

## Editorial – The innovation and access to landscape

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The biopharmaceutical industry is playing a vital role in both innovation and access to medicine through intensive research and development (R&D), partnerships, patient access programs, and through contributions to good governance.

Firstly, it is a high-technology sector that invents and develops life-saving and life-enhancing medicines, reinvesting more of its net sales back into innovative research than any other industry (14.4% on average) [1].

As evidence of the above, despite the complexity and unpredictability of the innovation process, the industry has developed more than 550 medicines in the last 15 years for some of the world's most critical and emerging health needs, including oncology, cardiovascular disease, and diabetes [2,3]. During the past 5 years, 182 novel drugs to treat major public health concerns have been approved by the US Food and Drug Administration (FDA), with 45 approved in 2015 alone [4]. Industry continues to be instrumental in exploratory research, as well as translating research into patient-ready life-saving and life-enhancing medicines to those in need [5].

The new medicines and vaccines springing from the work of scientists over decades created a legacy from which every one of us benefits today. Effective medicines and vaccines do more than prevent and treat diseases, and patients are not the only ones who are helped by new developments. When new medicines improve a population's health, also the economy benefits from a healthier workforce.

Having the right medicines is just one step in improving public health. A shared goal in the global health community, including the industry, is to ensure the world's patients receive the medicines they need to live longer and healthier lives. Expanding access to health care and to medicines can be complex and challenging, particularly in low- and middle-income countries, and requires a structured, collaborative effort that ensures health systems use resources effectively and efficiently. Ensuring that patients receive the correct medication, at the appropriate time and from a convenient location, requires a complex 'value chain' [6]. There are many gaps in health care systems that have an unequal impact on populations.

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It should be recognized that a holistic approach to access to medicines should be adopted and enforced by the competent international and domestic health authorities. National procurement and supply systems for medicines are often inefficient, or poorly calibrated to meet current needs. As a result, scarce resources are wasted, the introduction of vital new medicines is delayed and stock-outs may occur, presenting a significant barrier to health.

Strong regulatory systems are needed to ensure that people around the world have timely access to quality medicines and vaccines that are both effective and safe. Today, only 20% of the World Health Organization's Member States have well developed pharmaceutical regulatory systems, due to considerable human and financial resources that such systems entail. In a globalized world, however, the regulatory landscape needs to evolve continuously to address old and new challenges. The safe and effective supply of medicines will become an increasingly important global priority in the 21<sup>st</sup> century [7]: providing effective protection against falsified medicines is to be considered a shared goal, in the interests of individuals and communities all over the world.

The most promising solution is to make regulatory systems work more efficiently through convergence and harmonization. For example, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) brings together the regulatory authorities and pharmaceutical industry representatives to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development [8]. Another important and more recent example is offered by the African Medicines Regulatory Harmonization (AMRH) Programme [9]. As stated in the goals of this initiative, in "harmonizing medicines regulations, a positive impact will be made on:

- Access: Communities get quicker, greater access to priority essential medicines of good quality.
- Availability: The availability of affordable essential medicines can be improved through simplified, harmonized, efficient and transparent regulatory approval processes.
- Affordability: With more generics (lower priced) on the market, patients can achieve greater savings. Governments and donors can enjoy cost savings from subsequent downward pressure on prices through enhanced competition and pooled (shared) procurement."

The UN Sustainable Development Goal 3.8 calls upon the world to "achieve universal health coverage, and provide access to safe and effective medicines and vaccines for all" [10]. Every year, the pharmaceutical industry develops new solutions that have potential to transform health outcomes; for many, however, even basic healthcare services are beyond their reach. Weak systems and incoherent policies exacerbate inequalities rather than resolving them, making poverty both a primary determinant and ongoing consequence of poor access to healthcare.

In order to secure continued business investment in innovation, and to ensure access to care and achieve strong health systems around the world, all actors, including industry, need to collaborate, share accountability and target sustainability across all health system components and especially for essential medicines, vaccines, diagnostics and health technologies. The Agenda for the Sustainable Development Goals 2030 calls for a “revitalized global partnership,” including the private sector, particularly to address access to medicines [11].

The constant quest for new mechanisms to improve access to medicines will not be successful unless they are pragmatic and respond to the realities of the complex global health landscape, engaging a coalition of actors in both the public and private sector.

Product development partnerships, innovative financing mechanisms, voluntary licensing and non-assert declarations, have helped the biopharmaceutical industry reach hundreds of millions of people in under-resourced settings already. Few essential medicines are covered by any intellectual property. Where IP does exist, the industry has demonstrated that it is prepared to work on new models and approaches to expand access for patented products. Where IP is not a sufficient incentive to stimulate R&D for diseases of poverty, the industry has an impressive track record of pursuing innovative partnerships and collaborative approaches to share the costs and risks of R&D on which no commercial return can be expected [12].

The viability of the pharmaceutical industry depends on the existence of functional pathways that bring medicines to the people who need them, and industry is committed to engage in strengthening health access as a central part of its global operations.

Together with government, non-profit organizations, and multilateral organizations, industry is addressing healthcare access as a complex, multidimensional issue that requires comprehensive and varied approaches.

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