VAD
German Association of Pharmaceutical Parallel Distributors

COST EFF
alliance for cost-efficiency in healthcare

PHARMACEUTICAL DIALOGUE 64

+ + + INFORMATION FROM THE PARALLEL TRADE INDUSTRY + + + DECEMBER 2018 + + +

PHARMACEUTICAL & HEALTH CARE POLITICS

The Single Market needs to be reinforced to remain the robust foundation of European integration

iStock / gopixa

Thirty-two years after the Single European Act was signed, the European single market is under threat. Even if a break-up of the single currency was averted, the euro crisis and lacking political will has already altered the Single Market and greatly changed the prospects for its future. In fact, effort will be required to re-establish a strong Single Market as it was during the carefree years in the early 2000s.

A global showcase for European integration

Three decades after its inception, the outlook for the Single Market is not bright. This may have consequences for Europe's standing in a world of global uncertainties. For years, people all around the world have admired the peaceful integration of Europe. In fact, a host of regional groups of countries from Asia over Africa to South America have actually tried to copy European integration when drawing up their own regional institutions and rules.

But with cracks in the Single Market appearing, it too could lose some of its shine. This will have important consequences for the EU's influence in global trade negotiations and international policy coordination. First, emerging markets will be less willing to accept advice from Europe if the general perception is that the old continent is unable to have a strong Single Market at its core. This will make it harder for Europe to pursue its interests in international institutions like the G20 or the International Monetary Fund.

Strengthening integration at the core of the Single Market

Furthermore, it will be harder for the EU to negotiate preferential trade agreements and free trade agreements. If the Single Market is diminished in any way, getting access to it will become less attractive. Other countries around the world could therefore be less willing to make concessions in return for a trade agreement with the EU.

Especially in times when the exit of the United Kingdom from the EU reveals the fragility of European value chains, a look at the cooperation within the Single Market will be necessary. It is above all policymakers who can limit any potential fallout. >>>

EDITORIAL

Dear Readers,

The European Single Market is at the heart of European success, enabling people, services, goods and capital to move freely. A strong Single Market does not only have highly positive effects on the opportunities for European businesses, but as well a strong impact on the European healthcare system.

This issue of the Pharmaceutical Dialogue is devoted to the Single Market as the foundation of European integration. In times of global uncertainties and nationalistic endeavours, the only way forward is a reinforcement of the European Single Market **(page 1 and 2)**.

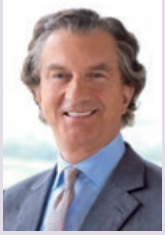
Strengthening the Single Market will be a priority for the upcoming year. 2019 is within reach and in the next few months the European Union will enter a year of change, encompassing Brexit, European Parliament elections and new mandates for the European Commission and the President of the European Council. At this crucial point, Romania will be taking over the presidency of the Council for the first time. **(page 3)**

VAD is actively participating in the ongoing debates on the future of European health care. We remain committed bringing affordable high-quality medicine to European patients across the Union. I hope you join us in this effort. Enjoy reading this 64th edition of our Pharmaceutical Dialogue.

Sincerely,

Prof. Edwin Kohl

Chairman of COSTEFF and the VAD



A leap towards strengthening integration at the core seems to be the only option for the Single Market, before it risks being reduced in size and exposed to potential disintegration at the fringe, as we currently witness with Brexit negotiations.

Effectiveness of the Single Market

The Single Market enables people, services, goods and capital to move more freely, offering opportunities for European businesses, greater choice and lower prices for consumers. A functioning Single Market stimulates competition and trade, improves efficiency, raises quality, and helps to cut prices. The European Single Market is one of the EU's greatest achievements. It has fuelled economic growth and made the everyday life of European businesses and consumers easier and safer.

Of course, safeguarding the Single Market is not the only objective for policymakers. They have to weigh the cost and benefits of different policy paths. But it is important that they do not deceive themselves and believe that the Single Market can be separated from policy fields. This principle applies for the all sectors, from automotive or groceries to pharmaceuticals.

