New PQ financing strategy

Meeting with ARV manufacturers

Marie-Paule Kieny

ADG/Health Systems and Innovation

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Purpose of the new PQ financing strategy

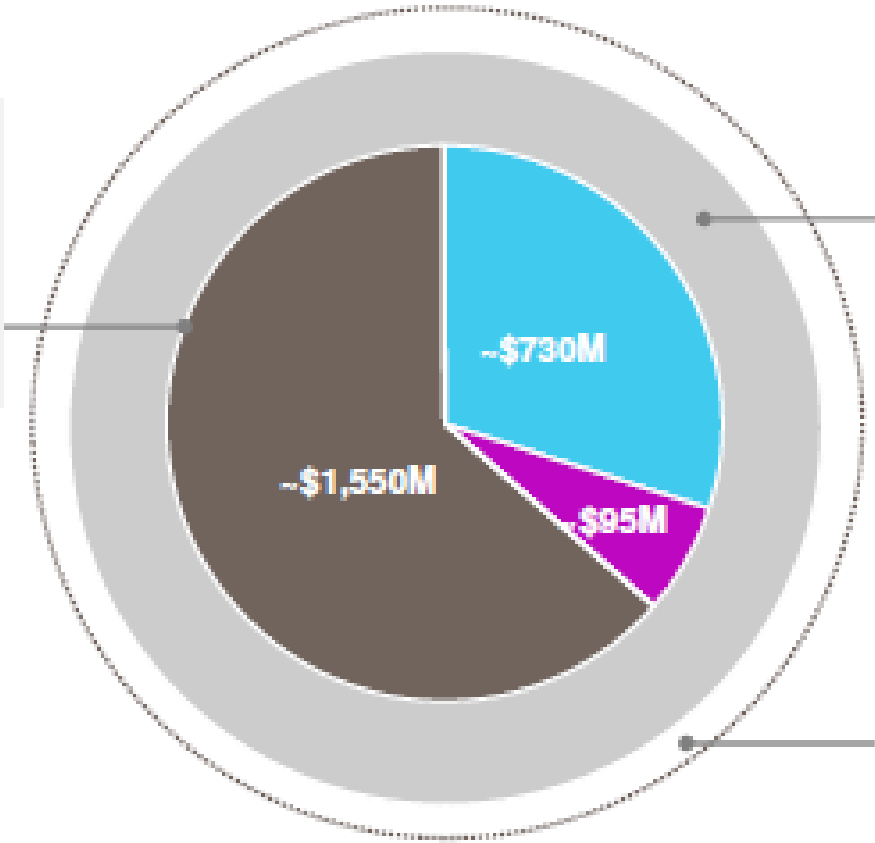
- Maintain the overall objective of PQ to provide assured safe, efficacious and quality drugs, vaccines, diagnostics and devices while increasing supply and access
- Need for an innovative, practical and sustainable funding approach for the WHO PQ programme
- Reduce reliance on grants from BMGF, UNITAID and GAVI; noting request of donors for PQ to become self -sustainable.
- Target: 50% of needed operational funding

- Based on options' study conducted on behalf of WHO by McKinsey in 2014.

What is the value of the PQ-enabled market?

1 PQ enables a core market of ~$2.4 bn, and potentially an additional ~$300-600M of national and private markets

Sales of PQ products (PQ-enabled sales)[1]
US$ M, 2012



Large donors and procurers (based on detailed PQ market sizing by each disease area and procurer)

Sales: ~$ 2,400M[2]

