AFFORDABLE MEDICINES EUROPE
WORKING IN PARALLEL FOR A BETTER DEAL

VAD
German Association of Pharmaceutical Parallel Distributors

PHARMACEUTICAL DIALOGUE 74

04 21

INFORMATION FROM THE PARALLEL TRADE INDUSTRY

PHARMACEUTICAL & HEALTH CARE POLITICS

Secured pharmaceutical supply in the EU through strategic autonomy?

The COVID-19 crisis has disrupted global pharmaceutical supply chains and tested the resilience of health systems we hoped are immune to crises. As the pandemic revealed severe challenges related to the supply and availability of medical products, discussions on the EU's dependency on pharmaceutical products from non-EU countries significantly increased.

A structured dialogue to make EU health systems more resilient

As a response, the European Commission launched a structured dialogue involving all actors from the pharmaceutical supply chain to address vulnerabilities in the supply of medicines and strengthen the resilience of EU health systems. The launch follows calls from EU leaders to identify and reduce strategic dependencies in the area of health and to "achieve strategic autonomy while preserving an open economy". Similarly, in its pharmaceutical strategy, the Commission recognised the need to develop an "open strategic autonomy and ensure robust supply chains so that Europe can provide for its needs", proposing actions to foster pharmaceutical production in Europe.

While the resettlement of the pharmaceutical industry to the EU gained momentum as an approach to mitigate medicine shortages, it is a long-standing development and involves potential trade-offs, such as increased production costs due to higher environmental standards and higher labour costs. An independent pharmaceutical supply chain runs deep, requiring a backward integration towards raw materials, fine chemicals and intermediates.

Strategies to avoid medicines shortages in Europe

Alternatively, the diversification of the production and pharmaceutical supply chain may be another strategy to prevent pharmaceutical shortages. Spreading the production of selected raw materials, intermediates, APIs or finished dosage formulations across multiple production sites and jurisdictions reduces the dependency on individual manufacturers, thus decreasing negative effects of one production site's supply difficulties.

Other than that, a functioning EU Single Market is indispensable to meet short-term demand spikes and mitigate shortages of medicines. If a Member State experiences a shortage of pharmaceuticals due to inefficient supply from manufacturers or unforeseen regional supply requirements, parallel trade can help to fill the gaps caused by those shortages by quickly moving pharmaceuticals from one Member State to another. Conversely, national measures restricting the free movement of pharmaceuticals are detrimental to the security of supply of pharmaceuticals. It is therefore crucial to maintain a functioning internal market to avoid any risk of medicine shortages and ensure the pharmaceutical supply in Europe. ■

EDITORIAL

Dear Readers,

A concept that has increasingly been discussed as a response to the challenges revealed by COVID-19 is the EU's "strategic autonomy". In this vein, the relocation of pharmaceutical production to the EU gathered political attention as a strategy to secure pharmaceutical supply. **(page 1)**

The security of medicines supply and the three A's – availability, accessibility and affordability of medicinal products – are in fact high on the political agenda of the EU institutions and will determine health policy-making in the months to come. **(page 2)**

A functioning internal market is indispensable to ensure pharmaceutical supply and the availability of affordable medicines. Parallel trade of pharmaceuticals can be instrumental in mitigating medicines shortages. **(page 3)**

The main goal of VAD and Affordable Medicines Europe is to ensure the availability of affordable medicines for European patients. To achieve this, we aim to contribute to ongoing debates in the field of health policies. May you discover many informative insights as you read this 74th edition of our Pharmaceutical Dialogue.

Sincerely,

Prof. Edwin Kohl
Chairman of VAD

Jörg Geller
President of AFFORDABLE MEDICINES EUROPE

The 3 A's high on the EU agenda: availability, accessibility and affordability of medicinal products

Photo: 2021Portugal.eu

Although they are not new challenges facing healthcare, the past year has put high on the agenda the topics of availability, accessibility and affordability of medicines and medical products. The COVID-19 pandemic has underlined the importance of resilient health systems and the urgent need for the EU to take action on this front.

