



*European Association of  
Euro-Pharmaceutical  
Companies*

## **Evaluation of Medicines Shortages in Europe: An EAEP C contribution to the birgli report**

### **Introduction to the birgli report**

Shortages of medicines at pharmacies, at wholesalers, and sometimes at patient level, have increasingly become an issue for the pharmaceutical market operators. Appearing as an easy scapegoat, parallel distribution has recently come under the spotlight as being a major cause of shortages. The working of the pharmaceutical supply chain and the process of delivering medicines to patients is more complex than is generally perceived, and even a small failure in one part of the system can have lasting consequences for the whole supply chain. In fact, shortages affect generics as well as patented brands, though there is very little parallel distribution with the former. Shortages are also found in countries totally unaffected by parallel distribution, such as in the US and Switzerland. With a view to bringing a valuable contribution to the debate, the EAEP C has commissioned a report from independent consultants birgli, Switzerland. The authors are familiar with pharmaceutical supply chain issues, thus adding the extra benefit of practitioners' experience.

### **Patient safety at risk?**

The issue of medicine shortages has attracted significant media and political attention over the last few years, and has seemingly, with the economic crisis and austerity programmes, become a crisis in its own right. The topic is important. Patient welfare requires that they have access to the best possible care that can be provided under the national system they are covered by. Shortages need to be anticipated and prevented to minimise the impact on patients. It is thus essential that all stakeholders, not only those involved in the business side, but also policy makers and media, understand the reasons behind the shortages.

While the conclusions and recommendations of the report are the authors' own, the EAEP C wishes to put the report, and its findings, into a wider context of past and current volumes of parallel distribution in Europe.

## **The context: past and current levels of parallel distribution**

Drawing from annual reports of EAEPC members, the volume of parallel distribution of medicines in the EEA area of Europe has remained fairly stable over the past 5 years, at around 4.5 bn € (at pharmacy purchasing prices). However, there have been significant fluctuations in the level of activity between national markets due to a number of factors: currency fluctuations, for example, have reduced parallel import into UK while at the same time favouring conditions for exporting from UK, albeit of different medicines; price adjustments in Germany (AMNOG) have reduced the appetite for German imports which, in turn, allows other importer markets to access these sources, which may result in completely new trade flows. Manufacturers' supply quotas make medicines less available for parallel distribution, and in response to smaller batch sizes, parallel importers will turn to other products; their product portfolio is generally between 400 and 2000 product lines and thus much larger than that of the average pharmaceutical manufacturer. More products (and manufacturers) and more markets are therefore likely subject to parallel distribution, and this may well lead to the perception of growing trade while the reality speaks of an overall stable volume. While the notion of shortages was not an issue a few years back, it is now, and appears to be linked in the media – more or less exclusively – to “undesirable” exports in the context of parallel distribution. Simple logic dictates that there must be more, and other, causes for the phenomenon to come to prominence now.

As a way of example, in an opinion released in July 2012, the French Competition Authority found that the issue of shortages in France is multifaceted and complex, and far from being purely related to parallel exports. Similarly, the birgli study is the first exercise of this kind that helps demonstrate that the causes of medicine shortages are quite nuanced, and vary over time according to market and product. This can make it difficult at times to compare one case of shortages with another. There is not such a thing as a perfect snapshot of the shortages situation.

### **Why are there medicine shortages?**

The birgli report documents the key causes for shortages, or supply difficulties, based on surveys among stakeholders. Some of the causes are known, but with this report the EAEPC had hoped to be able to bring data to the table and provide quantifiable outcomes. Regrettably, that has not been possible, as the authors declare to their regret. Yet, data of more or less systematic composition, sometimes also only of anecdotal character, appear to exist, but sharing these between commercial competitors can provide legal and practical obstacles, which should be overcome in order to bring needed medicines to patients. It is in stakeholders' interests to make an attempt to that effect, as otherwise authorities may respond with increased regulation, which in itself can be a cause for complicating the supply chain.