The Single Market needs an active guardian

When Jean-Claude Juncker became President of the European Commission in 2014, he said he wanted to make the European Commission 'more political'. His motto was to 'be bigger and more ambitious on big things, and smaller and more modest on small things'. While some are welcoming the expansion in previously unchartered policy-fields, such as a common social agenda, others bemoan the fact that the Commission services put political expediency over its tried- and-tested role as 'Guardian of the Treaties', ensuring the proper application of the Treaties' provisions as well as arrangements made by the institutions pursuant thereto. Especially regarding the Single Market, these are worrying developments.

The case of parallel trading

In fact, until recently, the Commission considered restrictions on parallel trade of pharmaceutical products to be among the most serious violations of EU competition law. For that reason, it seems even more disturbing that the Commission decided in May 2018 to close its infringement procedures and the treatments of complaints in the area of parallel trade of medicines for human use against Poland, Romania and Slovakia. Instead, the Commission opted for a 'structured dialogue among all stakeholders'. While recognising that reconciling the respect to the free movement of goods with the right of access to healthcare to patients is a fine balancing act, restrictions on parallel trade would segregate the European Single Market and consequently undermine the foundation of the European project.

A strong Single Market to benefit citizens

However, straying away from the 'Single Market imperative' along the lines of political and ideological biases would affect the work of the Commission as 'Guardian of the Treaties', its credibility and, ultimately, its ability to take decisions. The EU executive would also be less likely to find compromises among and enjoy the trust of the different EU member states, which are governed by different political forces. Therefore, it seems high time for the European Commission to refocus and concentrate on its important role, in lieu of political expediency to swiftly and efficiently deal with issues that might have negative impact on the European health care systems and the well-being of European citizens.

The Single Market has been an immensely important project that has brought a large number of benefits to Europe, from better consumer choices to easier production sharing to a vast market for European firms to develop and test their products. 32 years after the Single European Act established the Single Market, it now needs all the support Europe can collectively muster. The EU cannot afford nationalistic egoism at its core in times of global uncertainties emerging from the East and the West. Only a strong Commission can guard the Single Market and allow it to be the robust foundation of the currently tumbling stronghold of European integration. ■

© European Union 2013 EP Louise WEISS building

NEWS IN BRIEF

HTA proposal enters final stage

The European Commission's proposal to develop a Health Technology Assessment (HTA) Regulation has entered its final phase in recent weeks. The European Parliament's environment committee adopted the rapporteur's proposed report in late September. The report was further endorsed by a large majority in the plenary session in Strasbourg, which consequently provide a strong mandate for the rapporteur to further negotiate with the Member States. However, the adopted report shows a number of differences compared to the initial Commission report. The rapporteur's report has now entered into negotiations with the Member States to negotiate a joint agreement. ■

EAHP publishes new survey on medicine shortages

The European Association of Hospital Pharmacists (EAHP) released the results of its 2018 Medicines Shortage Survey. Particularly, EAHP's finding underline that access to medicines remains a key component for delivering the best care to patients, increased significantly compared to the initial survey from 2014. Further, hospital pharmacists highlighted the necessity for more timely and accurate information on medicines shortages.

According to the survey, antimicrobial agents were the type of medicine most frequently reported as having shortage problems, with 77%. Problems were also reported frequently with preventative medicines – vaccinations – 43% and oncology medicines (39%).

The results also cover reports for markets in France, Germany, Italy, Spain and the United Kingdom. ■

Romanian Presidency: European visibility can serve as an enabler for progress in the health system

iStock / visual7

From January 2019 till the end of June 2019, Romania will assume the Presidency of the Council of the European Union. It does so at a time, when the EU will be driven by the two predominant developments: Brexit and the upcoming European Parliament elections. The incoming Romanian presidency already presented its four main action pillars for the upcoming presidency: convergence, safety, global action and common values. Being at the helm of the European member states' representation provides a country with unique visibility, but at the same time also results in emphasised scrutiny of national structures.