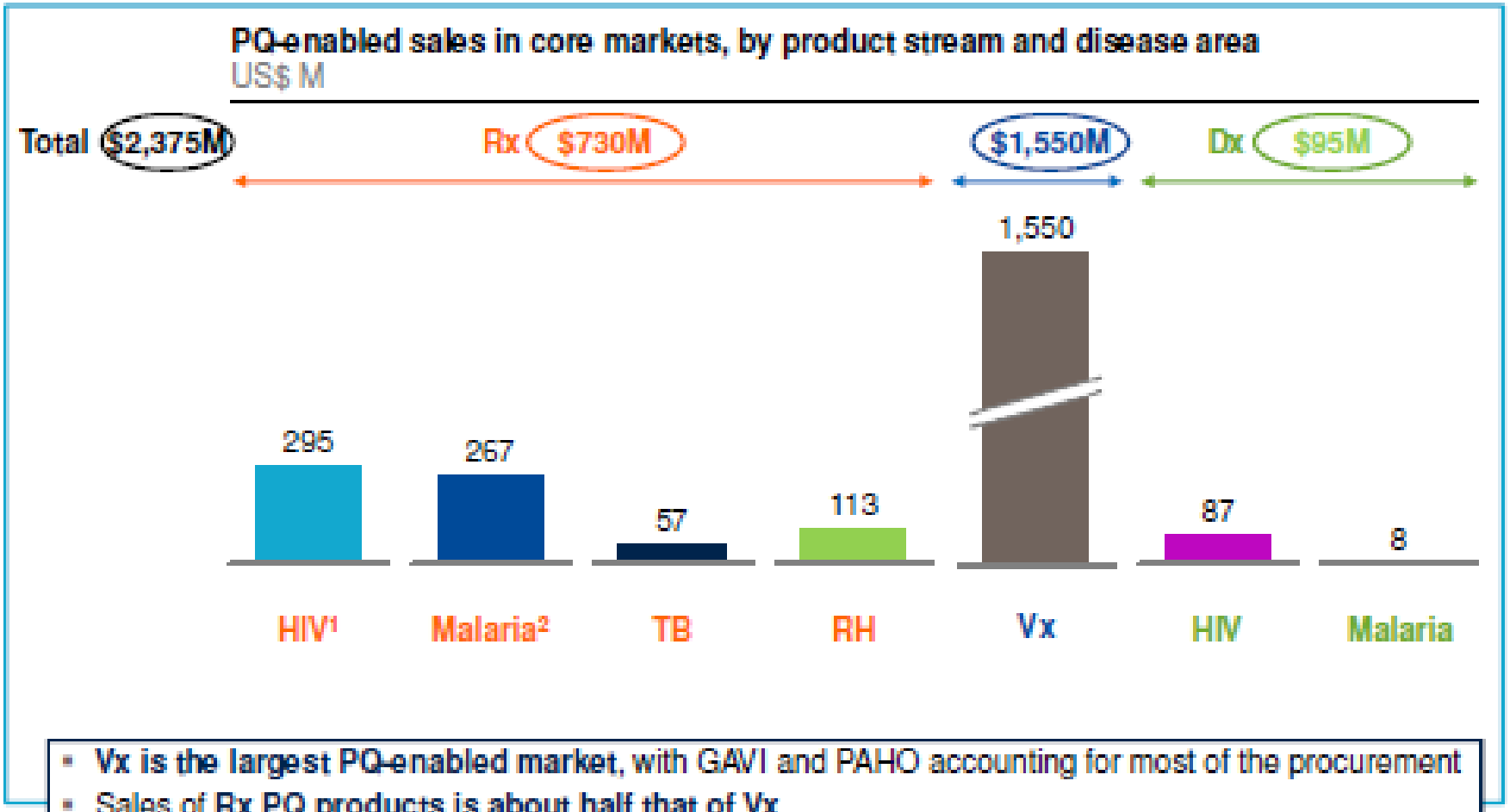
National markets[3] (based on LMIC market estimation for each disease area and manufacturer perspective on access enabled by PQ)

Sales: ~$300-600M[4]

Private market[3]
Minimal benefit of PQ approval on private markets *(except Rx-Malaria)*

1 Includes all product streams and disease areas; separated into: donor-funded, government-funded, and private markets
2 Additional sales to small procurers (funded by bilateral donors) may exist but is expected to be <$100M
3 Refers only to Low and Middle income markets

PQ sales across disease areas



- **Vx is the largest PQ-enabled market**, with GAVI and PAHO accounting for most of the procurement
- Sales of **Rx PQ products is about half that of Vx**
- ARVs are the **largest Rx category of PQ products sold** with significant non-PQ supply (~$230Mn) to donors due to FDA tentative approval

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Manufacturers value access to the donor market through PQ

- **Vx:** PQ is the only way to access a large birth cohort – GAVI-funded Vx, UNICEF/PAHO purchases