The EAEPC stands ready to assist in this “comparing of notes”.

The birgli report demonstrates how dramatic price cuts and reined-in state spending on pharmaceuticals in Europe's financially stricken countries have impacted the business decisions of pharmaceutical companies to reduce costs and streamline manufacturing, and to some extent the portfolio of products.

On top of this, in markets in financial distress, such as Portugal and Greece, where there have been significant delays in payment via the reimbursement system, there has been a tightening of payment terms in the supply chain sometimes providing “cash only” terms - such as in Greece - which reduces the availability of medicines to patients, and forces some operators to turn to exporting in order to generate liquidity (in fact, the only liquidity available in such a situation).

Some low price markets (Greece, Romania, the Czech Republic for example) have witnessed reduced product introductions and even market withdrawals, as it has not been sufficiently profitable for companies to sell certain drugs there. In Greece, for example, 203 products have been withdrawn from the market in 2012, of which 25 have no generic equivalent.

Quota systems are another facet that has been analysed by birgli. In the aftermath of the Adalat ruling, these have spread like wild fire across the pharmaceutical wholesale market exerting control over the flow of medicines available in the supply chain. Initially designed to prevent parallel distribution, their unchallenged and pre-emptive application is now seen as a cause in itself which provokes shortages. And although patients can usually access a medicine within 24/48 hours under a quota system, manufacturers’ supply quotas often do not respond quickly enough to demand fluctuations.

Other contributing factors are manufacturing and quality issues. Over the years, many manufacturers have streamlined their production facilities and processes, and acquired competitors in the process, resulting in far fewer manufacturers and production facilities globally for most products. Shortages in the UK recently occurred for isosorbide mononitrate (ISMN) due to safety concerns leading to shortages of the compound while alternative solutions were sought. The facility in question produces a third of the world’s supply of the product. Further, supply chains have become considerably compressed, and buffer stocks eliminated, over the last years to reduce working capital. Finally, manufacturers have begun to implement ‘direct to pharmacy’ practices in a number of markets in Europe, which process has been accused of leading to inefficiencies and disruptions in the supply chain and negatively impacting ‘public service obligations’ of wholesalers.

### **The role of parallel distribution**

It is clear that there has been an evolution in recent years in the market for parallel imported/exported medicine. Nowadays, data show trade in medicines occurs Europe-wide as price differentials have become more diverse. Fluctuations can now be seen between markets, as currencies, prices and reimbursement policies change more fluidly.

It is worth noting that Greece, where medicine shortages have been particularly pronounced, has actually witnessed decreasing exports over recent years. In 2007, when shortages were not regarded as an issue, export levels were above €800 m, double today’s level.

Of course, with significant differences in prices between various markets in Europe and measures taken to control cost, parallel distribution is bound to occur. The practice is also encouraged by various countries because they understand and value the competitive effect it has on prices. Just a few days ago, the French Competition Authority recognised the competitive impact on prices from parallel distribution and called for a check on obstacles to trade. Parallel distribution also has greatly helped pharmacies and wholesalers, which have in many markets struggled to survive with declining

margins, and therefore rely on exports and imports to keep up liquidity, and this extra revenue helps to keep the wholesaling structures in many of these countries afloat.

## **Conclusions**

The birgli report demonstrates clearly that the reasons behind the current medicine shortages in Europe are complex and multifactorial, and should be treated as such. The role of parallel distribution in the shortages debate has been blown out of proportion. The level of trade in medicines within the European Economic Area (EEA) has remained relatively flat for the past five years. The practice can even be seen to fill a gap to maintain supplies with the original product when a manufacturer needs to withdraw product from one national market.

The EAEPC hopes that following the publication of the report by birgli, all stakeholders involved along the pharmaceutical supply chain, as well as media, policy-makers and regulators, come to a better understanding about the reasons behind shortages in Europe, so that patients and health professionals can begin again to trust the supply chain and access much-needed medicines in a timely manner.