The 3 A's as a priority for the EU institutions

At the outset of its Council Presidency, Portugal brought the topic of access to and availability of affordable medicines to the fore. To address these issues, the Portuguese Presidency set out to reinforce Europe's strategic autonomy in pharmaceutical production, assess patients' access to medical products and promote health systems' sustainability. Having advocated for an ambitious EU health programme, the European Parliament similarly calls for the EU to increase efforts to tackle medicine shortages, become more self-sufficient regarding medical products and make health systems more resilient.

These commitments of Parliament and Council in the area of healthcare reflect the actions proposed by the European Commission. In November last year, the Commission took first steps to create a future-proof, resilient regulatory health framework by presenting a European Health Union and the Pharmaceutical Strategy.

A resilient regulatory health framework

Responding to lessons learned from the pandemic, the creation of a European Health Union aims to strengthen the EU's health security framework and crisis preparedness. Interinstitutional negotiations between the Parliament and Council on the proposal for a reinforced mandate of the European Medicines Agency in crisis management are ongoing. In addition, the Commission presented a Regulation on serious cross-border threats to health and on reinforcing the role of the European Centre for Disease Prevention and Control.

As part of its pharmaceutical strategy, the Commission proposed to evaluate and revise the EU's general legislation on medicines. The aim is to ensure access to affordable medicines, improve the security of medicines supply and enable innovation for developing high quality and safe medicines. Policy options include revising the system of incentives, enhanced transparency of the supply chain, revising manufacturing and distribution provisions and improving provisions related to market competition.

Efficient use of existing tools at EU level

The EU's actions constitute important first steps towards achieving availability, accessibility and affordability of medicines. However, to effectively tackle these longstanding problems, it is crucial to promote an efficient use of already existing tools in the area of healthcare.

The last year has significantly underlined that a strong, functioning EU Single Market and solidarity shown between European member states may act as a guarantor for access to and availability of affordable medicines. Thus, increased enforcement of EU competition rules, prevention of export restrictions of pharmaceuticals and medical devices imposed by national governments and enhanced transparency in pharmaceutical prices and pricing are key to ensure the security of supply of medicines in Europe. ■

NEWS IN BRIEF

European Commission presents roadmap on revision of pharmaceutical legislation

On 30 March, the Commission published a roadmap on the revision of the EU's pharmaceutical legislation. The revision intends to establish a crisis-resistant regulatory system for pharmaceuticals with the goals of ensuring access to affordable medicines for patients, enabling innovation for developing medicines, and enhancing the security of supply. The Commission is expected to present a proposal at the end of 2022. ■

EU member states agree on negotiation position on HTA

After EU member states agreed on their negotiation position regarding the proposal on health technology assessment (HTA), interinstitutional negotiations with the European Parliament started at the end of April. The proposal from the Commission aims to establish a regulatory framework and foster cooperation among European member states for joint clinical assessments in the area of new medicines and certain new medical devices. ■

European Commission updates its Industrial Strategy

At the beginning of May, the Commission published an updated EU Industrial Strategy to adapt its industrial policy to the circumstances following the COVID-19 crisis. New measures aim to make the European single market more resilient and address dependencies in strategic areas. To this end, the Commission proposes the creation of a Single Market Emergency Instrument to ensure the free movement of goods and services in case of future crises. ■

Photo: EC - Audiovisual Service/ Xavier Lejeune

Reform of the EU pharmaceutical market must be based on solid facts

As policy-makers are warming up to reform the EU pharmaceutical market, the debate on how to obtain the best possible outcome has already been hitting the high notes for quite a while. The COVID-19 crisis has highlighted many important dynamics, but to most people how the EU pharmaceutical market is functioning remain opaque and untransparent.

Relying on perceptions of coherence between level of GDP and medicine prices

It is a persistent myth, that prices of medicines are necessarily lower in low-income countries than in high-income countries. For medicines under competition (generics), where prices tend to be relatively

Graphic: Kohlpharma

transparent, it has been demonstrated, e.g. by the Swedish Dental and Pharmaceutical Benefits Agency in its 2018 International Price Comparison Report, that countries like Denmark, Sweden, and the Netherlands, have significantly lower prices than e.g. Greece, Poland, and Czechia.