The Romanian health system

In health care, Romania has a social health care system that has remained highly centralised despite efforts for decentralising regulatory functions. It provides beneficial overall packages to the 85% of the population that is covered, with the remaining population having access to a minimum beneficial package. While every insured person has access to the same health care benefits, regardless of their socioeconomic situation, there are inequities in access to health care across many dimensions, such as rural versus urban, and health outcomes also differ across these dimensions.

Its performance in European comparison

The European Observatory on Health Systems and Policies finds that 'reform in the Romanian health system has been both constant and yet frequently ineffective, due in part to the high degree of political instability'. In the review on the Romanian health system from 2016, it further concludes that reforms have mainly focused on cost-saving measures, for instance shifting health care costs to drug manufacturers by claw-back taxes and to the population through co-payments.

In European comparison, the Romanian – like other Eastern European countries' – health care system shows room for improvement. The Euro Health Consumer Index (EHCI) compares all European health systems based on 48 analytical indicators. Regarding Romania, the study concludes that 'Albania, Romania and Bulgaria are suffering from an antiquated healthcare structure, with a high and costly ratio of in-patient care over out-patient care'.

A priority for the Presidency

In the past years, Romania has followed a trend of adjustments in its health care system, focusing on digitalisation, effective financial expenditure and access to medicines. The Presidency programme's first pillar on convergence also covers sustainable development, the reduction of disparities, employment and social rights. While the Presidency certainly exposes Romania to further scrutiny, also on its health care system, it is also a window of opportunity to drive for reform and showcase the willingness to work on the health care system on the European stage. ■

IMPRINT

VAD e.V.
German Association of Pharmaceutical Parallel Distributor

Prof. Edwin Kohl
President of VAD
Im Holzhau 8 | D-66663 Merzig
Phone: +49-6867-920-1301
Fax: +49-6867-920-1303
Email: kontakt@vad-news.de

COSTEFF e.V.
alliance for cost-efficiency in healthcare

Prof. Edwin Kohl
Chairman of COSTEFF
Jägerstraße 41 | D-10177 Berlin
Phone: +49-30-20 61 59 23
Fax: +49-30-20 61 59 24
Email: info@costeff.eu

GLOSSARY

European Single Market

The Single Market regards the EU as one territory without any internal borders or other regulatory obstacles to the free movement of goods and services. A functioning Single Market stimulates competition and trade, improves efficiency, raises quality and helps to cut prices.

Already in the early days of European integration, one of the original core objectives of the European Economic Community was the development of a common market offering free movement of goods, services, people and capital. The Single European Act, signed in 1986 lead to the launch of the Single Market in 1993. Remaining one of the key pillars of European integration, the four freedoms of the Single Market include the movement of goods, capital, services and persons. ■

Public Service Obligation

The Public Service Obligation (PSO) denotes the equal obligation upon manufacturers and distributors to supply the national market with pharmaceuticals in the first place. This obligation is stipulated in Article 81 of Directive 2001/83/EC and was amended in 2004.

However, not all Member States have implemented the PSO so far. Manufacturers have unlawfully benefited and often not supplied the markets sufficiently. More precisely, they have followed several strategies as market observers assume. One strategy aims to harm competition via parallel distribution by establishing quotas.

Another one aims to exert pressure on national health insurance in countries who are partly not able to pay the bills due to economic and financial difficulties. And sufficient market supply is always a hostage for actual and future pricing bargains. Hence, the resulting imbalances cause availability problems. A positive example of the PSO implementation is France, where obligations on pharmaceutical manufacturers have been enforced. The implementation and use of PSO will prevent shortages and will balance out the supplies. ■

EXPERT OPINION

Pharmaceuticals must be provided in an appropriate amount

By Jo Leinen, Member of the European Parliament

In recent times there have been repeated cases of shortages in pharmaceuticals supply within the European Member States – even in Germany. This results in the situation that patients cannot be sufficiently treated with the necessary medicines, even though it is necessary. Some Member States believe that parallel trading is to blame for that cause and further draw their conclusions. Consequently, exporting pharmaceuticals was made even more difficult. This seems reasonable on the very first glance, because the patients in the national countries suffer most from shortages.