- **Rx:** Value prop varies by disease area; primarily market access and flexibility vs. other regulators:
  - **Access to donor market:**
    - PQ is primary route to donor funded procurement for TB and Malaria medicines
    - For ARVs, PQ does not offer better market access than USFDA tentative approval, but it offers other advantages (below)
    - RH and LIC manufacturers see low value in PQ, because approval does not often translate to increased product sales
  - **Faster variation approvals:** PQ approves variations in ~6mo vs ~2yrs for USFDA; variation approvals can allow manufacturers to unlock cost savings (passed on to price savings) or overcome capacity constraints to meet unmet demand
  - **More flexibility when sourcing APIs:** PQ's standalone API approvals offers greater choice to prequalified FPP mfgrs. when changing source of API
  - **Easier NRA registration:** Some countries favor PQ over SRA approval[1], though this advantage is not widespread

- **API:** Greater access to FPP manufacturers who bid on donor-funded tenders

- **Dx:** PQ is strongly preferred in HIV, almost no additional benefit for Malaria

Willingness of manufacturers to contribute to PQ funding

- **All manufacturers expect that higher fees will be accompanied by PQ enhancements, without which the fee increase will likely be passed on to donors through higher prices; in particular:**
  - Streamlined NRA registration
  - Faster PQ review (dossier review as well as variations)
  - Consistency in Vx inspections
  - More clear guidelines and processes in Dx (e.g., defining variations or process timelines)
  - Rationalize and streamline PQ (e.g., eliminate redundancy with SRA for full reviews / inspections)

- **Better sales prospects for RH (new entrants) and Dx-Malaria:** Manufacturers in these segments would be willing to contribute if standards for PQ are meticulously followed by procurers

