



The critical role of regulatory systems in enabling the vaccines of the future

Regulatory systems are a key enabler of scientific advances both for vaccines and across other product types. Poorly functioning regulatory systems can: prevent uptake of innovative clinical models; introduce up to 7 years delay in access to new products; and be a key barrier to local manufacturing.

Without advances in global regulatory architecture, we won't see the innovation we hope for in vaccines to tackle escalating infectious disease threats or equitable access to products.

Why now?

The global regulatory system depends on National Regulatory Agencies (NRAs). At present few NRAs are able to efficiently regulate complex products such as vaccines. The system relies on regulators from high income countries approving products for low-income markets. Even with these 'mature regulators', acceptance for new clinical methods can be very slow or non-moving, holding back potential innovation.

The need to rapidly approve Covid-19 vaccines has seen regulators work much more flexibly to assess data on new types of vaccines. Without Covid-19 it could have taken many years if not decades to see the first mRNA vaccine emerge. But gaps in global regulatory capacity continue to be a significant problem. In the absence of improvements on this front, efforts to build more globally distributed manufacturing for vaccines will be held back. In addition, we will continue to see vaccines and products which primarily affect low-income settings, de-prioritised by the global regulatory system.

We must start to build the regulatory system of the future to enable regions and countries to authorise and oversee the clinical trials, manufacturing, and products that they need. Parallel to this, regulatory science and mature regulators need to keep pace with scientific potential.

What are the potential solutions?

We need a multilayered regulatory system with capacities at national, regional and global levels.

- **Improving regional and country level regulatory capacity** – National regulators have a pivotal role to play in supporting R&D, manufacturing and market access for vaccines and other pharmaceutical products, they undertake the following roles:
 - Approve all clinical trials and oversee clinical labs
 - Oversee all manufacturing facilities to ensure quality and safety standards are followed.
 - License vaccines and pharmaceutical products for national use including how products are marketed and labelled.

At present most national regulators lack the capacity to undertake these roles fully. WHO estimates that globally only 30% of NRAs can effectively regulate vaccines. In Africa, over 90% of NRAs have minimal to no capacity. The impact is profound; where capacity is low clinical trials are more difficult for developers to conduct, locally relevant products are more difficult to approve, and local manufacturing will be stymied.

- **Increased regulatory harmonisation and reliance** – With each country authorising every vaccine, there can be delayed access to products (up to 7 years between authorisation in a high income and low-income setting). The cost and time for developers to engage hundreds of national regulators is also high, compounding the lack of market incentives to develop vaccines for diseases which don't have a clear commercial market.

It simply isn't feasible to build full regulatory capacity in every country across the world. As a result, regional regulatory capacity and improving harmonisation, work-sharing and reliance between countries will be vital. In practice this means countries accepting decisions made by other national regulators, or pre-agreement on common standards for packaging and labelling or processes for approving clinical trials.

What needs to happen?

The critical role of regulatory systems in enabling vaccine innovation and ultimately equitable access to lifesaving products needs to be recognised. Improving regulatory capacity has the potential to enable more global manufacturing of vaccines and hasten access to products. Tackling these has the potential to cut development time by an estimated 3 years and reduce costs by over \$50 million.

- **Support and investment for regional regulatory capacity** – The African Medicines Agency has just received ratification from 18 countries and offers the potential to be a platform to support greater regional reliance and sharing of capacity. Its role should be strongly supported by those involved in vaccine development as should other regional initiatives.
- **Improving regional harmonisation and reliance** – Moving away from individualised licensing, packaging and other requirements across hundreds of countries would reduce the costs and time of bringing vaccines to market. For vaccine development for neglected and epidemic diseases this could be critical. No major technical hurdles stand in the way of this, but the desire of countries to maintain their own full regulatory competence should not be under-estimated.
- **Clearer roles and responsibilities in regulation of vaccines** – Stakeholders in vaccine development need to define and agree upon what a right-sized global regulatory system would look like. A broader consensus will be needed on which activities would be conducted by the most mature regulators, which could be done regionally or nationally, and how best WHO can support the needs of regulators overall. This will help reduce overlapping efforts which otherwise compounds low capacity.