What I miss in this case is the investigation into the reasons for the shortages. Almost reflexively, parallel trade is blamed as the main cause. However, it cannot be ruled out that too many pharmaceuticals have been sold abroad because wholesalers reach a higher profit compared to the domestic market sales. This has never been further investigated, including whether shortages were caused due to insufficient drug supplies by the manufacturing industry.

Appropriate and continued supply

At one point, the European Court of Justice (ECJ) pointed out that the markets need to be supplied better by the manufacturing industry than the industry itself deemed to be necessary. Today, the Lelos-decision of September 2008 has been forgotten. Among other things, this case specifically defined what sufficient supply would require according to the ECJ.

> 'In the present cases, the orders for reference show that, in the disputes which gave rise to those orders, the appellants in the main proceedings have demanded not that GSK AEVE should fulfil the orders sent to it in their entirety, but that it should deliver them quantities of medicines corresponding to the monthly average sold during the first 10 months of 2000. In 6 of the 11 actions in the main proceedings, the appellants asked for those quantities to be increased by a certain percentage, which was fixed by some of them at 20%.'

The Public Service Obligation

Having appropriate and continued supply would help avoid shortages in the Member States. The European legislators itself have established the 'Public Service Obligation' (PSO). Article 81 of Directive 2001/83/EC, addresses Member States to impose a PSO onto manufacturers and wholesalers. A Member State must impose the PSOs on both levels of the distribution chain within the limits of their respective responsibilities in our view, which is currently not the case in most Member States.

> 'The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.'

All Member states that have already implemented this directive are able to react immediately in the case of shortages and oblige wholesalers to only supply their own national market, or to sell the drugs within the national market.

Patients should always have access

This further assumes, that the Member States clearly define 'shortages' in order to be able to react with the PSO. In addition, it must be further clarified if the markets are adequately supplied by the manufactures, or if the shortages have been caused by insufficient supply.

On closer examination, it can be seen that not all aspects of the Single Market's functioning for pharmaceuticals have been investigated properly. To conclude, the European patient should always have access to the prescribed pharmaceuticals, while the role of the manufactures has to be examined very carefully. ■

CALENDAR

05 – 07 FEBRUARY 2019
VIENNA, AUSTRIA

DIA Europe 2019

The DIA Europe 2019 provides a global, neutral forum where stakeholders can openly and freely exchange knowledge information and insights to advance innovation in healthcare product development.

Topics in the programme pose questions about the future of treatment development and bring together cross-functional leaders to propose answers. These topics will be presented within seven specific presentation streams: Clinical Development, Data and Standard, Patient Engagement, Pharmacovigilance, Regulatory Science, Translational Medicines and Science, and Value and Access.

For further information, please see:
https://www.diaglobal.org/en/flagship/dia-europe-2019/about/conference

21 – 22 FEBRUARY 2019
BRUSSELS, BELGIUM

Annual Conference on EU law in the pharmaceutical sector

The annual conference will bring legal practitioners working with the pharmaceutical sector up-to-date on the latest relevant regulatory developments, legislative initiatives and case law. Topics range from intellectual property law and data exclusivity, digital health, emerging technologies and access to medical data, pricing and reimbursement of medicinal products for human use to EU trade policy and the impact of Brexit.

Stakeholders include in-house counsel, lawyers in private practice, lawyers in national ministries and authorities dealing with regulation of the sector.

For further information, please see:
https://www.era.int/upload/dokumente/20896.pdf