

IndustriAll European Trade Union: The pharmaceutical industry in Europe

Introduction

On 25 November 2020, the European Commission published the “Pharmaceutical Strategy for Europe”, building on four pillars: 1) Delivering for patients: fulfilling unmet medical needs and ensuring accessibility and affordability of medicines; 2) Supporting a competitive and innovative European pharmaceutical industry; 3) Enhancing resilience: Diversified and secure supply chains; environmentally sustainable pharmaceuticals; crisis preparedness and response mechanisms; 4) Ensuring a strong EU voice globally.

Since then, the rapid approvals of Covid-19 vaccines and the ensuring global race to get hold of available doses have dominated the political and public debate. IndustriAll European Trade Union wishes to highlight some elements of the strategy and the debates and explain its own positions.

Workers and society

The pharmaceutical industry is in constant change: mergers, acquisitions, outsourcing, focusing on a limited number of therapeutic areas, while discontinuing engaging in others, etc. New players have entered the market; in the context of Covid-19 vaccines and medications we see the success of previously unknown biotech firms.

We clearly share the European Commission’s assessment that it is essential to continue creating quality employment opportunities in the EU throughout the pharmaceutical value chains. A competitive pharmaceuticals industry depends on a skilled and specialised workforce. The Pharmaceutical Strategy calls on all key players in the pharmaceutical sector pool their resources and invest in upskilling and reskilling of all employees throughout the value chain.

As the use of digital technology increases in the sector there is a requirement for coordinated investment in necessary reskilling and training of workers to support good jobs.

The European Skills Agenda aims to increase STEM specialists, STEM graduates and teachers. IndustriAll Europe welcomes these initiatives but cautions that the focus should be on quality education alongside “boosting numbers” and to be mindful of the many different strands within the STEM fields. We call for more foresight and anticipation, skills development must not be retroactive but proactive.

However, quality employment is about more than skills. Europe must foster innovative and supportive workplaces; the pharmaceutical industry must continue to provide good jobs and career opportunities.

Social Dialogue and trade union involvement are key to implementing the pharmaceutical strategy and to the future development of the sector as a whole. Only our contribution can guarantee good

and fair working conditions throughout the value chain and ensure that a prosperous and innovative pharmaceutical industry fulfils its societal role.

Address medicines shortages

Shortages of certain medicines have been a concern for a while. IndustriAll Europe draws attention to the regional differences. Some countries are more at risk than others given their geographical location (distribution logistics) or a rare language (adequate labelling).

A company usually receives the permission to market a medicine in all EU countries. However, there is no obligation to do so. It may decide not to offer their medicines in, or withdraw them from, one or more countries. IndustriAll Europe would advocate for a mechanism that ensures that medicines are marketed wherever there is a certain level of demand and appeals to the Commission to review the system of incentives in this area.

We are also keen to see the results of a pilot project launched by the European Commission to understand better the root causes of deferred market launches.

The availability of new and improved pharmaceuticals depends on research, development and innovation. The development of new medicines takes decades and costs millions or even billions of Euros. Companies investing in R&D need a strong business case to do so. This is not always true for medications for all purposes. Publicly funded research can step in. Moreover, academic institutions or small companies encounter difficulties to make the step from development to production and marketing. In this context, industriAll Europe calls for:

- Support of private-public partnerships
- Support of the creation of start-ups in medical research
- Fostering of research collaboration between universities, research centres and industry

IndustriAll Europe welcomes the Commission's efforts to enable faster repurposing of off-patent medicines for new therapeutic uses.

The Commission announced that it will consider targeted policies that support greater generic and biosimilar competition. IndustriAll Europe asks to proceed with caution and find a good balance. While this competition is desirable from the perspective of availability and affordability it must not remove the incentive for companies to invest in research and development.

Public procurement can be an adequate tool to foster competition and improve access to medication through e.g. price conditionality, timely delivery and security and continuity of supply.

IndustriAll Europe will closely follow the Commission's announced legislative and non-legislative initiatives in this area in the coming years.

