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strategy paper

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Changing the Public Procurement System – An approach to ensuring sustainable health care and supply in Europe

Guiding questions:

- Influence of public procurement of medicinal products on innovation, sustainability and competition?
- Changing/ clarifying the current legislation as a mean to mitigate existing shortages in Europe?
- Does the market work properly? Competition barriers, internal market concerns?
- Public procurement as strategic tool for companies?
- BPI slogan: Ensure ***sustainable healthcare systems while supporting a competitive pharmaceutical industry in Europe***

Overview/Problem

Public procurement of medicinal products is regulated in national legislation. It is however influenced by directive 2014/24/EU better known as the Public Procurement directive. Although it has been established that including other factors than price in a tender is in compliance with European Law (see e.g. Sweden), many member states still try to justify their practices (e.g. having price as the sole criterion) with this directive. Most of them claim that changing their practices would not be compliant with European procurement law.

As shortages of medicinal products in Europe are increasing and the production of active pharmaceuticals ingredients oligopolies outside of Europe, it is about time to foster a public debate on how to ensure sustainable healthcare systems, while maintaining a competitive pharmaceutical industry in Europe and Germany. As we will show in this paper, there is a strong correlation between shortages – especially in the generic sector- and the current procurement practices. Thus, including this aspect is of essence when discussing ways to mitigate shortages in Europe.

The BPI and its member companies are well aware of the difficult situation: Ensuring sustainable healthcare systems while at the same emerging medical technologies and the demographic change put pressure on them. Although, public procurement methods have been employed in many European Member States and are widely recognised as an effective cost saving tool, the long term effects this might have on the provision of care remain underestimated.

Example: Procurement practices in Germany

In Germany (mainly) generic drugs are procured in a so-called rebate contracting practice (§130a (8) SGB V), which was introduced in 2003 as a cost-saving tool and allows the statutory health insurance (SHI) to conclude rebate contracts for medicinal products directly with manufacturers. These contracts last in general for two years. The legal framework for rebate contracting has been intensified ever since their introduction.

After almost seventeen years of this practice, consequences on innovation, sustainability and competition may be identified.

Innovation

The only criterion for tenders being concluded in Germany is the price. This has a tremendously negative impact on incremental innovation which is of major importance for patients and leads to a substantial amount of added benefits. However, if the only reference point for substitution is the active substances, companies have no more incentives to develop new or improve generic drugs. In addition to this, the fact that as sick funds only reimburse the lowest possible price creates more pressure for companies. This may ultimately result in the need to relocate production and the revision their portfolio.

Sustainability

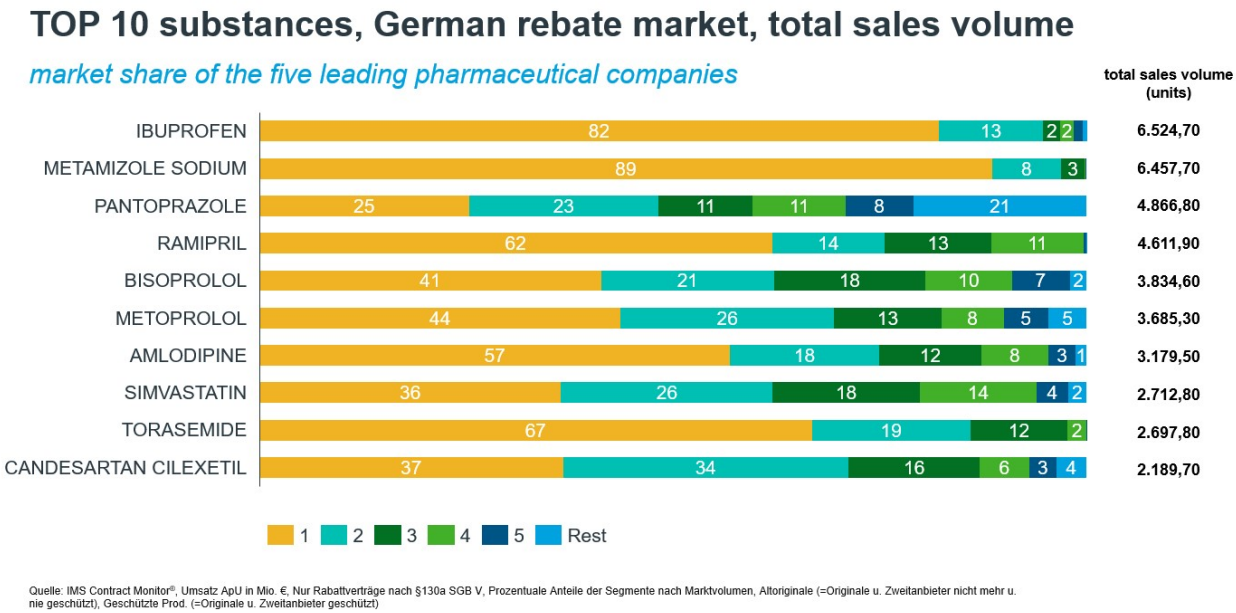
As has been anticipated by the Expert Panel on Effective Ways of Investing in Health in its opinion on competition among healthcare providers (2015) and the European financed study by the London School of Economics (LSE) and the EMINET (2009), the long term effects on the generic and research-based industry are creating problems for the provision of medicinal products. Not only are companies driven out of the market and innovation is stunted. The market concentration also leads to shortages of medicinal products. One of the adverse effects of a market concentration / oligopoly in Asia is the European dependence on foreign producers of active pharmaceutical ingredients (API) as well as the loss of a competitive industry accompanied by economic decline.

