Improving the availability of medicines – shortages monitoring systems for public health emergencies

Date
10 December 2020

Improving the availability of medicines is a key priority for regulators, supply chain stakeholders and patients alike within the EU. Shortages create challenges for the medicine supply chain with a serious impact on the health of citizens. Unfortunately, shortages will always occur and full-service healthcare distributors will support any mechanism to mitigate the problem. EU policy makers therefore are urgently searching for solutions to monitor shortages on a national and European level.

In November 2020, the European Commission proposed a range of measures aimed at the empowerment of the European Medicines Agency (EMA) to act in times of crisis.

GIRP fully endorses the definition of a 'shortage' as outlined in the Proposal for a Regulation on a reinforced role of the EMA in crisis preparedness and management for medicinal products and medical devices as meaning that **supply of a medicinal product does not meet demand** for that medicinal product.

Building on the experience of the current COVID-19 pandemic, the proposed Regulation puts temporary arrangements and exceptional measures on a permanent footing. The proposal, which is a key part of a "European Health Union" seeks to strengthen the EMA's role from monitoring and evaluating the safety of medicines to monitoring and mitigating shortages of critical medicines during health crisis.

Under the proposal, the EMA will be mandated to monitor and mitigate potential and actual shortages for the duration of a public health emergency or major event, especially for products considered critical in addressing a given public health emergency. In this regard, the EMA will activate a dedicated crisis management structure – Executive Steering Group on medicines, which will play a leading role in coordinating and supporting the response to shortages during pandemics. The group will be mandated to establish a list of critical medicinal products during a major event or public health emergency and the criteria necessary to monitor their supply and demand. It also has a role in reporting, providing recommendations and coordinating measures on shortages. Obligations will be placed on marketing authorisation holders, wholesalers, pharmacies, and Member States to provide the necessary data through streamlined IT tools. Such a framework should reduce the risk of uncoordinated stockpiling of products, ensure the smooth functioning of the internal market and allow for the continued flow of medicines. GIRP is fully supportive of this approach.

Whilst an important step in the fight against the negative health impacts from medicines shortages, additional efforts by regulators and stakeholders alike (as outlined later in this paper) at systemic level during non-crisis times will be another key pillar in overcoming the many challenges related to shortages.

Current and future IT solutions will no doubt play a role in supporting the monitoring of the demand and supply situation. The dual nature of the competences in the area of public health as reflected in article 168 of the Treaty on the Functioning of EU (TFEU) will also certainly see dual solutions at national and European level.

In regard to IT solutions, some stakeholders are advocating the use of the European Medicines Verification System (EMVS). As outlined in the GIRP position paper from 2019, the EMVS is not designed and therefore not by itself usable for the monitoring of shortages. A position supported by other EMVO board members.

Rue de la Loi 26, Box 14
1040 Brussels, Belgium
T +32 (0)2 777 99 77
F +32 (0)2 770 36 01
E girp@girp.eu
W www.girp.eu

GIRP takes the view that the EMVS can only be of use with a number of pre-conditions, especially as far as the '**real world availability data**' of uploaded packs is concerned. This additional information should prove beyond doubt, that a pack uploaded to the EMVS was actually physically supplied to a certain market and is available for consumption by patients.

Forecasted demand (as a potential outcome of an expanded European Medicines Agency pilot project on "Forecasting demand for medicinal products in the EU/EEA") **would need to be matched with "real world supply figures"**. This is the first step in checking, whether the supply situation generally meets demand during a certain period of time in certain markets. **The figures of decommissioned products from the EMVS for demand forecasts would be highly misleading, especially in shortages situations as only available medicines can be decommissioned.** In summary the EMVS would always show higher than actual supply and lower than actual demand so GIRP cannot support its use at this time.

Furthermore, GIRP deems it absolutely crucial, that in addition to institutionalised demand forecasting and the requirement to prove sufficient supply on national markets to fulfil the forecasted demand, national early warning systems about shortages, **collecting signals about the current supply situation from all stakeholders involved in the distribution of medicinal products** (wholesalers, pharmacies and hospital pharmacies) **are taken into account as integral part of any shortages monitoring system for critical medicines** on national and subsequently at EU level. These market signals provide an early warning if the continuous supply is at risk for any reason (i.e. unforeseen demand). Based on their unique knowledge of the supply chain, **all stakeholders need to work together on finding solutions**.