Finally, a substantial part of shortages are due to the increasing decentralization of manufacturing. An interruption at one point in the chain (due to lack of availability or due to insufficient quality) can affect the availability of medicines worldwide. Long ordering and logistics chains make it difficult to

respond quickly to increased demand, as shown during the pandemic. IndustriAll Europe urges the European Commission to foster the reshoring of value chains into the European Union. This could be done through, e.g.:

- Tender specification that link the public health spending on medicines to a certain degree of domestic (national or European) production
- When stock piling for emergencies, conduct national/European purchases from companies with domestic production
- Tie research funding to a compulsory share of domestic production (national or European) of the marketed pharmaceutical/active ingredient

Unmet needs

We know about 6500 rare diseases without treatment options today. Moreover, some more common diseases such as paediatric cancers or neurodegenerative diseases (e.g. Parkinson's or Alzheimer's) still lack therapies.

IndustriAll Europe agrees with the Commission's assessment that investment does not necessarily focus on the greatest unmet needs, be it due to the absence of commercial interest or the limitations of science in some areas. It is clear that action is needed: public incentives, funding for R&D as well as for production and marketing. Cooperation between players is highly welcome where it can help to meet patients' needs. Support could be especially useful for SMEs and start-ups with new research approaches.

Fighting antimicrobial resistance

Antimicrobial¹ resistance (AMR) has been a growing problem is likely to pose major difficulties to health systems. AMR decreases the capability to treat infectious diseases, and threatens the ability to perform even routine surgery. IndustriAll Europe sees the first and most important step in a more prudent use of existing antimicrobials, i.e. better information to patients and restrictions on prescriptions. However, new medicines will be needed. We call on authorities to facilitate cooperation between academia and industry and on researchers for open-mindedness to new or rediscovered sources.

In its Pharmaceutical Strategy for Europe, the European Commission proposes to “Pilot innovative approaches to EU R&D and public procurement for antimicrobials and their alternatives aiming to provide pull incentives for novel antimicrobials” as well as to “Promote investment and coordinate research, development, manufacturing, deployment and use for novel antibiotics² [...]”

IndustriAll Europe welcomes the initiatives, both scheduled to start this year.

¹ An ANTIMICROBIAL is any substance of natural, semisynthetic or synthetic origin that kills or inhibits the growth of microorganisms but causes little or no damage to the host.

² An ANTIBIOTIC is a low molecular substance produced by a microorganism that at a low concentration inhibits or kills other microorganisms.

Affordability

Medicines prices are mostly justified considering time and investment required and the risk involved, they are the needed incentive to keep R&D in Europe. Especially when taking into consideration that patents often run out shortly after marketing. However, prices must not overburden public health system or impoverish patients. Where public funding has supported the development of a medicinal product, authorities must require transparency and be able to influence price setting. In other cases, pressure on prices can be applied through strong public negotiation stance, cooperation of buyers, esp. in the case of public procurement, through parallel prescription rules, etc.

The shift from mass medicinal products to personalised medicines is likely to increase in the coming decades. IndustriAll Europe agrees with EC assessment that gene and cell therapies may offer treatments that would require new business models to address the shift in cost from chronic to one-time treatment. It is necessary that this trend is monitored and shaped by a dialogue involving all stakeholders.

The role of artificial intelligence

Big data mining and processing can speed up the discovery and design of new compounds, can help uncover or repurpose drugs, facilitate research through (predictive) modelling, speed up the trend towards quality personalised medicines. Moreover, with regards to the drug life-cycle, opportunities lie e.g. in optimised production processes, the gathering clinical data and assessment of responses.

However, biased data (fed into systems at the beginning) used by algorithms risks to inform outcomes forever. Due care must therefore be given right at the start.

The questions of data ownership and data protection have to be addressed. The Pharmaceutical Strategy reads: "Industry and regulators require access to data through a robust EU-wide data infrastructure to support innovation. An interlinked system that gives access to comparable and interoperable health data from across the EU would be a real multiplier in terms of research, regulation and evidence generation. The Commission will propose a European health data space and establish interoperable data access infrastructure, which will improve exchange, federated access and cross-border analysis of health data in the EU." While the reasons and aims are certainly commendable industriAll Europe demands caution. Patients' health data must not be openly accessible and tradable. The Finnish example highlights this problem: The country has had the most comprehensive health data base in Europe for decades, drawing on the entire population. Pharmaceutical companies have access to this data at low cost. A heated public debate has questioned this system for years.

