FINAL

PDPs AND ACCESS: WHAT WORKS; WHAT DOESN'T

Objectives of meeting

1) Develop a common understanding and record of PDP experiences, best practices and challenges in the area of access, both in the public and private sectors.
2) Compare the access pathways for novel drugs, vaccines, and vector control and identify the gaps in information and processes that will impact PDPs.
3) Develop channels for future investigation, collaboration and coordination, and discuss the possibility of future meetings.
4) Define the role of PDPs within the overall framework of research, development, and access activities.

Participation: PDP representatives + invited experts. All participants are to pay their own airfares and hotel costs plus a US$400 per person attendance fee to cover the costs of the meeting room. After the meeting, DNDi will send out invoices (one per organization) to collect the attendance fees, which will by payable to DNDi via wire transfer.

Date: September 17-18, 2008

Venue: Saasfee Room, Crowne Plaza Hotel, 34 ROUTE FRANCOIS-PEYROT, GENEVA, 1218 SWITZERLAND
Hotel Front Desk: 41-22-7470202 | Hotel Fax: 41-22-7470303

Format: Each of the four main sessions (after the introductory session) will include the following:

1) some brief case studies with critical analysis and discussion of effectiveness of the models employed
2) a mapping, via a roundtable discussion, of who is doing what in the listed areas of interest. One person per PDP / disease-specific initiative will contribute. In 5 minutes they will summarize: (1) the problem(s) their PDP has addressed in this area; (2) 5 major lessons learned; and (3) 5 remaining issues and challenges.
3) a moderated discussion (with a panel or general participation); and
4) a concluding summary of successes, gaps, way forwards, and the formation of future working groups.

Meals: Outside the Saasfee room, the hotel will provide morning coffee/tea, and two tea/coffee breaks. Lunch on both days is included, and will be in the Carlights Restaurant in the hotel. Breakfast (other than coffee/tea) and dinner are not provided. On one of the days, GAVI will host an informal Q&A session over lunch.

Day 1

SESSION 1

8.30-8.40am Opening (Rich Mahoney, PDVI; William Wells, TB Alliance)
8.40-9.20am Round Table Discussion: With reference to the matrix of access activities (see below), what areas of experience do you bring to

	the table? What is the goal of your access program and how will you define success? What do you hope to learn here?
9.20-9.35am	General Discussion: How can we run the meeting to maximize future impact? Capturing the proceedings; defining next steps.
9.35-9.50am	Case Study: A Bilateral Funder's Strategy & Bilateral Work on Metrics of PDP Success (Saul Walker, DFID)
9.50-10.05am	Case Study: Access Planning (Alan Brooks, MVI)

- *Advance materials:* Matrix of PDP pipelines, timelines, licensing arrangements, target markets, and access activities.

SESSION 2: Planning for Introduction and Implementation

- *Moderator*: Saul Walker, DFID

10.05-10.20am	Case Study 1: Demand forecasting as a tool for building access commitments (Lois Privor-Dumm, PneumoADIP)
10.20-10.35am	Case Study 2: Surveying stakeholder needs and assessing introduction pathways in countries with high TB burdens (William Wells, TB Alliance)
10.35-10.50am	Urban-Peri-Urban-Rural: An Access Model for Paromomycin IM Injection for Visceral Leishmaniasis in Bihar State, India (Rajshankar Ghosh, iOWH)
10.50-11.05am	Break

Discussion during the remainder of the session will cover the following four topics:

- Building consensus (international and national guidelines, recommendations and policies)
- Impact and Cost effectiveness estimates
- Pilot introduction projects
- Devising a full-scale launch plan

11.05am-12 noon (5 minutes per PDP)
Roundtable: Discussion and Mapping of Experience and Expertise Among PDPs

12-12.45pm	Moderated Panel or Open Discussion
12.45- 1.15pm	Summary of successes, gaps, way forwards, and the formation of future working groups
1.15-2.15pm	Lunch

Session 3: Manufacturing

- *Moderator:* Rita Khanna, Aeras

2.15-2.30pm Case Study 1: Price-Volume guarantee negotiations as part of commercial relationships (Marc LaForce, PATH Meningitis Vaccine Project)

2.30-2.45pm Case Study 2: Manufacturing strategies in Emerging Economies (China and India) (Rita Khanna, Aeras)

2.45-3pm Case Study 3: Uncommon partnerships: An access strategy for semisynthetic artemisinin (Nina Grove, iOWH)

Discussion during the remainder of the session will cover the following four topics:

- Working with manufacturers in developed and developing countries
- How to build "affordability" into contracts and IP agreements
- What is the role of PDPs in scale-up?
- Of the different options (PDPs as manufacturers, manufacturing by patent holders, generic manufacturing), which ones are viable when?

3-3.55pm (5 minutes per PDP)
Roundtable: Discussion and Mapping of Experience and Expertise Among PDPs

3.55-4.15pm Break

4.15-5pm Moderated Panel or Open Discussion

5-5.30pm Summary of successes, gaps, way forwards, and the formation of future working groups

Day 2

Session 4: Pricing, Finance, and Procurement

- *Moderator*: Tom McLean, IVCC

9-9.15am Case Study 1: AMCs and processes for demand aggregation (Tania Cernuschi, GAVI)

9.15-9.30am Case Study 2: Estimating the Return on Investment for an Intervention - Lessons from a Malaria Vaccine (Vicky Cardenas, MVI)

9.30-9.45am Case Study 3: Pharma's "lessons learned" in pricing, distribution and regulation while making HIV medicines accessible in LICs (Thomas Mertenskoetter, IPM)

Discussion during the remainder of the session will cover the following four topics:

- Working with the Global Funds (GFATM, GAVI, UNITAID, GDF)
- Building an investment case
- Assessment of Advance Market Commitments (early and late stage)
- Private sector participation

9.45-10.40am (5 minutes per PDP)
Roundtable: Discussion and Mapping of Experience and Expertise Among PDPs

10.40-11am Break

11-11.45am Moderated Panel or Open Discussion

11.45-12.15pm Summary of successes, gaps, way forwards, and the formation of future working groups

12.15-1.15pm Lunch

Session 5: Global Regulatory Pathways for Introducing New Products

- *Moderator*: Mike Brennan, Aeras

1.15-1.30pm Case Study 1: Two different paths to regulatory approval for 2 registered products ASAQ and ASMQ (Africa & Latin American regulatory agencies), and WHO prequalification process (Jean Rene Kiechel, DNDi)

1.30-1.45pm Case Study 2: The regulatory pathway for a new TB vaccine: challenges and solutions working with RAs in both developed and developing countries. (Michael Brennan, Aeras Global TB Vaccine Foundation)

1.45-2pm Case Study 3: Regulatory considerations for a vaccine for use predominantly in developing countries (Rich Mahoney, PDVI)

Discussion during the remainder of the session will cover the following four topics:

- WHO prequalification
- How FDA and EMEA can facilitate regulatory processes in developing countries
- Working with Developing Country Regulatory Agencies (Developing Countries' Vaccine Regulators Network, African Vaccine Regulators Forum etc)
- Working with the USFDA and the EMEA, and ICH quality standards

2-2.55pm (5 minutes per PDP)
Roundtable: Discussion and Mapping of Experience and Expertise Among PDPs

2.55-3.15pm Break

3.15-4pm Moderated Panel or Open Discussion

4-4.30pm Summary of successes, gaps, way forwards, and the formation of future working groups

Session 6: Summary and Conclusions

4.30-4.50pm Summary reports on Sessions 2-5 by newly appointed / volunteered Working Group Chairs

4.50-5pm Concluding Remarks: Conference Co-Chairs