

PDP Access Discussion Paper Interview Guide - PDPs

Overview of PDP Access Strategy

1. How does your PDP **define success** for its access activities? What are the implications of this definition on developing an access strategy?
2. (Probe on the **major components** of the access strategy) **How did you prioritize** these over others? (e.g., country prioritization, regulatory, manufacturing, demand forecasting, education, policy, financing, delivery, marketing)

Major Strategy Issues Considered

3. How have you approached **country prioritization** for product introduction? (e.g., disease burden, strength of health sector, clinical trial countries) Were other approaches considered? What are the perceived tradeoffs associated with this approach?
4. To what extent will your PDP be involved in **downstream activities** (e.g., manufacture, training, pharmacovigilance, sales, etc.)? Where partners are involved, what role do you envision for your PDP? How far downstream will you seek to “own” activities? Does this differ by issue (e.g., in demand forecasting versus practitioner education)? What have been the most important tradeoffs in determining your approach? What are your plans for managing downstream relationships?
5. How are you considering the tradeoffs between a **branded versus generic product positioning**? What are the major factors that have influenced your views?
6. What are the opportunities you have evaluated for **bundling your products** with others? (e.g., with other PDP products, with existing products, diagnostics) How were your conclusions reached?
7. How does your **access strategy relate to your approach to advocacy**? Where are the two activities synergistic (e.g., adoption by countries)? How does your strategy balance global versus country level activities? How did you determine this mix?

Access Strategy Management

8. What steps have you taken in **developing your access strategy**? What resources were involved? How has the access strategy development aligned with major product development milestones?
9. What is your expected process for **evaluating your access work and refreshing** your strategy? To what extent do you expect the experience of other PDPs to inform your strategy?
10. How are **access considerations embedded in R&D decision-making**? In the TPP? As part of the portfolio review process? What are the greatest challenges associated with your approach? How have you overcome these challenges?
11. How does your PDP **distinguish between the access strategy, launch plans, market access plans, and marketing plans**? What is the difference? Which is the most important? How have your plans been developed (e.g., resources, timing)? How are each used in your work?

12. Are there any **other issues or observations** you would like reflected in the discussion paper?

PDP Access Discussion Paper Interview Guide - Experts

Overview of PDP Access Strategy

13. How do you **define success** for PDPs in their access work? Which elements of access do you see as universally important to all PDPs?
14. What successful **approaches to developing an access strategy** have you seen? What made them successful?

Major Strategy Issues Considered

15. What are the **three most important factors for PDPs to consider in country prioritization**, other than disease burden? How do these vary for vaccines, therapeutics, or diagnostics? How do these vary by disease?
16. How far “**downstream**” would you expect PDPs to go in their planning? What is realistic in terms of what PDPs seek to address downstream?
17. Are there particularly effective models for **coordinating access activities across downstream partners**? What is critical to the success of these models? How can PDPs best consider these factors in their access strategies? At what point in the product development cycle should the downstream handoffs be considered in detail?
18. What tradeoffs should PDPs consider between a **branded versus generic product positioning**? What are the major factors that have influenced your views?
19. How important is it that PDPs consider **bundling** their products with others in their access strategies? (e.g., with other PDP products, with existing products, diagnostics) What are the main factors that should influence a decision to bundle? Are there bundling opportunities that seem especially powerful in terms of increasing uptake? (e.g., ORS and zinc)
20. How should PDPs **balance their access and advocacy efforts** at the country and global levels? How integrated should these strategies be? How should the strategy evolve as a product moves through clinical trials and is closer to market introduction?

Access Strategy Management

21. What processes for developing access strategies have you seen be especially successful? (e.g., in-house v. outsourced) What considerations should PDPs weigh in their approach to the strategy planning process (other than time and expense)? In what areas is it most powerful to engage outside experts, or undertake original research?
22. How can PDPs best evaluate their access work and refresh their strategies? To what extent does it make sense for the PDPs to invest in learning from each other?
23. How can access considerations be most efficiently embedded in R&D decision-making? In the TPP? As part of the portfolio review process?

24. What is the relationship between access strategies, launch plans and marketing plans? How should PDPs prioritize between these and/or undertake these as separate efforts? Which is most important?
25. Is there any **other advice** you would like to offer PDPs as they address the challenges associated with developing access strategies for products that are at various points in the pipeline?

PDP Access Discussion Paper Interview Guide - Donors

Overview of PDP Access Strategy

26. How do you **define success** for PDPs in their access work? Which elements of access do you see as universally important to all PDPs? How do PDPs relate to your mandate for access? Why?
27. What successful **approaches to developing an access strategy** have you seen? What made them successful?
28. What are your expectations in terms of **timing for access strategies** (e.g., in terms of the product development lifecycle)? What elements should be addressed first?

Major Strategy Issues Considered

29. What are the **three most important factors for PDPs to consider in country prioritization**, other than disease burden? How do these vary for vaccines, therapeutics, or diagnostics? How do these vary by disease?
30. How far **“downstream”** would you expect PDPs to go in their planning? What is realistic in terms of what PDPs seek to address downstream?
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Access Strategy Management

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