Table 41: Patient Access: Bringing Biologics to Everyone

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SCOPE:
Currently medicines created using biotechnology are expensive. Biosimilars will be less expensive, but are targeted to the same market as the innovator. With the collective knowledge provided by the top process developers, and with some technologies which we are using today like 100g/L processes, is it possible to bring biological pharmaceuticals to the third world? Can we develop a 10 cent HepC treatment, or a product with no cold chain requirement at a price affordable by a poorer population? This session will explore some ideas to help make this a real future.

QUESTIONS FOR DISCUSSION:
1. What are some of the primary biological diseases impacting developing and third world countries?
   a. Pneumonia, HIV, Malaria, tuberculosis, etc.

2. What are the primary challenges with bringing biologics to developing and third world countries?
   a. Costs, intellectual property (IP), supply shortages, trained health workers, counterfeiting, lack of local infrastructure, service delivery, storage, refrigeration, product shelf life, etc.

3. What are some recent innovations helping to bridge the gap to support the earlier supply of biologics to developing and third world countries?
   a. Needle-less syringes, heat-tolerant medicine, improved biologic Mfg yields, etc.

4. What are the common types of partnerships today supporting development of affordable biologics?
   a. Academic, private sector, non-profit organizations, governments, non-government agencies, etc.

5. What opportunities may a partnership offer for providing biologics to developing and third world countries?

6. What are some common strategies for bringing biologics to developing and third world countries?
   a. Donation programs, tiered pricing, pricing based upon local economies, reduced IP protection enabling generics in certain developing countries, etc.

NOTES:
- Understanding of limits/restrictions/barriers to delivering biologics to certain regions (production/supply chain/social context).
- Cost/Investment:
  o Incentives
  o Partnerships
  o Understanding the gap between global demand and current supply
- Diagnosis: cheaper access to diagnostic tools
- Manufacturing and cold chain management:
  o Alternative manufacturing (large scale central manufacturing, small scale, etc.)
  o Delivery options: final product, DS, or sharing of technology
  o Advice/training
  o Management of cold chain with lyophilization being more favorable but more expensive.
• Future increasing need for drugs for chronic diseases and not only drugs for infectious diseases.
• Need for increased regulatory expertise regarding development countries.