



PGEU GPUE

Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

Statement

Medicine Shortages in European Community Pharmacies

INTRODUCTION

Today, shortages of medicines are a worldwide problem. Shortages are occurring across the supply chain and evidence suggests that the problem is getting worse. Persistent shortages of medicines are already recognised as a public health problem¹ which directly affects patient care.

The number of reports of medicine shortages in the EU is increasing^{2,3}. All classes of medicines are affected, from complex chemotherapy agents and anaesthetics to diabetes, hypertension, and asthma medication. However, there is still very little reliable EU wide data available and therefore there is no clear understanding of the scope and extent of the problem. Furthermore there is little understanding of how medicine shortages affect community pharmacists and ultimately the patients they serve.

At the beginning of 2012, PGEU conducted a survey among its members, national community pharmacy associations, in order to better understand the extent of medicine shortages in the EU. According to the survey results, although some countries are more affected than others, medicine shortages have been reported by all respondents to the survey and the problem is increasing. According to the survey, a broad range of medicines is affected, including even basic medication such as aspirin⁴. The survey suggests that the prevalence of medicine shortages has increased in the past year- just in the UK over 1 million branded medicine supply failures occur each year⁵.

In response to the problem national authorities in a number of EU Member States have started monitoring the situation and have set up websites for the public where information about current shortages is available^{6,7}. For example, KNMP, the national pharmacist association in the Netherlands has established a website⁸ which informs pharmacists about the problem, the expected date of resuming normal deliveries, alternatives on the market and the impact on the patient if alternatives are not available.

CAUSES

What is causing the shortages? No single response exists. There are a number of reasons why some medicines are sometimes unavailable. The medicines supply chain is highly complex and its efficiency relies on the performance of each individual supply chain actor including raw material suppliers, manufacturers, wholesalers, community pharmacies and intermediaries. If there is a disruption at any point of the supply chain, shortages can occur.

Such disruptions can be caused by:

- The increasingly globalised nature of pharmaceutical manufacturing, with production concentrated in fewer sites distributed around the world. This tendency can have a severe impact on production

¹ <http://www.npr.org/blogs/health/2011/11/14/142311786/drug-shortages-affect-more-than-half-a-million-cancer-patients>

² <http://www.guardian.co.uk/world/2012/jun/08/greek-drug-shortage-worsens>

³ <http://www.dailymail.co.uk/news/article-2163593/NHS-drug-shortage-scandal-Patients-life-threatening-conditions-struggle-medicine.html>

⁴ <http://www.bloomberg.com/news/2012-01-10/greek-crisis-has-pharmacists-pleading-for-aspirin-as-drug-supply-dries-up.html>

⁵ <http://www.appg.org.uk/APPG%20Pharmacy%20-%20Report%20of%20Inquiry%20into%20NHS%20Medicines%20Shortages.pdf>

⁶ http://www.fagg-afmps.be/fr/items-HOME/indisponibilites_de_medicaments/

⁷ http://www.agenziafarmaco.gov.it/sites/default/files/elenco_dei_medicinali_carenti_22_marzo_2012.pdf

⁸ <http://farmanco.knmp.nl>

capacity when for example, quality issues arise, or where there is difficulty in sourcing raw materials.

- Shifts in demand, resulting from longer term factors such as demographic change, but also short term factors such as tendering of medicines leading to difficulties in providing sufficient quantities of medicines for some markets.
- Extreme cost-pressure on the supply chain, resulting in concentration of manufacturing capacity, reduced stock-keeping.
- In some cases, pricing strategies and regulatory changes may impact on supply.
- The imposition of fixed quotas of medicines by the pharmaceutical industry, often inaccurately judging the true level of patient needs as well as removal of traditional role of the full line wholesalers as a result of DTP schemes in some markets.
- The abolition of public service obligation /minimum national stock keeping requirements in some countries.
- The lack of priority given to smaller markets.
- The effects of the European internal market (e.g. exports) and different medicine prices.