For medicines with no competition (patent), the picture is far more complicated, due to the ever growing use of secret agreements. Hence, while official list prices remain very high in e.g. Germany, they are fictive in the sense that no payer in Germany has actually paid that list price. Rather they ensure higher prices in countries using Germany in their External Reference Pricing system. A reality that led the Netherlands to exchange Germany for Norway in their price basket this year – leading to a 6% drop in medicine prices in the Netherlands.

Actual flows of medicine in the Internal Market should be understood

It has been a strong narrative from the pharmaceutical industry for years, now perpetuated by some "independent" voices, that based on simplified economics of low- and high-income countries, parallel trade must deprive lower-income Member States of their medicines. However, looking at the facts, more than 50% of parallel imports come from the 10 highest income Member States. Actually, while being the largest parallel importer, Germany is also a large parallel exporter to the rest of Europe. This is partly driven by the fact that medicines supply is not subject to free market forces. Rather all trade in medicines is under significant regulation, including the fact that only excess stocks may be exported.

Are the right players properly regulated?

A key topic in the current debate on the pharmaceutical market is shortages. While previously manufacturers produced a myriad of excuses, in the last few years – and certainly during the COVID-19 vaccine roll-out – it has become clear that manufacturers are responsible for the vast majority of shortages. Poor planning, quality issues, and manufacturing disruptions are some of the more frequent causes.

Whereas parallel exports are easily blamed, no evidence actually substantiates a systemic problem. In fact, the Public Service Obligation (PSO) ensures that no exports may take place before national patient demand is met. Furthermore, most Member States have export restriction legislations in place – albeit such restrictions may also result in more shortages when applied disproportionately. A key take-away is that the PSO is working in relation to distribution, but very poorly so for manufacturers. ■

GLOSSARY

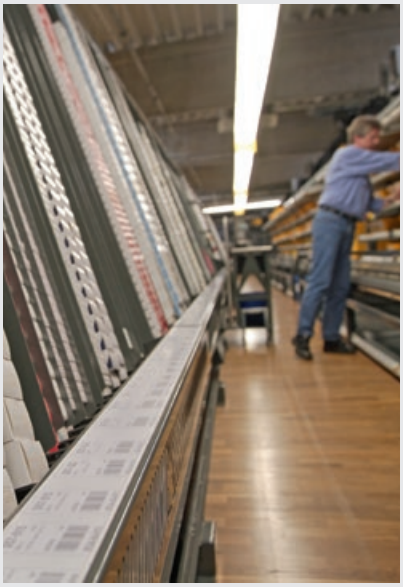

Photo: kohlpharma

EU legal framework governing medical products

As part of its Pharmaceutical Strategy, the Commission aims to revise the EU's general pharmaceutical legislation. The EU's regulatory framework introduces standards to ensure the quality, safety and efficacy of medicines. It refers to the Directive 2001/83/EC on the Community code relating to medicinal products for human use and Regulation (EC) No 726/2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency. ■

Health technology assessment

Over recent years, several European member states have introduced health technology assessments (HTA). HTA refer to the systematic evaluation of the safety, efficacy and added value of health technologies. The main objective of HTA is to provide reliable information to support decision-making. In 2018, the Commission 8 proposed joint clinical assessments for the most innovative health technologies, joint scientific consultations and identification of emerging health technologies to further foster cooperation among member states. ■

EXPERT OPINION

Key deliverables for the pharma strategy

With Kasper Ernest, Secretary General of Affordable Medicines Europe

Photo: xxxxxxxxx

While we are awaiting the concrete proposals from the European Commission, it is worth reflecting already on the key deliverables the reform of the pharmaceutical market must deliver. While the 3 A's, access, availability and affordability, are not new in the debate, no solid response have been offered so far from the European level. Undoubtedly, Council will be dragging their feet over concerns of health policy subsidiarity etc., so the Parliament and Commission will have to align on an ambitious strategy – and stay ambitious.

