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PRESS RELEASE

The off-patent medicines industry is a vital part of the solution for healthcare resilience

30 June 2022, Sitges, Spain

Health systems face tremendous challenges across Europe. The management of COVID-19, war in Ukraine and high inflation rates are challenging supply chains for the most essential medicines.

Off patent medicines account for 70% of those dispensed in Europe, treating severe conditions such as cancer, auto-immune conditions, respiratory diseases, and cardiovascular disease. These medicines are clearly part of the solution for resilient health systems.

Policy reforms are needed to strengthen health systems in Europe with off-patent medicines. When revising the EU pharmaceutical legislation, the EU must:

- **Encourage the use of generic, biosimilar and value-added medicines** to increase patient access to medicines and ensure budgetary sustainability
- **Support the off-patent medicines industry response to inflation** by revising procurement guidelines for medicines and safeguarding the medicines manufacturing sector in emergency response plans
- **Commit to durable supply chains and manufacturing** for medicines, by allowing access to EU funds
- **Critically assess the IP infrastructure on medicines**, taking action to eliminate abuses, and fully supporting the entry into force of the SPC manufacturing waiver on 01 July 2022.

At the Medicines for Europe annual conference this week,

Elisabeth Stampa, President, Medicines for Europe commented: *The role of the EU in health policy took on a new life during the pandemic and should continue to do so if we want our health systems to be resilient. Europeans now expect strong EU leadership on health policy and our industry, as the biggest supplier of medicines to patients in Europe, is ready to play its part. We consistently bring solutions to improve access to medicines and reduce pressure on healthcare budgets. Today we are launching a report to optimise market policies for the secure supply of medicines. Our recommendations will ensure that medicines remain available, affordable, and accessible for patients, and also reduce the risk of medicines shortages and increase European strategic autonomy.*

Margaritis Schinas, Vice President of the European Commission for Promoting our European way of life, said *"We are revising the pharmaceutical legislation at EU level. The objectives are clear: having medicines at affordable conditions for all, and ensuring European industry remains an innovative world leader. These are not antagonistic objectives, on the contrary, both are possible, and we should make them a reality."*

Dolors Montserrat, Member of the European Parliament, (EPP, ES), said "*Since the first drafting of the European Parliament report on the New Pharmaceutical Strategy for Europe, as Rapporteur, I've stressed the importance of generic and biosimilar medicines for patients' equitable access as well as for the healthcare systems sustainability in a European Union where access is still a matter of inequalities. Moreover, we need to*

take concrete action at EU and Member States level, to promote research, development, and production of generic and biosimilar medicines in Europe. This should be also reflected in all the policies that will build on the Covid-19 lessons learned – included the outcomes of the EU structured dialogue on security of medicines supply - because, especially in the first pandemic outbreak, off-patent medicines played a pivotal role for our patients"

Nicolás González Casares (S&D, ES) said "*A few months ago, we approved the Regulation reinforcing EMA's role in crisis preparedness and management of medicinal products and medical devices. This report enhanced EMA's capacity to deal with future emergencies by supporting the role of healthcare professionals and the synergies between EU agencies. It also aimed to avoid possible shortages of medicines by providing the Agency with a new European medicines supply database, which will always ensure a comprehensive overview of the volume of stock at member states and European level. In the coming months, we will continue on the path of ensuring equitable and timely access to medicines in the European Union, in the context of the revision of the general pharmaceutical legislation and the Orphan and Paediatric Regulations.*"

Ángel Luis Rodríguez de la Cuerda, Secretary General, AESEG said: *In the last two years, generic medicines pharmaceutical companies in Spain have been absorbing a 10% cost increase due to the price rise in energy, transportation as well as in raw and conditioning materials, without being able to augment the final price of medicines as these prices are fixed and regulated by law. A medicines price increase, with minimum profitability thresholds, would be a necessary and justified provision to ensure cost-efficient manufacturing and supply continuity for our National Health System, as well as patient access to treatments. In alignment with the European Pharmaceutical Strategy, committing to the reindustrialisation of a country such as Spain, with 20 manufacturing sites for generic medicines, would reduce dependency on third countries, attract investments from nations outside the EU, increase gross domestic product (GDP) and ensure supply.*

Jordi Valls, Afaquim Vice President said*: The European API manufacturing industry has shown its strategic and essential role as well as its commitment to health systems and customers, generic medicines manufacturers, during these difficult times. We should all keep in mind that active ingredients are the first step in the value chain in the manufacture of medicines and are responsible for the therapeutic effect we seek with their prescription. We need the clear support of legislators, governments and medicine manufacturers to ensure that our APIs produced with the highest quality and safety standards in the world, continue to provide the best health for European patients. We can remain strong and competitive with flexible regulations, truly available recovery funds, reference prices adjusted to manufacturing costs and a determined promotion of European production.*

Stella Kyriakides, European Commissioner for Health intervened virtually. Her full speech can be viewed here https://www.youtube.com/watch?v=BE5e63tx6Vs

Resource hub

- The report titled 'New pricing models for generic medicines to ensure long-term healthy competitiveness in Europe' is available here in full form, and dedicated strategic recommendations available here.
- For more information on Medicines for Europe annual conference, see here.

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health

outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.