Catalogue of measures proposed by full-service healthcare distributors to ensure the continuous supply of medicines during the COVID-19 crisis

Executive summary

- The Marketing Authorisation Holder (MAH) should give an early warning to National Competent Authorities (NCAs), the European Medicines Agency (EMA) and full-service healthcare distributors as soon as it is foreseeable that stock levels of medicines are insufficient to cover demand. The MAHs should provide information on the extent to which they can meet orders of full-service healthcare distributors.
- Full-service healthcare distributors' competence could be further utilised to support and ensure the supply of medicines to hospitals, in addition to nursing and special care homes (under pharmacy supervision).
- Full-service healthcare distributors should be granted the right to be supplied with all approved and available medicines in the Member State from the Marketing Authorisation Holder (MAH).
- Full-service healthcare distributors' distribution centres and warehouses can be used for storing centrally procured products, especially COVID-19 therapies, PPE equipment, medical products and for safety stocks of supply-critical/essential medicines.
- Essential information sharing, serving for the exclusive purposes of supplying medicines in times of crisis and limited to what is strictly necessary, should be temporarily exempted from certain regulatory prohibitions and data protection laws.

I. Introduction

Over the past number of weeks during the ongoing COVID-19 crisis, GIRP members, full-service healthcare distributors (pharmaceutical full-line wholesalers), have proven time and time again their efficiency in ensuring the continuous supply of medicines.

Across Europe retail pharmacies, GPs and hospitals have been confronted with an unprecedented level of demand from customers and patients. Full-service healthcare distributors were able to respond to the high number of orders in a timely manner with great additional effort. Citizen, government, customer, and patient confidence in the supply chain at community pharmacy level has been maintained.

In order to respond to future threats from the COVID-19 crisis, full-service healthcare distributors have rapidly developed coordinated contingency plans and aligned their quality and risk management systems. This allows for the deployment of measures at short notice to respond to newly arising needs.

The overview of measures below outlines essential actions for full-service healthcare distributors to cope with and further support with their infrastructure and knowledge in the event of an escalation or changing developments and operative priorities caused by this crisis. Above all, we would like to highlight the necessity for transparency on existing stock levels from pharmaceutical manufacturers and manufacturers of other medical products and the extended use of the safe and reliable distribution infrastructure of full-service healthcare distributors.

II. Situation – status quo

In recent weeks, demand for medicines and other medical products has at times exceeded 2 to 3 times normal levels. Currently, a noticeable decline in demand for medicines prescribed for acute therapies, such as antibiotics, has been observed. However, an immediate increase of demand is likely to occur at any time in the near future.

Patients are not anticipated to use their existing stock of medicines before collecting new prescriptions due to the fact that they are expected to maintain safety stock at home. A further decline in demand is therefore not anticipated. Governmental, physician and pharmacist driven communication towards patients are in place to prevent over-stocking at patient level.

The supply chain for medicines is currently well functioning. However, obtaining new supplies from pharmaceutical manufacturers essential to the treating of COVID-19 patients is already becoming increasingly difficult.

III. Supply shortages

1. Scenario: supply shortages in retail pharmacies

In the event of supply shortages at retail pharmacy level, it is necessary for full-service healthcare distributors to take measures to minimise the effect of shortages of essential medicines.

Full-service healthcare distributors are already experiencing challenges in relation to supply shortages caused by the gap between increased demand at pharmacy-level with unchanged inbound quantities received from manufacturers.

It is expected that this gap will widen even further when supply quotas imposed by manufacturers at Member State-level are exhausted.