EFFECT ON COMMUNITY PHARMACY PRACTICE

Patients are the ones ultimately affected by medicine shortages. The unavailability of a medicine causes unnecessary inconvenience and distress to the patient, but worse, may affect patient outcomes. If a prescribed medicine is not available, the patient may be given an alternative, which in some cases is not adequate and may be more expensive. Where there are no alternatives available, and the patient does not receive his/her treatment, the outcome may be fatal. Ultimately, patients may lose confidence in the health system. Some governments have allowed emergency importation of medicines from other countries where there are no alternatives to medicines in short supply on the national market. However this could ultimately create a shortage in the exporting country.

Shortages are of great concern to community pharmacists, and in some countries already affect our daily practice. It is reported that in the UK, pharmacy staff spend an average of three hours each week sourcing medicines which they are not able to order from their usual wholesaler⁹. This equates to 156 hours per UK pharmacy per year. Community pharmacists often turn to the national or regional community pharmacy network to source medicines. Patients, who have been traditionally accustomed to a highly reliable medicines supply in Europe, often have difficulty in understanding why a medicine is unavailable, and can become distressed.

Time solving problems caused by shortages is time that could better spend advising and caring for patients. Furthermore, often pharmacists do not have legal rights to assist the patients in need, even if they have the right skills. Therapeutic substitution by the pharmacist¹⁰ or alteration of prescriptions is illegal in the majority of Member States.

An additional source of frustration among community pharmacists is the lack of communication about the shortage, its severity, and how long will it take to be resolved. This information, if it is provided in a timely and efficient manner, would allow pharmacists to serve their patients better and plan their practice and stock accordingly. Italian medicines supply chain partners including community pharmacists

⁹ <http://www.npa.co.uk/Documents/Docstore/Press-Releases/Pharmacy%20Voice%20Cutting%20Red%20Tape.pdf>

¹⁰ Dispensing of a different chemical entity within the same medicine class.

have started an initiative which encourages communication of such information once the shortage is experienced by all stakeholders. The reasons for the shortage, the extent of the problem and the time when it will be resolved is among the information which is communicated to community pharmacists, allowing timely information to be provided to patients.

CONCLUSIONS AND RECOMMENDATIONS

The findings of our survey confirm that most community pharmacists in Europe are experiencing some medicine shortages during their practice. Addressing shortage problems is a frustrating and time consuming diversion from patient care. Worse, medicines shortages can hinder therapy and may ultimately be fatal.

We propose a set of recommendations to address this problem at European and national level:

- 1) In developing business policies and national laws and strategies all stakeholders and governments must ***put patient needs first***. These strategies should first and foremost aim to ensure timely and adequate supply of medicines to patients.
- 2) The full impact on the supply and availability of medicines of policies aimed at reducing medicines prices needs to be taken into account by policy makers.
- 3) ***The scope of pharmacy practice*** should be extended when medicines are in short supply, so pharmacists can use their skills to better manage patient care. Where a medicine is not available, an alternative medicine could be supplied following local guidelines and in consultation with a treating physician.
- 4) ***Supply chain partners should be encouraged to communicate disruptions in medicines supply to community pharmacists*** once they occur, as well as the cause and duration of the disruption (as now happens in Italy). In addition, wholesalers should be encouraged to exchange information about minimum stock levels of medicines, so medicine shortages can be anticipated.
- 5) ***Government policies should promote the adequate supply of medicines***. Although no government can order manufacturers to manufacture certain medicines, they can request the maintenance of a minimum national stock of certain medicines by wholesalers and manufacturers so to ensure adequate supply, and place public service obligations on wholesalers where these are not currently in place. Article 81 of the EU Directive on Medicines for Human Use¹¹ was intended to ensure adequate supply of any given product to the market. However, there is extensive evidence of situations where pharmacies can't obtain the medicines that they need for their patients. Consideration should be given to strengthening the provisions of Article 81.

Finally, we invite our medicines supply chain partners, governments and EU Institutions to work closely together to better plan the supply of medicines in Europe and inform each other about possible shortages well in advance, so as to ensure that European patient needs are met and patients can receive their medicines in time.

¹¹ DIRECTIVE 2001/83/EC <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF>