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Challenges to Implementing a Regulatory Science Agenda

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Description

The Decade of Vaccines Collaboration and development of the Global Vaccine Action Plan provides a catalyst and unique opportunity for regulators worldwide to develop and propose a global regulatory science agenda for vaccines. Regulatory oversight is critical to allow access to vaccines that are safe, effective, and of assured quality. Methods used by regulators need to constantly evolve so that scientific and technological advances are applied to address challenges such as new products and technologies, and also to provide an increased understanding of benefits and risks of existing products. Regulatory science builds on high-quality basic research, and encompasses at least two broad categories. First, there is laboratory-based regulatory science. Illustrative examples include development of correlates of immunity; or correlates of safety; or of improved product characterization and potency assays. Included in such science would be tools to standardize assays used for regulatory purposes. Second, there is science to develop regulatory processes. Illustrative examples include adaptive clinical trial designs; or tools to analyze the benefit-risk decision-making process of regulators; or novel Pharmacovigilance methodologies. Included in such science would be initiatives to standardize regulatory processes.

Transform Current National Efforts into a Coordinated Action Plan

The aim of a global regulatory science agenda is to transform current national efforts, mainly by well-resourced regulatory agencies, into a coordinated action plan to support global immunization goals. This article provides examples of how regulatory science has, in the past, contributed to improved access to vaccines, and identifies gaps that could be addressed through a global regulatory science agenda. The article also identifies challenges to implementing a regulatory science agenda and proposes strategies and actions to fill these gaps. A global regulatory science agenda will enable regulators, academics, and other stakeholders to converge around transformative actions for innovation in the regulatory process to support global immunization goals. Regulatory science is the foundation of regulatory decision-making and is used to assess the quality, safety, and efficacy of human and veterinary medicines throughout their life-span. The domains covered by regulatory science are considered to include both basic and applied biomedical sciences (such as microbiology, genetics, pharmacology, and biostatistics), clinical trial methodology and epidemiology, and social sciences (such as decision sciences, risk assessment, and communication). Regulatory science aims to contribute to the development of new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of regulated products. The first vaccine of its kind normally undergoes full clinical protection studies for licensure, as was the case for the 7-valent pneumococcal conjugate vaccine first licensed in 2000. However, with robust biological assays to support their use, correlates and/or surrogate markers of immunity were used to licence several second-generation vaccines, thus accelerating vaccine approval and availability.

New Approaches to Vaccine Clinical Trial Design by Improvements in Post-Marketing Safety Studies

WHO Recommendations for the production and control of pneumococcal conjugate vaccine were developed on the basis that due to practical and ethical considerations, it would be difficult to perform protective efficacy studies on new pneumococcal conjugate vaccines and that their licensure should be based on immunogenicity studies against a licensed comparator vaccine. Regulatory science should also explore new approaches to vaccine clinical trial design by taking advantage of improvements in post-marketing safety studies. Enhancing post-market surveillance of vaccine safety by using novel real-time surveillance methods as well as mining of social media is also envisaged. It would also be beneficial to develop standard benefit-risk methodology to aid regulatory decisions on vaccines, including refining risk-benefit analysis for use throughout a licensed vaccine's lifecycle. Indicators to monitor and evaluate the progress of such activities could be targeted but not be limited to narrowing the gaps in regulatory sciences between the developed and developing countries and increased convergence of regulations on vaccines. This concept paper can be used to develop a plan of action to implement the first ever global regulatory science agenda.

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