- **Equitable fee structure**

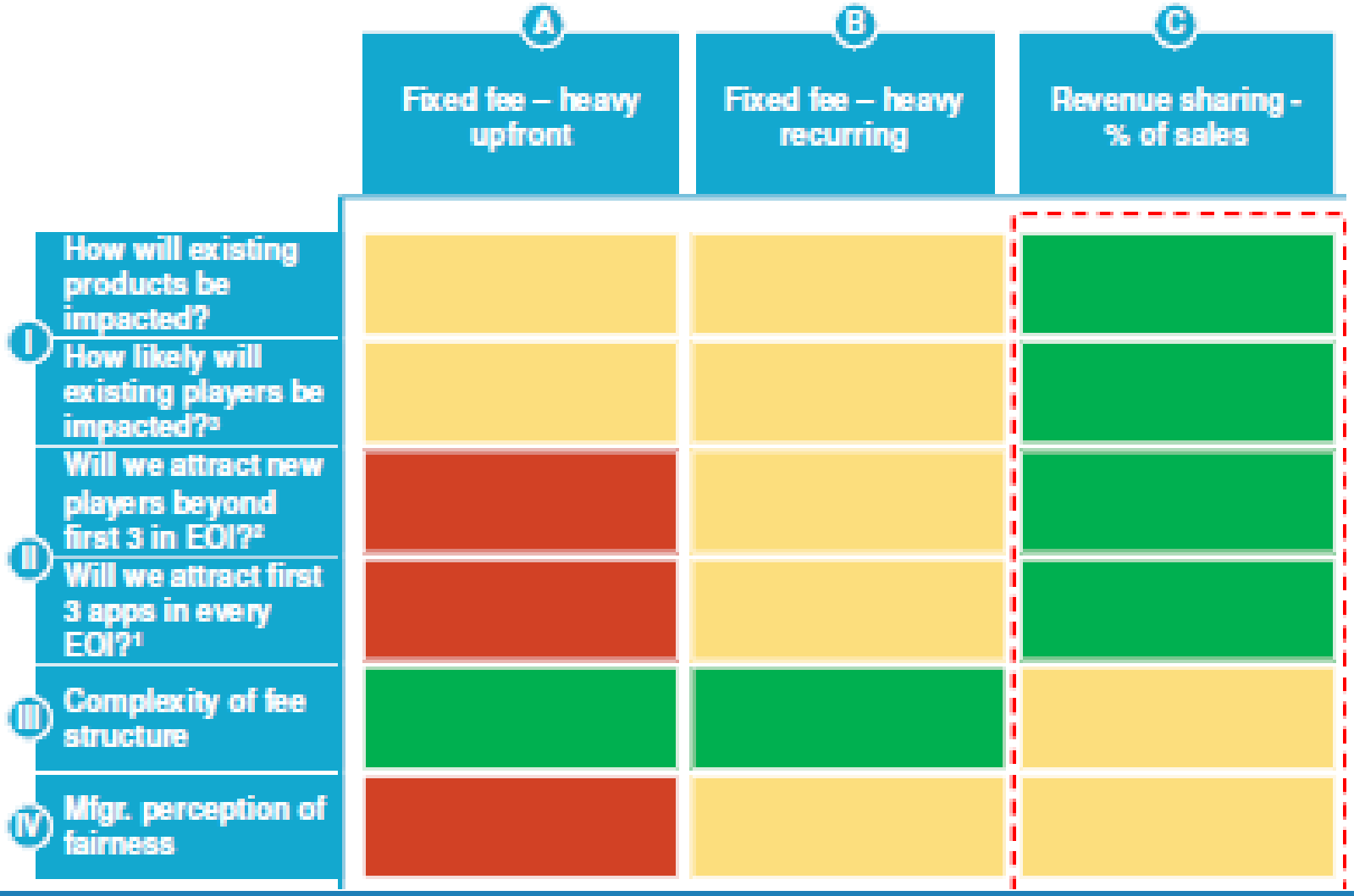
Perspective from donors

- **Donors unanimously agree that charging manufacturers is the best solution, though most of them seemed open to considering a small transaction fee to procurers**
  - Believe most manufacturers are able to pay higher fees and would adopt their business model/pricing
  - Manufacturer fees will dis-incentivize frivolous applicants to WHO PQ
  - Donors believe user fee would be simpler to implement and a % of sales (if not implemented with clarity) would be prone to debate
  - However, several donors seem open to discussing inclusion of "% of sales" fee, for WHO-PQ, in tenders
- **All interviewed donors believe higher PQ fees must be justified by PQ enhancements that encourage more manufacturers**

Guiding principles for new financing model

- **Simple to understand, execute and monitor**
- **Generate at least $20M per year** (50% of WHO PQ and RHT costs) and be sustainable under multiple scenarios
- **Equity within a product type, to avoid altering competitive landscape. However,** selected exemptions to:
  - Encourage access to essential medicines
  - Acknowledge nascent PQ value proposition in certain areas
- **Across product streams, fees are approximately scaled to PQ value prop**, i.e. Vx > Rx > Dx[1]
- **Within a product stream, fees are adjusted to account for major differences in product type**, e.g. SRA approved; simple vs complex products
- **Maintain upfront fees** in all models to discourage frivolous applications
- Additional cost-burden on manufacturers to be **accompanied by transparency and commitments on performance targets**

Overview of potential integrated approaches



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Selected financial proposition

Initial fees similar to today's levels and annual contribution 0f 1% of "eligible" sales (i.e. Global Fund, UNITAID, GAVI, UNICEF, UNFPA, PAHO RF)

		Rx	Vx	Dx	API	
❶ Initial assessment fee (per application)	*Simple*	$8,000	$25,000	$12,000	$8,000	*Applications follow the same definition as used today, i.e., separate applications submitted for different dosages / formulations of the same compound*
	Complex[1]	$12,000	$67,000		$12,000	
❷ Major variation[2] fee (per variation)		$6,000	$10,000	$3,000	$3,000	*Major variations as defined by WHO guidelines on variations to a prequalified product*[2]
❸ Annual contribution	• Scaled based on eligible sales of PQ products: around ~1% of sales					• *Manufacturers self-identify the sales band they fall under* • *Honor-based system (roughly validated with data from donors/procurers)*

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Discussion

- Recognized need for improvement of PQ processes, e.g. speed, transparency, promotion of joint reviews by NRAs, single dossier as much as possible

- Fee based on small (1%) contribution to PQ on value of "eligible sales" (only)
  - *Fair between product streams*
  - *Fair within product streams*
  - *No sales – no payment !*
  - *Honour based but verification through procurers*

- Timing for introduction: Announcement in April 2015,
  Implementation start in January 2016