How WHO prequalification makes a difference and why it is still needed

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Role of Indian generic manufacturers

Adult ARVs delivered to Principal Recipients in 2009 and 2010

By value

- India: 88%
- Other: 12%

By number of packs

- India: 93%
- Other: 7%

Source: Data reported to the PQR on 14 July 2011
Why is WHO PQ essential

- “WHO is the only independent international institution that can represent the interests of patients that live in countries that do not have sufficiently robust regulatory capacity.”
- Trusted
- Transparent
- Expertise (shared)
- Dissemination of global standards
- Saves money
- Saves lives
Role of PQ in access

Moon et al. Globalisation and Health 2011, 7:39
http://www.globalizationandhealth.com/content/7/1/39
PQ’s importance for producers

- Creates a market for generic products
- Offers a level playing field
- Accelerates registration in > # countries
- Accelerates access to high value markets
- Increases confidence in generic suppliers by reducing # products of unknown quality
- Increases acceptance of generic products
Future of PQ

- Medicines market is in constant motion
- Essential to respond to new environment and developments e.g. Medicines Patent Pool accelerate availability of innovative meds
- Assist new generic players
- Play a role in innovation to address the needs of developing countries e.g. the development of new treatments for neglected diseases
- Donors increasingly require WHO PQed products to ensure “value for money”
Use of the Global Fund Grant Funding

37% percent of funds are used for medicines and health products procurement
Conclusions

- PQ is and will remain an ongoing core function of the WHO*
- Investment in PQ makes good economic sense
- Direct and indirect benefits to producers are significant
- The health of millions of people depend on it

*http://apps.who.int/medicinedocs/fr/m/abstract/Js17577en/