Interview Guide for Regulatory Discussion Paper

Questions for PDPs:

1. What approach is your PDP currently taking to handle the regulatory pathway for products in development?
2. How has this process worked to date?
3. What other approaches have you considered, and what are the pros and cons of each?
4. In the best of all possible worlds, what would be your ideal approach? What are the constraints to that?
5. Who currently is handling adverse events for your studies? Is this the same group that will continue to do so post-licensing? Who do you think should handle adverse events? Why?
6. Do you intend to seek prequalification for your products? What are the pros and cons of so doing?
7. Do you consider registration by FDA and/or EMEA to be necessary? If so, why? If not, why not? Could it be a drawback?
8. Would you consider it important to have a list of countries where your products must be licensed?
9. What entity is best placed to coordinate the registration of an individual product in low income countries? What are the relative advantages and disadvantages of each approach?
10. How can PDPs encourage timely registration of products for use in non-lucrative markets?

Questions for Prequalification of Medicines Programme

1. I am aware that vaccine prequalification currently relies first and foremost on the existence of a competent regulatory authority to oversee the entire product development, manufacturing, and distribution process – this means that products made in some countries, either for example, in EMEA countries, which are only for developing country use, or those made in developing countries lacking a strong regulatory, will have a difficult regulatory pathway. How does the pharmaceuticals prequalification process differ?
2. Is prequalification an option without the oversight of a competent DRA? And if so, how is "competent" defined?
3. Do you think that prequalification has been/will be helpful to PDPs in increasing access to their products? If so, how? Or detrimental? And if not, how ? Or perhaps neutral ?
4. How are adverse events handled for prequalified medicines ? Who takes the primary responsibility for their collection and analysis?
5. Do you have additional comments on the relative advantages or disadvantages of the process for medicines compared to vaccines?
6. Any other comments on how the prequalification process might be useful or not for PDPs?

Questions for Additional Stakeholders

I am writing you regarding a paper I have been commissioned to do on behalf of the Access Steering Committee of the Product Development Partnerships, on “regulatory affairs.” The paper is looking at the various regulatory strategies that PDPs are using: What are the common approaches? What have been the results? What are the lessons learned? How can PDPs work together?

I would be very grateful to have your thoughts on this subject, from the point of view of a stakeholder in an emerging medicines regulatory authority:
Are the approaches that PDPs are using for regulatory strategies, which vary from PDP to PDP but seem to be focused on WHO prequalification, FDA or EMEA review or opinion, and joint review in developing countries

- achieving the desired results in terms of assuring safety, quality, and efficacy of the products?
- achieving the desired results in terms of assuring eventual access for the products to their target population?
- achieving the desired results in terms of building regulatory capacity in the target countries?

How could the PDPs work together to achieve better results in the 3 areas above?