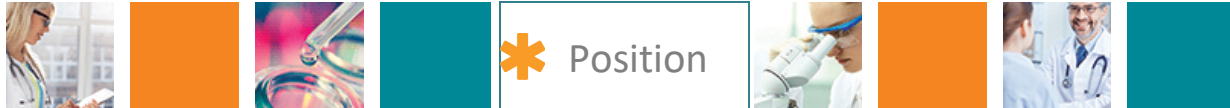




Convergence of Regulatory Requirements benefits Patients and Society

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Today, the development of medicines and vaccines is a global endeavour and new scientific methods and tools are enabling innovations that can bring important healthcare benefits for patients. Robust regulatory systems are important to ensure appropriate benefit - risk assessment of new technologies, which lead to country specific marketing authorisations. Converging regulatory requirements will strengthen public health, streamline product development, as well as regulators' technology assessments and avoid generation of additional data which do not add any value to Quality, Safety and Efficacy of a medicine or vaccine. This will ultimately benefit patients and society, because new healthcare innovations will become available faster.

Convergence of regulatory requirements means gradual adoption of international technical guidelines, standards and scientific principles (i.e. ICH, WHO), common or similar practices and procedures, or adoption of regulatory mechanisms that might be specific to a local legal context but that align with shared principles to achieve a common public health goal. It does not necessarily represent the harmonization of laws and regulations, which is not a prerequisite for allowing the alignment of technical requirements and greater regulatory cooperation¹.

Key Messages

- The pharmaceutical industry is a key stakeholder in the development of innovative healthcare solutions. We have a unique global perspective and are engaged in efforts with regulators and other stakeholders to support regulatory convergence.
- Consistent and appropriate regulatory and technical standards including pharmacopoeias are the basis of streamlined development of innovative medicines and vaccines, as well as

¹ Source FDA



efficient post-approval change management^{2,3} that is important to facilitate uninterrupted global supply.

- Convergence of regulatory requirements will further streamline medicine development; it will enable faster global submission and consistent and collaborative assessment of regulatory dossiers⁴. There is also a high likelihood that new medicines and vaccine will reach patients faster.
- Ongoing global and regional harmonization initiatives⁵ have been important drivers to achieve convergence on regulatory requirements; Industry is fully engaged and supportive of these activities.
- Industry believes that convergence of regulatory requirements is fundamental to Agencies' regulatory reliance⁶. It allows reliance on work performed by international peers who uphold the same scientific standards. This helps strengthening regulatory oversight by re-focusing available resources on activities that can only be performed by the local agency.

Background

Access to innovative and novel therapeutic treatment options continues to be a key driver for bringing significant health benefits to society and patients. Aligned, science-driven regulatory standards provide assurance of quality, safety and efficacy, and are important in making medicinal products available in a timely fashion across the globe. They support the initial approval of new products, their life cycle management, and their effective distribution through international supply chains. A strong regulatory framework is a prerequisite to safeguard the wellbeing and safety of public health.

The role of regulatory authorities is to oversee activities of the pharmaceutical industry and to ensure that high quality, safe and efficacious medicines are provided for the wellbeing of citizens. Authorities are required by national law to conduct assessments of submitted data, however individual countries and jurisdictions may use differing regulatory processes standards.

²Harmonisation of pharmacopoeia standards is very important in this context. Globalisation of pharmaceutical supply chains drives the need for aligned standards between pharmacopoeias, to simplify the requirements for compliance and facilitate the availability of medicines to all patients worldwide. See efpias position on pharmacopoeia harmonization <https://www.efpia.eu/media/412542/efpia-position-paper-on-non-harmonised-requirements-in-local-pharmacopoeias.docx>

³ Continuous safety data collection and quality improvements after the initial registration require the submission and assessment of post-approval change applications throughout the life-cycle of the product.

⁴ A good example is Project Orbis initiated by the US FDA Oncology Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among its international partners. Under this project, the FDA, the Australian Therapeutic Goods Administration (TGA) and Health Canada collaboratively reviewed applications for two oncology drugs, allowing for simultaneous decisions in all three countries.

⁵ Global harmonization initiatives such as those stemming from the ICH, PIC/s or the WHO are very important. Regional harmonization initiatives are driven by regional networks, such as the AMRH (African Medicines Regulatory Harmonization) initiative, PANDRH (Pan American Network for Drug Regulatory Harmonization), ASEAN PPWG (Association of Southeast Asian Nations Pharmaceutical Product Working Group), and APEC (Asia-Pacific Economic Forum). These regional harmonization activities are leading stepwise towards global convergence as they exchange best harmonization practices.