In addition, full-service healthcare distributors are facing a medium-term risk of supply shortage due to interruptions in manufacturing related to shortages of Active Pharmaceutical Ingredients (API) from China, India and Italy, the increased demand on other products used off-label to treat COVID-19 patients, other products for medical need, disruptions to transportation and logistics, etc…

Measures:

Full-service healthcare distributors play a vital role and function in managing the supply of medicines to pharmacies in such a way that patients in Member States can be assured fair and equal access to medicines through community pharmacy. If full-service healthcare distributors were to process orders received from retail pharmacies strictly according to the 'first come first served' principle, a misallocation of medicinal products could occur causing some pharmacies and patients to remain empty-handed.

In order to prevent this from happening, full-service healthcare distributors adapt incoming orders to ensure that all pharmacies receive a fair and balanced share of available stocks. This allocation is performed by reference to available data (including stock level data) and based on experience.

Allocation by full-service healthcare distributors based on demand and data is indispensable, especially in times of crisis, and requires them to know if, when and how many products they are likely to receive from manufacturers.

While the Marketing Authorisation Holder (MAH) has an obligation to report shortages, this obligation is not sufficient in a crisis as the information often comes too late and the time for reaction is too short.

> **The Marketing Authorisation Holder (MAH) should give an early warning to National Competent Authorities (NCAs), the European Medicines Agency (EMA) and to full-service healthcare distributors as soon as it is foreseeable that stock levels of medicines are insufficient to cover demand. The MAHs should provide information on the extent to which they can meet orders of full-service healthcare distributors.**

2. Scenario: supply shortages in hospital pharmacies

Hospital pharmacies are currently confronted with new dimensions of medicines shortages. There is a lack of experience in the overall handling and procurement of medicines needed to tackle COVID-19.

In many Member States, hospital pharmacies obtain their supplies directly from manufacturers.

Measures:

> **Full-service healthcare distributors' competence could be further utilised to support and ensure the supply of medicines to hospitals, in addition to nursing and special care homes (under pharmacy supervision).**

Full-service healthcare distributors can supply hospital pharmacies, thus supporting the rapid, flexible and demand-oriented delivery of medicines. Full-service healthcare distributors have the immediate ability to adapt and expand the range of products to meet hospital needs. In the first stage, this can be done for medicine therapies needed for treating COVID-19 patients, for products of medical need and, at a later phase, for vaccines. The complexity of the procurement process for hospital pharmacists, and therefore the workload, would be reduced and essential personnel could be deployed where it is needed most.

In addition, the impact of 'panic buying' by hospitals could be mitigated by channelling hospital medicines through full-service healthcare distributors since their robust and reliable distribution infrastructure could be used to ensure a fair and equitable balance of medicines throughout the country. In particular, medicines used for the treatment of COVID-19 patients can be delivered directly to where they are needed.

3. Scenario: direct supply

Even during the crisis, highly sensitive medicines continue to be supplied directly by manufacturers to hospitals. Concentrating on direct deliveries poses a risk to patients' access to medicines as they are prone to supply chain disruption.

Measure:

Full-service healthcare distributors should be granted the right to be supplied by the Marketing Authorisation Holder (MAH) with all approved and available medicines in the country.

The distribution infrastructure of full-service healthcare distributors can reliably guarantee medicine availability to dispensing points within a couple of hours. They can promptly reach every single delivery point in a Member State during moments of crisis.

IV. Making best use of existing distribution infrastructures

1. Scenario: New distribution channels

(a) - Centralised procurement of medicines by European and / or national authorities.
(b) - Safety stocks for supply-critical/essential medicines and PPE.
(c) - Distribution of therapies for COVID-19 and eventually vaccines in the target manner.
(d) - Incentivise distribution of hospital exclusive medicines to pharmacies, allowing community pharmacies to dispense these medicines to patients. This will reduce patients' frequency of visits to hospitals, contributing to mitigate the risk of infection and pressure on hospitals.

Measures:

Full-service healthcare distributors' distribution centres and warehouses can be used for storing and distributing centrally procured products, especially COVID-19 therapies, PPE equipment, medical products and for safety stocks of supply-critical/essential medicines.