Pressure to deliver on access – cost-containment vs. innovation only?

Delivering on access is not least connected to the willingness to pay for innovation if you ask industry. Others will argue prices are well high enough, and that medicines budgets are already out of control. Calls to reform patent rights and other intellectual property will not gain the political backing necessary, and therefore other tools need to be considered if we are to deliver tangible results in the legislature.

In this respect, taking a closer look at the Public Service Obligations for manufacturers are already on the drawing board. So far PSOs have always been considered country-by-country. However, as experience from the vaccination roll-out has also shown, if the EU is to make a difference, we need to consider whether manufacturers are supplying the European market in total, or whether an obligation in this respect is necessary.

Ensuring availability by tackling root causes and utilising the Internal Market

Shortages of medicines is a growing headache for Europe. Two main trends are relevant in this context; economic related causes, such as commercial withdrawals; and manufacturing related causes, such as production disruptions and quality issues.

On manufacturing related issues there is no doubt that diversification is key. That is diversification over jurisdictions/geography, number of productions sites, and technologies used to produce. This must be tackled through stronger requirements on sourcing and risk mitigation.

However, turning economic related issues again the already growing medicine budgets does not allow for the easy solution: send more money. Instead other tools should be investigated, not least the better utilisation of a well-functioning Internal Market. Fact is, that less than 5% of shortages are pan-European. Hence, 95% of shortages can be resolved by cross-border trade, and re-distribution. However, it requires better regulatory tools to be included in the reform work.

Is competition the realistic tool towards affordability?

No doubt that medicines budgets are under extreme pressure. The Commission has aired its ideas around earlier uptake of generic medicines – or in other words, how early medicines become subject to competition. No doubt, this is an important step. But medicine budgets are primarily constrained by patent medicines. So which concrete tools do we have available? Intra-EU brand competition is one obvious solution, but since that is denominated "parallel trade" there is a "hands-off" approach. This is a shame. Healthcare payers across Europe acknowledge the significant competitive pressure exerted via intra-EU brand competition, and the significant savings that follow. ■

NEWS IN BRIEF

Closer to an extended mandate for EMA

With the Trilogues as the next step, the negotiations on the regulation extending the mandate for EMA during crisis, are coming to their final stage. It seems Council and Parliament agree on having a broad definition of shortages, clear obligations for manufacturers, and better monitoring of shortages. One take-away already concluded, is that the European Medicines Verification System, established to combat falsified medicines, is not considered part of the solution for such monitoring. As both PGEU and GIRP, representing respectively community pharmacists and wholesalers, have repeatedly made clear, using the system would overestimate supply and underestimate demand. ■

.

EMA reflection paper on forecasting demand

On 3 June, EMA published a reflection paper on the forecasting of demand of medicines. Considering that "marketing authorisation holders are responsible for the continued supply of medicinal products", the paper seeks to help national authorities in forecasting demand – especially during crisis. Several elements are key to such forecasting as evidenced by the example of COVID-19 ICU medicines, but most importantly EMA again recognises the need for some minimum stock – that is the minimum amount of a medicinal product that should be present in the country's supply chain to assure continuity of supply to patients at any moment in time. ■

IMPRINT

VAD e.V.
German Association of Pharmaceutical Parallel Distributor
Im Holzhau 8 | 66663 Merzig
Germany
Chairman of the board:
Prof. Edwin Kohl
www.vad-news.de

AFFORDABLE MEDICINES EUROPE
Rue des Deux Eglises 26
1000 Brussels
Belgium
President:
Jörg Geller
www.affordablemedicines.eu

CONTACT AND CHIEF EDITOR
Person responsible according to the German Press Law
Karsten Wurzer
Im Holzhau 8 | 66663 Merzig | Germany
kwurzer@vad-news.de
Kasper Ernest
Rue des Deux Eglises 26 | 1000 Brussels | Belgium
ke@affordablemedicines.eu