, distributing by choice only a selective range of mostly high margin products.

17. Additional safety stocks for essential medicines should be held in cooperation with full-service healthcare distributors, as outlined under point 1. the possibility of holding rotating emergency stocks, preventing products from expiring by applying FEFO (first expired first out) principles, by integrating emergency stocks in normal operations (thereby strictly respecting the agreed buffer quantities) are unique features of our sector.

18. Collecting data with the sole aim of preventing medicine shortages should be exempted from competitive restrictions by law once the COVID-19 pandemic is over.

C. Regulating parallel trade

19. Temporary controls of parallel exports for specific listed medicinal products may be considered suitable if they (see EC recommendations):
    - apply only to medicinal products for which a shortage is likely or certain to occur and if the medicinal product is part of the essential medicines list;
    - are established by a medicines agency or an independent third-party which can verify the potential for a shortage of a particular product;
    - are established through transparent and auditable criteria that are known in advance having been confirmed following a consultation of all supply chain stakeholders;
    - take into account the possibility of substitution or the availability of alternative treatments in the Member State concerned;
    - are revised on a regular basis taking into account the latest occurrences or risks of shortages of essential medicines for public health;
    - are proportionate to the prevention of shortages, transparent and communicated in time;
    - are open to be contested before court / administrative bodies by all stakeholders.

20. We strongly encourage the European Commission as guardian of the Single Market to take a more active role in monitoring national export restrictions and counteracting any unproportionate measure.

D. Advancing the EU Single Market for Medicines

21. GIRP believes that a balance is to be found between the needs of governments and healthcare systems to contain healthcare spending and the need to provide the most efficient and innovative medicines to all European citizens through the advancement of the EU Single Market for medicines.

22. GIRP calls on the European Commission to propose that the issue of pricing and reimbursement for centrally (EMA) registered products should be separated from the availability of centrally registered products on national markets. In case of a detachment of pricing and reimbursement, products could be immediately placed on the market (with a European or a multi-country package including all necessary national requirements) after the centralised marketing authorisation has been granted. Pharmaceutical manufacturers should be able to set an ex-factory of their medicine for the whole EU market. Due to the principle of subsidiarity, Member States would then have to decide upon the public price and the reimbursement of the product. Derogations should be applied for Member States where the access to the market is not possible prior to a reimbursement decision. According to these derogations, a pharmaceutical product could access the market prior to a reimbursement decision based on a freely set ex-factory price.

23. Manufacturers at production level (or pre-wholesalers contracted by the manufacturers to do this), should have the right to make the necessary adaptations to the 'blue box' in accordance with the national requirements of an already standardised package, without having to obtain an additional manufacturing authorisation, so that the same medicines can be made available throughout the European Single Market. The existence of a single manufacturing authorisation valid for the entire EU granted by the EMA, together with the marketing authorisation, could be a first step towards a Single Market for medicines and would at least ensure immediate availability of the most innovative medicines for all European citizens.

4. Digitalisation

24. GIRP calls on the EU institutions and Member States to facilitate, promote and incentivise digitalisation to improve healthcare and its distribution. The ability to share data will become an essential factor in this process. Ethically sound governance system should be in place on how to share health data and healthcare stakeholders must be incentivised to innovate for the utmost benefit and safety of the patient.

25. GIRP calls for the implementation of a fair regulatory framework harmonising the use and access of personal and non-personal data across Europe. GIRP calls for a reliable governance over data ownership while also enabling data-led innovation. Interoperability must be a priority.

26. GIRP furthermore highlights the added-value benefits of electronic transmission of information on medicinal products between supply chain participants and asks for a direct application in national law of chapter 4.2 paragraphs 9 and 10. This is already common practice in Spain and Finland and complies with modern business practices.

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