

# Access to Medicines at Sustainable Price: Pharma Industry and Governments Transforming Challenges into Opportunities



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## Healthcare systems under duress

In Europe today, healthcare systems are faced with budget cuts while the demand for treatment from an ageing population is increasing and the costs of providing access to new innovative medicines is rising. This is hardly a formula for healthcare sustainability. Governments have tried to address the gap between rising healthcare costs and limited healthcare budgets by drawing attention to lifestyle choices driving non-communicable disease and high prices charged by the originator pharmaceutical industry, but this approach has not resulted in a sustainable solution. What is missing from the government dialogue is a proposal of concrete measures to increase the efficiency of healthcare delivery. The absence of coherent policies to stimulate competition in the pharmaceutical market is a missed opportunity for governments and patients. Generic, biosimilar and value added medicines have demonstrated their incredible capacity to increase access to medicines across Europe in a financially responsible way. It is time for governments to agree on effective policies to support generic, biosimilar and value added medicines competition rather than continuing to employ short-sighted, cost-containment measures (such as mandatory price cuts in the off-patent sector, External Reference Pricing (ERP), tendering and payback/clawback policies), which endanger medicines supply reliability and ultimately patient health. With a renewed and coherent

policy to stimulate competition in the market, the medicines industry can help transform a challenge into an opportunity.

## What is the contribution of the off-patent sector to healthcare sustainability?

In Europe the majority of prescriptions today are filled with generic medicines, although these medicines represent less than one quarter of total medicines costs, amounting to a mere 2-3% of total healthcare expenditure. As a result of generic medicines, patient access to high-quality essential medicines has doubled over the last ten years across Europe with no impact on treatment costs. Without generic medicines, European healthcare providers would have had to pay an additional €100 billion for medicines per year, according to IMS.

After only ten years, the availability of biosimilar medicines has also shown positive access trends for patients. For example, access to filgrastim, a biological treatment against neutropenia for cancer survivors, has increased across Europe by around 50% thanks to competition. In many countries the introduction of competitive biosimilar medicines has transformed the treatment options available to patients. With new biosimilar medicines on their way for therapeutic areas such as autoimmune diseases and cancer, it is anticipated that health systems will be able to deliver even greater access to biologic treatment at a sustainable cost.

Moving from a one-size-fits-all to a much more tailored and patient specific approach, value added medicines contribute to addressing unmet patient needs and are one of the key components of the customisation of healthcare. By answering patients' unmet needs, they represent a new horizon for those who are currently looking forward to a better quality of life with their treatment. Value added medicines are based on known molecules that address healthcare needs and deliver relevant improvement for patients, healthcare professionals and/or payers.

Recently, the Council Conclusions<sup>1</sup> underlined the importance of the timely availability of generic and biosimilar medicines to improve patient access to therapy and to ensure the sustainability of national health

systems. This now needs to be translated into policy action.

## Can the off-patent industry do more for access and sustainability?

More should be done to increase the use of generic and biosimilar medicines for better access to medicines for patients without bankrupting healthcare budgets. The OECD<sup>1</sup>, the European Commission<sup>2,3</sup>, the European Parliament (INI report link here) and the European Council<sup>4</sup> have all highlighted this as a priority for 2017 healthcare reform.

To fully realize the potential of generic and biosimilar medicines, the EU and member states should develop coherent policies to stimulate competition in the off-patent pharmaceutical market. Underlying economic and regulatory root causes contribute to unsustainable market conditions; these aspects are squarely within government authority to rapidly address. Specifically:

- Ensure predictable market environments for healthy competition
- Implement clear incentives to stimulate the use of generic and biosimilar medicines
- Improve regulatory efficiency to reduce administrative and cost burden of keeping products in the market
- Support manufacturing jobs in Europe with SPC manufacturing waiver
- Remove market barriers to allow generic and biosimilar medicines to compete from day 1 after patent expiry

<http://www.medicinesforeurope.com/news/european-health-ministers-call-for-more-competition-in-pharmaceutical-markets/>

1 OECD, Fiscal Sustainability of Health Systems: Bridging Health and Finance Perspectives, 2015

2 Investing in Health, 2013, DG SANCO, European Commission, [http://ec.europa.eu/health/strategy/docs/swd\\_investing\\_in\\_health.pdf](http://ec.europa.eu/health/strategy/docs/swd_investing_in_health.pdf)

3 DG ECFIN and Economic Policy Committee (Ageing Working Group), Joint Report on Health Care and Long-Term Care Systems & Fiscal Sustainability, 2016, [http://ec.europa.eu/economy\\_finance/publications/eeip/ip037\\_en.htm](http://ec.europa.eu/economy_finance/publications/eeip/ip037_en.htm)

4 Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States - <http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/>