Medicines for Europe: Better Access, Better Health

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For most European citizens, access to healthcare and medicines is of fundamental importance to maintain a strong social fabric. Our industry shares this view and has consequently changed its name from EGA (European Generic and Biosimilar medicines Association) to Medicines for Europe: better access, better health. Our new approach is synonymous with renewed focus on delivering better access to high quality medicines for all European patients. We see better access to healthcare as an opportunity to improve the health of the population and reduce inequalities in Europe.

Generic medicines have delivered access for patients

In many ways, Europeans are blessed with healthcare systems that are helping them live longer, healthier and more fulfilling lives. Better access to medicines and improvements in care have significantly increased life expectancy across Europe. Our industry is proud to have played a big role in this development. When the EGA was established in 1993, generic medicines represented a fraction of Europe's medicine supply. 23 years later, our industry has not only become the largest supplier of medicines in Europe (56% in volume), it has also increased the access to key first line therapies such as hypertension or diabetes by a massive 100% over the last 10 years alone. All of this has been achieved without increasing the overall costs of medicines. Without generic medicines, Europeans would have to pay a staggering €100 billion per year on top of the current medicines bill to deliver the kind of access that we enjoy today.

The growth and expansion of generic medicines will continue to play an important role for the next few years as patents expire creating new opportunities for competition in pharmaceutical markets across Europe. While this is certainly positive, we also need to recognise how this fundamentally changes pharmaceutical policy. Europe is a continent of over 500 million people with growing healthcare needs which translate, for example, into 80 million patients relying on (mainly generic) hypertension medicine every day. Similarly, 30 million Europeans rely on (primarily generic) diabetes medicines every day.

Pharmaceutical manufacturing is important for medicines supply

Medicines for Europe recognises the tremendous responsibility in ensuring a stable supply of medicines for patients. This requires a more focused pharmaceutical policy that takes much greater account of manufacturing sustainability. The first element is to ensure that Europe's pharmaceutical industry is capable of supplying patients with the medicine they depend on. This requires a robust and efficient regulatory system to guarantee the safety, quality and efficacy of all medicines which can only be achieved through effective dialogue and cooperation between regulators, the industry and other stakeholders. With improvements in IT technology and more effective IT systems between the industry and regulators, we have a real opportunity to make Europe's regulatory system more efficient by focusing on the real patient needs and reducing administrative redundancies that waste time and resources for both regulators and industry. Moreover, thanks to its global leadership position in both regulation and manufacturing, Europe can take a leading role in promoting regulatory cooperation to improve marketing authorisation procedures, to manage global supply chains and to promote high EU-like global quality standards. The European Commission and the EMA – European Medicines Agency have already demonstrated the capacity to lead in this space in the context of the TTIP negotiations with the US, building on the concept of global development of biosimilar and value-added medicines.

Moreover, pricing and reimbursement policies need to promptly stimulate competition when pharmaceutical patents expire while at the same time encouraging the industry to invest in maintaining the production of essential medicines even when price competition is fierce. Treating medicines like a simple commodity is a recipe for trouble. Therefore our industry is reaching out to EU governments to negotiate stability pacts to create competitive and predictable markets for patients and healthcare providers as well as the pharmaceutical industry. Additionally, policy-makers need to stimulate more medicine manufacturing in Europe to avoid over-reliance on foreign suppliers. The recent Commission proposal to allow a "manufacturing waiver" under the Supplementary Protection Certificate (SPC) period is definitely a big step in the right direction to create manufacturing and employment opportunities for Europe.

More competition is needed in specialty pharmaceuticals

The high cost of new medicines has many healthcare policy-makers and advocacy groups concerned. Medicines for Europe is already addressing this concern by investing heavily (up to 17% of turnover into R&D) in biosimilar and value added medicines which bring competition to biopharmaceuticals, to specialty medicines and to pharmaceutical innovation. This is not only a development opportunity for our industry, it is also an opportunity for Europe to re-establish its leadership in pharmaceuticals through an accessible innovation policy.