⁶ <https://www.ifpma.org/resource-centre/ifpma-position-paper-on-regulatory-reliance/>



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However, divergent and sometimes incompatible regulatory requirements can hamper the timely development and accessibility of medicines and have the potential to cause delays in initial product availability or ongoing supply. As expressed by the former FDA Commissioner Margaret Hamburg: “...in our modern world, the mosaic of regulations that govern drug development and oversight nation by nation are creating unnecessary barriers” ⁷. It is the duplication and variety of requirements, not the requirements themselves that constitute the problem.

For example, requirements regarding post-approval changes – in particular Chemistry, Manufacturing and Control (CMC) variations – that follow initial approvals throughout a product’s life cycle are numerous and complex. The different classifications of a given change, absence of co-ordinated timelines and misaligned data requirements generate a heavy burden on both industry and national regulators.^{8,9}

Regulatory convergence is a prerequisite for greater collaboration and work-sharing between authorities. Reliance on trusted peers provides for the effective management of resources allows regulators to focus on value-adding activities that cannot be performed by others. This is important as science and technology advance with increasing speed and regulatory capacity needs to be adapted to keep pace.

Likewise, patient expectations for greater involvement are increasing and the health care environment becomes increasingly cost constrained. Therefore, the regulatory stakeholder system is becoming more complex.

The pharmaceutical industry is undergoing a fundamental “digital” transformation; this means an expansion of sources of data used in regulatory decision making. Patient data from different electronic sources continuously collected during clinical use will be broadly accessible in real-time to healthcare systems, payers, regulators and industry. The regulatory system is currently not adapted to cope with these changes and there is a risk that future legislation and policies in these complex innovative areas may be divergent if countries develop new requirements in isolation. Preventing such divergences will be critical for spurring future innovation.

Pharmaceutical R&D productivity is affected by many factors; any resources saved on meeting divergent regulatory requirements could be allocated towards supporting innovation in areas of unmet medical need. For society and patients, increased innovation means more therapies to cure or alleviate unmet medical needs. Suffering endured by patients may therefore be reduced and expectations of patients may be met faster.

⁷ Zerhouni, Elias. and Hamburg, Margaret. The need for global regulatory harmonization: A public health imperative. *Sci. Transl. Med.* **8**, 338 ed6 (2016)

⁸ https://www.efpia.eu/media/25953/efpia-post-approval-change-position-paper_final_feb2017.pdf

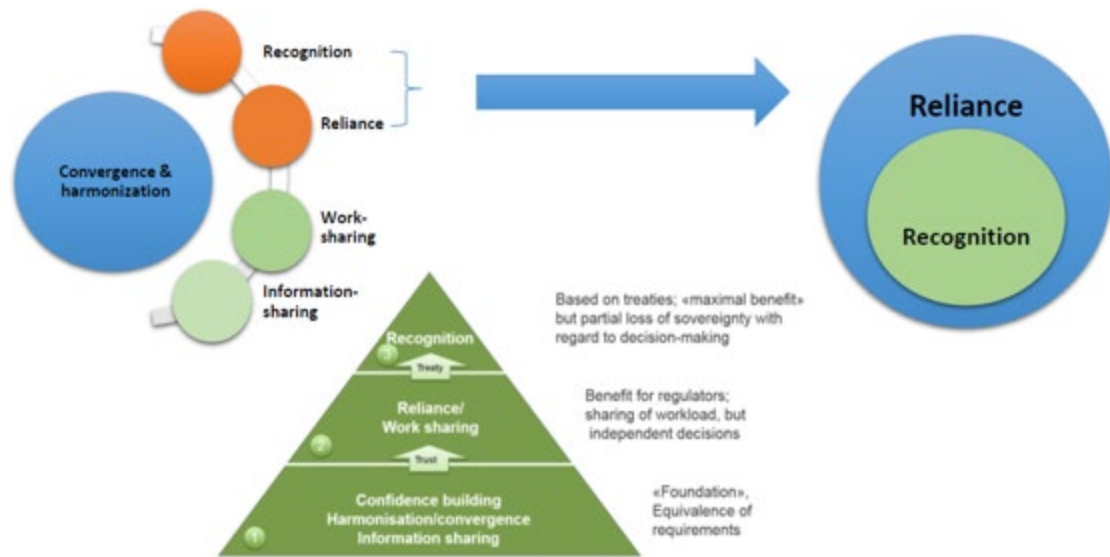
⁹ <https://www.ifpma.org/resource-centre/handling-of-post-approval-changes-to-marketing-authorizations-position-paper/>



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WHO views on Regulatory Cooperation



Source: WHO Presentation



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