As a consequence of subsidiarity in health matters and as provided for in Article 168 TFEU, the ways to deal with medicines shortages are very much dependant on the regulatory framework in place in a certain Member State. As a result, many different national shortages monitoring systems are already in place in the Member States and their design as well as their operating principles vary significantly. They are either stakeholder-led systems like in Ireland, the Netherlands, France, Portugal and Spain or government-led systems like in Belgium, Germany and Bulgaria. **GIRP strongly supports the continuation of the usage of existing national shortages monitoring systems instead of the introduction of completely new systems**. Furthermore, **GIRP fully supports connecting available national shortages monitoring systems with the future EMA-led shortages monitoring solutions for public health emergencies.**

In countries where there is no current institutionalised monitoring of the supply situation, GIRP proposes the introduction of an early warning system that collects market signals from all supply chain stakeholders including wholesalers, meeting the following criteria:

- **Includes information sharing concerning shortages with the National Competent Authority**
- **Measures wholesalers' demand against the manufacturers' delivery capacity**
- **Includes pharmacies' demand**
- **Includes weekly reports on the at-risk stock availability**
- **Covers entire geographical scope of the Member State**
- **Includes designation of why medicinal product is in or at risk of short supply**

(see examples in Annex 1)

GIRP would also like to highlight, that as outlined in Article 9 of the Proposal for a Regulation on a reinforced role of the EMA, reference is made to the information from the points of contact, which should include information from the wholesale distributor and legal persons entitled to supply the medical products to the public. Full-service healthcare distributors are ready and willing to provide this information to the National Competent Authorities (NCAs) and subsequently to the EMA (Article 11, paragraph 2). However, based on anti-competition concerns, full-service healthcare distributors are not in a position to provide such information to the marketing authorisation holder (MAH).

SUMMARY OF RECOMMENDED FURTHER STEPS:

- Ensure that any discussions on using the EMVS for shortages monitoring focuses on how to check the information from the EMVS against "real world data" as described above.
- Make use of existing national systems in place, providing market signals by involving all supply chain stakeholders
- Suggest improvements of national systems (as per the criteria outlined above), which do not take market signals into account
- Elaborate the approach in Annex 1 as a "blueprint" for countries, which currently have no system in place
- Support interoperability between the national systems
- Elaborate a method to aggregate data at a European level

Rue de la Loi 26, Box 14
1040 Brussels, Belgium
T +32 (0)2 777 99 77
F +32 (0)2 770 36 01
E girp@girp.eu
W www.girp.eu

Annex 1 - Early warning shortage monitoring systems operating in Germany and Spain – building a blue-print approach for other countries

1. Development of a methodological approach

1.1 Methodical approach in Spain

Wholesalers compare the size of their orders with the corresponding deliveries from the manufacturers.

Advantage:
The percentage of order fulfilment proves the manufacturers' delivery capacity measured against the demand of wholesalers.

Weakness:
The percentage of order fulfilment does not provide information about the demand of pharmacies/patients but assumes that the orders from wholesalers reflect demand. Although this may in general be correct, occasional, disproportional orders from wholesalers may distort the picture (e.g. the beginning of a wave of a disease or the new launch of a medicinal product).

1.2 Methodical approach in Germany

All full-service healthcare distributors report weekly for the products in scope, their availability / ability to deliver on the stock level of each warehouse, using only the "yes/no" attribute. At the same time, these reports reflect the extent to which orders from pharmacies and deliveries from manufacturers are balanced. The evaluation thus forms an indicator of increasing and decreasing availability.

Advantage:
The survey of this status in two dimensions - the time axis through weekly reports and the full geographic coverage through the inclusion of all full-service healthcare distributors in Germany - gives a clear picture of the nationwide supply situation over time. The demand from pharmacies is taken into account. The authorities can identify critical developments.

Weakness:
If the report paints the picture of an inadequate supply situation, it remains open if the root-cause is a misguided disposition by the wholesaler, a defective delivery by the manufacturer or an overstocking of individual pharmacies.

1.3 Combination of both methodical approaches

As soon as both approaches are combined by way of a parallel collection of the above described data, the mentioned weaknesses will no longer apply. The data collected according to the German approach provides information if supply and demand are balanced. The data collected according to the Spanish approach provides information whether a possible lack of supply is caused by a manufacturer's failure to deliver the required quantities to full-service healthcare distributors. Both systems have the advantage that no quantitative stock-level information is required or published.

Scope:
The current scope is defined by the national medicines agencies. It would make sense to cover the list of "essential medicines" as defined by the EMA and/or the WHO in the scope.

These recommendations should also be made for the improvement of existing national systems that currently do not meet the criteria outlined.

In order to grant a general overview of the supply situation throughout Europe (either for certain medicines / API's or in general) as desired by the various European authorities, a compilation of information coming out of the national monitoring systems is needed. Therefore, the interoperability between national systems is crucial to allow this essential compilation on European level. The necessary data aggregation can be done by the EMA itself within the SPOR-project or ultimately be provided by a qualified and trustworthy IT service provider. For the given reasons, the use of the EMVS cannot fulfil these requirements.

Rue de la Loi 26, Box 14
1040 Brussels, Belgium
T +32 (0)2 777 99 77
F +32 (0)2 770 36 01
E girp@girp.eu
W www.girp.eu