European Committee of the Regions

CoR INTERREGIONAL GROUP ON HEALTH & WELL-BEING

"Discussing the proposal for reforming the EU pharmaceutical legislation"

Thursday, 6 July 2023, 13:30 – 14:30

In person meeting

Minutes

13:30 Welcome and introduction by the Chair, Birgitta Sacrédeus

The Chair of the Interregional Group, **Birgitta Sacrédeus**, welcomed all the participants and explained that the meeting was organised to discuss the revision of the pharmaceutical legislation, which consists of a new Regulation and a new Directive along with a Communication and a Council recommendation on AMR. The event was structured around three speeches from Lilia Luchianov and Antonio Rodiadis, Policy Officer, Unit D1 "Medicines: policy, authorisation and monitoring" at DG SANTE, Dag Håkansson, Senior policy advisor, Department of Economy and Governance at SALAR, and Christine Erzberger, Policy Officer, Ministry of Social Affairs, Health and Integration, Representation of the State of Baden-Württemberg (GE) to the EU.

13.35 "The European Commission's proposal for a new EU pharmaceutical legislation" by Lilia Luchianov and Antonios Rodiadis

Lilia Luchianov started her speech by presenting a timeline of legislative endeavors that the European Commission took from 1965, when the European Commission adopted its first legislation establishing the need for medicines to be authorised before being placed on the market, with the aim of ensuring **safety, efficacy, and quality**. In 1995 the authorisation process was centralised with the **creation of the European Medicines Agency (EMA)**. In 2000, the EC published a legislation on medicines for rare diseases, and in **2004** there has been **the last major revision** that extended the scope of centralised procedure, simplifying them. In 2006, legislation on medicines for children has been created, and since 2007, a regulation on advanced therapy medicines was put in place. Then, New EU Pharmacovigilance rules have been published in 2010, followed by legislation against falsified medicines in 2011. **In 2020**, the COVID-19 pandemic triggered the creation of a **Pharmaceutical Strategy for Europe,** with the objective of creating a future-proof regulatory framework and supporting the industry in promoting research and technologies that reach patients to fulfill their therapeutic needs. The Strategy is composed of a Communication, a new Regulation, a new Directive, and a Council Recommendation

on AMR. Although the European Commission and EMA, through a network of Member States' experts and National Competent Authorities, take care of the authorisation procedures, inspections of manufacturing sites and pharmacovigilance, she stressed that Member States remain the main ones responsible for the delivery of health services and medical care and setting prices for medical products in the scope of national health insurance schemes.

Antonios Rodiadis took the floor explaining the overall political objective is to create a Single Market of medicines in the EU ensuring **access, availability, affordability**, competitive regulatory framework of medicines, while checking environmental sustainability and combatting AMR. The evaluation process and impact assessment took just two years because it was highly prioritized, normally this procedure takes four/five years. Regarding **access to medicines**, he shows that the access is not timely, and it differs across Member States so, some proposed solutions focus on the use of a **system of pharmaceutical regulatory incentives**, an **earlier market entry of generic medicines,** and a **faster authorization**. In this revision, patents have not been touched: they are discussing about a modulation of regulatory protection. Today a company has 8 years of protection. In the future, there is only 6 years of standard protection – with some exceptions such as unmet medical needs. The rationality is to **move from a "one size fits all" system** to a more targeted approach.

Lilia Luchianov presented the solutions to ensure the **availability of medicines**. The overall aim is to prevent shortages, and the proposed solutions focus on the **improvement of coordination, monitoring, and management of shortages** – both at the EU level by the EMA and at the Member States level, with earlier and harmonised notification of shortages and withdrawal. Moreover, each company will have a **Shortage Prevention Plan,** and there will be a **Union list of critical medicines**. To increase the **affordability of medicines**, the measures proposed are the **earlier market entry of generics/biosimilars** to increase competition and reduce prices, the **increased transparency** on public contribution to R&D, and the use of comparative Clinical Trials to support national decisions on pricing. In order to foster innovation, accelerate development and attract investment, the authorisation time will be reduced, and the regulatory burden lowered. Regarding **environmental sustainability,** she says that with this legislation, EMA will be able to refuse the authorisation if the **Environmental Risk Assessment** (ERA) is not completed or submitted. ERA will also be extended to medicines already on the market before 2023, and there will be stricter environmental rules for AMR. The last aim of this legislation is to combat **AMR**. The reform offers additional years of **data protection** through the **voucher system** to companies that invest in novel antimicrobials. Moreover, measures on the prudent use of antimicrobials will be put forward together with regulatory incentives with transferable exclusivity vouchers under strict conditions.