Biosimilar medicines: A European success story

Technological advances and innovation have had a massive impact on the pharmaceutical industry, including the development of new and highly innovative biological medicines – a medicine whose active substance is produced by or extracted from a biological source. We have responded to this opportunity

with biosimilar medicines – medicines that are highly similar to existing biological medicines, without any clinically meaningful difference in terms of efficacy. **With more than 10 years of positive patient treatment experience in the market,** the use of biosimilar medicines will massively increase access to biological treatments. For example, access to filgrastim, which is used for neutropenia in chemotherapy patients, has increased by 44% thanks to biosimilar medicines competition. However, to achieve these gains in access, Medicines for Europe understands the necessity of engaging with patients, healthcare professionals and governments to share the understanding and the benefits that these medicines provide as was pursued under the leadership of the European Commission Consensus Paper on Biosimilar Medicines. Actually, biosimilar medicines show that Europe can make a real difference, for patients by increasing access, for quality by creating the global high standard for biosimilar medicines approvals, for value but promoting a stakeholder benefits model for market uptake, for sustainability by supporting a technological leadership position in the research, development and manufacturing of these medicines and for partnership by encouraging stakeholders to work together to improve access to medicines.

Competing models of innovation

For most policy-makers, the pharmaceutical industry is a binary world of "innovators" developing new chemical entities and "generic companies" bringing competition at patent expiry and this is reflected in the binary structure of most pharmaceutical pricing and reimbursement systems in Europe with one (high) price for new drugs and a heavily discounted price for generic medicines. This binary world view prevents our innovative industry from challenging the dominant, and expensive, pharmaceutical innovation model in two ways.

First, it limits the possibilities for our industry to develop competitive pharmaceuticals at patent expiry for more complex products with value added component in comparison with the initial originator product, because the economics do not always work under a generic reference price system. This explains the huge potential in the respiratory therapies like asthma or COPD and the new technology opportunities to apply for improved products with known molecules. In a similar vein, our industry is restricted in its ability to compete in innovation with the dominant model limiting our capacity to improve on drug delivery for better health outcomes or even to address unmet needs through, for example, drug repurposing.

For this reason, we have expanded our industry into **value added medicines aimed at optimizing, rethinking and reinventing existing medicines based on known molecules**, addressing unmet healthcare needs of patients through improved care delivery systems. Value added medicines are based on known molecules that address unmet healthcare needs and/or deliver relevant additional improvement for patients, healthcare professionals and/or payers. Relevant benefits include improved efficacy, safety and tolerability profile, better adherence, better quality of life, better convenience of use and/or patient preference. As a novel contribution to the prevention of therapeutic escalation, the rational use of medicines and improving equity, value added medicines will play a key role in improving the efficiency of Europe's healthcare systems.

Better access for a better health across Europe

Generic medicines, and increasingly biosimilar and value added medicines, are fundamental to the **sustainability** of healthcare systems: allowing healthcare providers to care for an ageing population, respond to increased incidences of chronic diseases, and manage budgetary constraints compounded by the high cost of new branded medicines. Thanks to competition from our members, the access of patients to high-quality medicines has doubled over the last ten years with no impact on treatment costs. By driving efficiencies and reducing avoidable costs for healthcare systems through improved medical adherence and better patient outcomes, generic, biosimilar and value added medicines are an opportunity for an efficient, access-driven healthcare system. To be successful in achieving this, our industry also needs to operate in an environment that stimulates competition at patent expiry including through increased cooperation with healthcare stakeholders.

With our deep expertise and knowledge and our ability to deliver positive change for healthcare, we are committed to working in **partnership** with all the healthcare community and policy makers to create **better access and better health for all European patients**. Our association is actively engaged in stakeholder and regulatory dialogues – providing objective and accurate information to help improve access to high quality medicines and create a more stable and competitive pharmaceutical markets in Europe.

Medicines for Europe remains engaged and committed to building on the relationships established over the last 22 years as the EGA. We will continue to be a trusted source of high quality information about generic, biosimilar and value added medicines as well as a passionate advocate of better access to better health for Europe.

We look forward to the next opportunity to provide you with further information about **Medicines for Europe**, its engagement and its strong commitment to deliver access to high quality medicines for all European patients.

About Medicines for Europe

Medicines for Europe (formerly EGA) represents the pharmaceutical companies supplying the largest share of medicines across Europe and is the voice of the generic, biosimilar and value added medicines industries. As a leading partner for better healthcare, we aim to increase the health and wellbeing of all Europeans through better access to high quality medicines. 80% of therapy areas are covered by the portfolios of the members of Medicines for Europe, thereby safeguarding the sustainability of Europe's healthcare systems for future generations. The vision of Medicines for Europe is to provide sustainable access to high quality medicines for all patients, based on 5 important pillars: patients, quality, value, sustainability and partnership. For more information please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.