Competition

In the seventeen years of rebate contracts, the German pharmaceutical market has experienced major shifts mainly at the expense of Small and Medium-sized Enterprises (SMEs). Not winning a tender is equal to a complete exclusion of the market and drives, especially, SMEs out of the market.

In addition, the market concentration among producers of APIs is one of the main reasons for shortages of medicinal products. The lack of suppliers increases the risk of delivery problems. In addition to this, the few remaining suppliers are mostly located outside of Europe. A famous example is the production of antibiotics.

Analyzing the TOP 10 substances in the German rebate market, in some case strong market concentration can be seen, for example looking at the first substance in the following picture shows, that the first supplier has 82 % of the substance alone and together with the second these two companies hold a share of 95 percent. In general the first one to five companies are almost in all substances the winner. And if over several years the awards go to the same companies or global players on the market, it is difficult for the other companies without rebate contracts to maintain their supply as in German pharmacies per definition the pharmacist has to primarily hand out rebated drugs.



Quelle: IMS Contract Monitor®, Umsatz ApU in Mio. €, Nur Rabattverträge nach §130a SGB V, Prozentuale Anteile der Segmente nach Marktvolumen, Altoriginale (=Originale u. Zweitanbieter nicht mehr u. nie geschützt), Geschützte Prod. (=Originale u. Zweitanbieter geschützt)

As tenders are increasingly targeting patented drugs as well, participating in tenders has become a strategic tool for some players in the industry. A tender effectively provides the company with market exclusivity, thus a delayed entry of generic competition, which in return means more financial pressure on the healthcare system.

Conclusion

There are many different reasons for shortages of medicinal products. One not mentioned, is as well the global growing demand.

However, studies show that a reasonable number of suppliers are needed to secure a continuously provision. If there are less than three companies for one substance the risk that severe impacts such as long lasting shortages can occur. To sustain a robust pharmaceutical industry, different action should be taken to prevent shortages.

The BPI strongly believes that it would be necessary to revise the current procurement legislation with regards to the existing situation. However, we are aware that the EC does not wish to review this immense file in the near future. We therefore strongly suggest at least the establishment of sector specific guidelines which would clarify the situation for member states. Price should not be the sole criterion a decision is based on, there should be a possibility to consider other criteria such as a European production site as a condition for tenders.

To maintain the number of bidder and enough supplier it should be possible to accept tenders of more than one supplier to avoid shortages. For critical substances it should be possible to have a prohibition of tenders.
All these measures taken together could in the long run reduce the dependence on only global acting players and keep a strong European pharmaceutical Industry and avoids shortages.