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Major challenges in formulation development: From the perspective of a developing state

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Reducing the disease burden timely and cost-effectively is one of the prime goals of every national health policy, as health and access to safe, effective, quality and affordable medicine is the basic right of people. According to the World Health Organization (WHO), the world consumption of pharmaceutical products has increased drastically from US$ 70 billion to US$ 1.1 trillion (Since 1975), with a consumption of medicines per capita growing from US$ 17 to US$ 531. Regardless of this increase in world consumption, more than 80% of all pharmaceutical products are consumed by 15% of the world population located in 'developed countries'. In order to mitigate this global health inequity, pharmaceutical industries of developing world need to accelerate the development and production of pharmaceutical products of optimal quality. Formulation development, being a very crucial and lengthy process, involves different pharmaceutical technologies and presents a number of challenges to the pharmaceutical industry of countries like Pakistan, India, Bangladesh, etc. Pakistani pharmaceutical market is of US$ 326 billion. In Pakistan, the major challenges that pharma industry faces while developing a new product are stricter and non-supportive pharma regulations of the national drug regulatory body that discourage new drug development, national insufficiency of research and development in producing active pharmaceutical ingredients (APIs), lack of bioequivalence and clinical trials facilities and inadequate commercial and economic feasibility regarding export of new drugs. Besides these, the complex science of drug designing which require novel technologies and well-trained talent is also a crucial challenge. This study recommend to promote harmonization of regulatory processes by adopting globally harmonized standards, establish targeted capacity-building for quality APIs, train the talent, improve research and development sector, develop bioequivalence and clinical trial facilities and set transparent pricing rules. For Pakistan, it is a high time to improve health and access to quality medicine. The recommendations in this presentation may prove helpful in improving the development rate of safe, effective, affordable and high quality drug formulations.

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