The Medicines Patent Pool (MPP) and WHO-PQP: Expanding access to quality, generic ARVs

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Advancing Innovation, Access, and Public Health
The Medicines Patent Pool

Advancing Innovation, Access, and Public Health
The Medicines Patent Pool expands access to innovative HIV medicines, at affordable prices, by:

• Enabling the development of fixed dose combinations (FDCs) of which the patents are held by different entities

• Enabling the development of adapted formulations for children or for specific developing country needs (e.g., heat stable)

• Accelerating the availability of generic versions of new ARVs in developing countries
**Bridging Innovation and Access**

- Public health oriented licences that consider interests of all parties
- MPP licences:
  - Ensure maximum possible low- and middle-income countries receive access to HIV medicines
  - Pursue win-win terms and conditions for wide access to HIV medicines
  - Create measurable impact: drugs are developed, approved, and distributed at the right prices
  - Measure and report the impact

**How the MPP works**

- **Licensors**
- **Patents**
- **Royalties**
- **Out-Licenses**
- **License Management by the MPP**
- **Product introductions**
- **Market Impact**
The MPP Model

- Patent holder bears cost of managing multiple licensees
- “Bandwidth” pressure
- Low development speed
- Limited ability to terminate licenses

- Transactional simplicity
- Easy licensee management via MPP
- Greater visibility and acknowledgement of impact
- Surer access – Patent holders free up capacity for profitable markets
Role of Generic Competition

Source: Moon et al. Globalisation and Health 2011, 7:39
http://www.globalizationandhealth.com/content/7/1/39
Licensing Processes to Ensure Maximum Impact

1. Sign in-licences
   - Help liaise with WHO PQ, USFDA, NDRAs
   - Monitor registration status

2. Online Expression of Interest submissions by generics
   - Conduct quarterly progress review
   - Monitor royalties
   - Dispute resolution
   - Conduct annual review with licensors and sub-licensees

3. Negotiate out-licences
   - Kick-Off generic collaboration
   - Conduct/coordinate technology transfer
   - Assess & report impact
   - Collect market feedback on performance

Phase 1: Out-licensing
Phase 2: Development
Phase 3: Commercialisation
Collaboration with WHO PQ
Importance of WHO PQ

For patients
- Access to quality, affordable medicines

For companies
- Hedging risk; filing product with both WHO PQ and USFDA
- Faster variation filings
  - Important for cost reduction; timely approvals help reduce price earlier
- Minimal regulatory fees
- Special provision for HIV, TB, Malaria, OI drugs

Greater Access to Quality Medicines
Recognition for WHO PQ

- Local regulatory authorities in developing countries recognize PQ and accelerate local registration of products that have been PQed
- Funding agencies and donors should require that products eligible for funding be prequalified

Faster approval => Earlier access => Greater Impact
**Future co-operation with MPP**

**PQ and MPP development of needed formulations**

- Identification and prioritisation of needed formulations (e.g. paediatric dispersible tablets)
  - PQ and MPP can create list of needed FDCs for fast tracking approvals
- Fast-tracking incentivises companies to make needed formulations
- MPP and generic partners to ensure development and filing of formulations
  - MPP can coordinate discussion between sub-licensees and PQ when required e.g., regulatory pathway for new formulations, prioritisation of limited source or niche products

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Proactive engagement; better planning => Avoid Surprises => Timely Impact
Thank You

www.medicinespatentpool.org