To conclude, she points out some **elements of special relevance at the regional or local level**. Access to all markets will **increase access to medicines**, while decentralised manufacturing will **allow manufacturing very locally** under the supervision of a qualified person of the central site, and finally more **transparency of public funding** could be useful for **negotiations at the local level**.

13.45 "The regional perspective: insights from the Swedish Association of Local Authorities and Regions" by Dag Håkansson

Dag Håkansson started his speech by giving some context of Sweden which is composed by 290 municipalities and 21 regions. Together, municipalities and regions account for about 20% of GDP and 70% of public consumption. The public sector employs 25% of the working population. The **Swedish healthcare system** is **tax-financed and decentralised**. Even though the regions are bearing the cost of pharmaceuticals, there are government grants system providing regions funds.

He says that **SALAR agrees with the 3As namely affordability, access, and availability**. However, they believe that access and affordability have been overshadowed by availability, indeed in their opinion, the proposal focuses more on creating and introducing new medicines rather than providing access and affordability. By focusing too much on the introduction of new medicines, the proposal does not inquire whether these medicines are useful and in demand on the market. Regarding **unmet medical needs,** they believe there is the need for a stricter interpretation of unmet medical needs that should include the patient's perspective. Today, on a global level, 95% of patients with rare diagnosis lacks access to treatments. Moreover, in the proposal, **multiple levels of approvals (such as fast tracks)** have been introduced, which might be positive because it facilitates interactions that are crucial in times of crisis for example. However, according to SALAR's position, the faster introduction of new medicines can lead to a scenario where these new medicines lack of safety and effectiveness. This might lead to an increase in distrust and difficulties in finding the predictability of costs. Swedish regions also believe that pharmaceutical legislation should better strengthen access to both older and new treatment options. It should also create more robust supply chains and increase efforts to predict and prevent shortages. Their main concern regards the **voucher system** that, in the worst-case scenario, **might create a second-hand market**. Finally, they believe that the regulatory framework should more clearly **promote interchangeability and the availability of generic medicines and biosimilars**. Indeed, shortened data protection periods are expected to lead to faster introduction of generics and biosimilars, but it is doubtful whether this will be the case since the substance patent often lasts the longest.

13.55 "The regional perspective: insights from Baden-Württemberg (GE)" by Christine Erzberger

Christine Erzberger started her speech by giving some context of the **Banden-Württemberg region** which is located in the South-West of Germany, bordering both France and Switzerland. It is the region with the highest number of pharmaceutical companies, which counts, to date, 88 companies. Indeed, the interest and impact of this Pharma legislation are particularly strong in this region. Three aspects of the legislation have been particularly appreciated by the region: first, **the need for up-to-date legislation** that fits today's market and challenges; second, **the improvement of EU-wide access to innovative pharmaceuticals** to avoid supply bottlenecks and combat antimicrobial resistance; third, **the reduction from 400 to 180 days of the assessment phase,** that will save time for companies and patients. However, there are some aspects that have been considered critical and that they potentially even be counterproductive. The **reduction of the regulatory data protection** from eight to six years **is seen as problematic** for Europe's attractiveness as a location for the research-based pharmaceutical industry and rapid access to new medicines. In addition, **the definition of ''unmet medical needs''** seem very **narrow** and the link to incentive mechanisms could contribute to neglecting further developments in other therapeutic areas. Regarding the environmental risk assessment, it has to be made sure that in case of a possible withdrawal of the marketing authorisation there will not be a supply shortage. Lastly, the region is concerned about the **problem of drug shortages**, which is not addressed in the pharma package although it is a major concern everywhere in Europe. To conclude, they believe that the coming years of negotiations will be intensive and certainly not easy, and they express their willingness to be involved in the discussion.

14.05 Open debate with stakeholders

The **European Federation of Pharmaceutical Industries and Associations (EFPIA)** puts the need to address a huge problem in Europe which is access inequalities. The legislation intends to decrease such inequalities through R&D incentives and regulatory data protection. However, EFPIA thinks that this approach alone will not solve the problem.

The **European Commission's DG Research and Innovation** stated that this legislation intends to benefit all patients through innovation. For that reason, the European Commission focused on areas such as unmet medical needs or the introduction of regulatory sandboxes to put together developers and regulators. The overall objective of the regulation is to make Europe more attractive for investments in innovation.

The **Salzburg region** raised a question on the proposal's aims regarding unmet medical needs and shortages. Both are huge obstacles in Europe that will not be solved through innovation.

14.30 Close of meeting