Environmental impact

Most literature on the environmental impact points to discharge and excretion as main sources. But clearly, manufacturers are responsible for clean production processes.

IndustriAll Europe calls for the greatest possible limitation of the negative environmental impact of medicines for human and veterinary use through:

- Clear labelling of environmental risks of a medicinal product to allow informed choices among equivalent therapeutic options
- Strict disposal rules for unused medicines
- Strict regulation and enforcement of waste products and residues from production processes
- Enhanced wastewater treatment if certain residues could be better removed

The Pharmaceutical Strategy elaborates that residues and wastes not only have a negative impact on the environment itself, but that some of them may have endocrine-disrupting potential and others may increase the risk of antimicrobial resistance.

Therefore, the Commission proposes “to revise the manufacturing and supply provisions in the pharmaceutical legislation to improve the transparency and reinforce oversight of the supply chain and clarify responsibilities to ensure overall environmental sustainability” and “to revise the pharmaceutical legislation to strengthen the environmental risk assessment requirements and conditions of use for medicines”.

Lessons from the Covid-19 pandemic

IndustriAll Europe welcomes the Commission’s objective to identify strategic dependencies in health, and to propose measures to reduce them through diversification of production and supply chains, strategic stockpiling, and through fostering production and investment in Europe. The proposed structured dialogue with the actors in the pharmaceuticals manufacturing value chain, public authorities, patient and health nongovernmental organisations and the research community is good approach. Some pharmaceutical legislation may (have to) be revised to enhance security of supply and address shortages through specific measures including stronger obligations for supply and transparency.

It deserves to be highlighted that in this emergency situation, the industry and regulatory bodies were in state to develop and review and approve vaccinations at record speed. The level of cooperation and the flexibility in processes have proven the capacity of crisis response in Europe.

IndustriAll Europe welcomes the announcement of a European Health Emergency Response Authority (HERA). HERA is designed to improve the EU’s crisis preparedness and response infrastructure, and will strengthen the coordination of operations across the whole value chain and develop strategic investments for research, development, manufacturing, deployment, distribution and use of medical countermeasures.

International solidarity

After an unprecedented effort to develop, approve and roll out cures, medicines and vaccinations, several are available. The world has come closer to overcoming the pandemic. And the common global

endeavour and public-private cooperation to find drugs and vaccines demonstrated the best internationalism. Current buying practices and public debates are less solidaric. But the case for international cooperation is just as strong as in the beginning of the pandemic.

The COVID-19 Vaccines Global Access (COVAX) facility³ is a laudable instrument but far from being fully financed and – according to today’s estimation - only able to have delivered two billion doses by the end of 2021. Efforts to increase its impact are urgently needed. The WHO COVID-19 Technology Access Pool (C-TAP)⁴ was created to voluntarily share knowledge, intellectual property and data necessary to accelerate the development, to scale-up manufacturing and to make products available globally. So far, the initiative has shown little success. Other options have to be explored. The WTO rules permit compulsory licensing in emergency situations. India and South Africa have proposed a TRIPS waiver⁵ for vaccinations and other medicinal products to combat Covid-19. So far, the EU, USA, Switzerland and Japan have opposed this initiative. IndustriAll Europe recognises that intellectual property rights are crucial to maintaining and fostering research and development but believes that an open and pragmatic discussion is needed about all possible tools that could help to overcome the global pandemic.

Conclusion

For the availability and accessibility of quality pharmaceutical products, it is essential to have a strong pharmaceutical industry in Europe: R&D as well as production, high quality employment, good apprenticeships and training. The Covid-19 crisis has opened a window of opportunity with heightened public awareness for the relevance of the industry, better reputation and attractiveness.

Financial or other incentives given to the companies should be tied to a requirement of social and environmental responsibility, i.e. good jobs in clean production processes in Europe. industriAll Europe calls on the Commission to shape all the elements of the Pharmaceutical Strategy for Europe and all future initiatives in close cooperation with all relevant stakeholders, including trade unions and their social partners.

The fight against the pandemic requires unprecedented levels of international cooperation and solidarity.

³ <https://www.gavi.org/vaccineswork/covax-explained>

⁴ <https://www.who.int/initiatives/covid-19-technology-access-pool>

⁵ <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>