The proven existing warehousing and distribution infrastructure of full-service healthcare distributors can be used for storing and distributing centrally procured products, especially COVID-19 therapies, PPE equipment, and other medical products, in addition to maintaining safety stocks of supply-critical/essential medicines.

This ensures that medical products are not only safely and professionally stored, but also accessible to all dispensing points in a Member State within a matter of hours. This ensures further the safe, timely, optimised and rationalised handling of medicines, medical products and PPE. In addition, information on available stock levels and quantities can be made transparent to authorities providing a real-time overview of the supply situation by demand demonstrable.

2. Scenario: Supply shortages require close cooperation

If the situation deteriorates further, shortages may occur in the intra and extramural context, where allocation of any remaining stock that is still available is crucial.

It requires intensive cooperation and communication between full-service healthcare distributors to ensure appropriate distribution across companies. Currently, communication between full-service healthcare distribution companies regarding market and inventory data is still quite limited mainly due to existing competition law and data protection rules.

Measures:

Essential information sharing serving for the exclusive purposes of supplying medicines in times of crisis and limited to what is strictly necessary should be temporarily exempted from certain regulatory prohibitions and data protection laws.

Sharing of essential information between companies to ensure the best possible supply of medicines for the protection of the population should not be impeded by existing legal restrictions.

At European level, the joint statement[1] issued by the 'European Competition Network' on the relaxation of anti-trust regulations in times of crisis and, more recently, the European Commission Communication on "Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak" are particularly welcome.

Further clarification is required at national level on all regulatory matter implicated in dealing with the crisis such as, but not limited to, Good Distribution Practice Guidelines (GDP), in order to provide necessary legal certainty for all parties involved.

V. Case study: Example from France on the use of existing distribution infrastructure to guarantee a fair, regular and equitable distribution of medicine

Below is a case study of measures taken by the French Medicines Agency (ANSM) to ensure nationwide distribution of oral corticoids following its shortage. The core role and function of full-service healthcare distributors (pharmaceutical full-line wholesalers), their competency and infrastructure (in combination with the lifting of manufacturer supply quotas and prohibition of manufacturer direct delivery) ensures the fair and balanced distribution of oral corticoids. The measure led to a significant improvement in the availability of oral corticoids in pharmacies. Similar measures can be deployed during the covid-19 crisis as outlined above.

CASE STUDY

Update on the availability of oral corticoids in France: lifting of quota measures - Enquiry point (11/12/2019)
https://ansm.sante.fr/design/afssaps/images/icone_health_product/32x32/icone_health_product_med.gif

For several months, many patients have faced difficulties in obtaining corticoid-based drugs from their pharmacies due to production problems encountered by some manufacturers.

The ANSM quickly took restrictive measures and monitored the situation on a weekly basis in conjunction with the players in the manufacturing and distribution chain to ensure that they mobilized all the necessary actions to ensure continued access to these essential medicines for patients:

- Direct sales from laboratories to pharmacies were suspended and **supplies were made by pharmaceutical full-line wholesalers only, that is to say**

[1] Antitrust: Joint statement by the European Competition Network (ECN) on application of competition law during the Corona crisis. Available at: https://ec.europa.eu/competition/ecn/index_en.html

according to a distribution circuit guaranteeing regular and equitably distributed supplies throughout the country;

- Exports of corticoids to other countries were stopped in order to guarantee supplies to the French market. This ban has been verified by several inspections;
- Equivalent medicines were imported and made available to pharmacies;
- Finally, the laboratories increased their production capacity and committed to building up safety stocks of at least 2 months in order to anticipate any new risk of shortage.

These actions led to a significant improvement in the availability of oral corticoids in pharmacies from September 2019 onwards, as indicated by the volumes of stocks and supplies published on the ANSM website.

Once Patient access to oral corticoids had improved, the ANSM lifted the quota put in place during the period of supply tensions and allowed the resumption of direct sales from laboratories to pharmacies.

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