



The de-linkage of the cost of research and development and the price of health products

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About Médecins Sans Frontières

- Independent Medical humanitarian organization founded in 1971 and working in over 70 countries
 - ~ 150,000 HIV patients on ARV treatment
 - ~ 25,000 cases of TB treated per year
 - > 1 million cases of Malaria treated per year
 - ~ 7 million vaccinated against meningitis in 08/09 season
 - ~40,000 cases of sleeping sickness treated in the past 20 years
 - ~75,000 cases of kala azar treated in Sudan alone
- Campaign for Access to Essential Medicines since 1999
 - Medical staff frustrated at not being able to diagnose and treat patients with appropriate and effective tools

The Access Campaign's main issues:

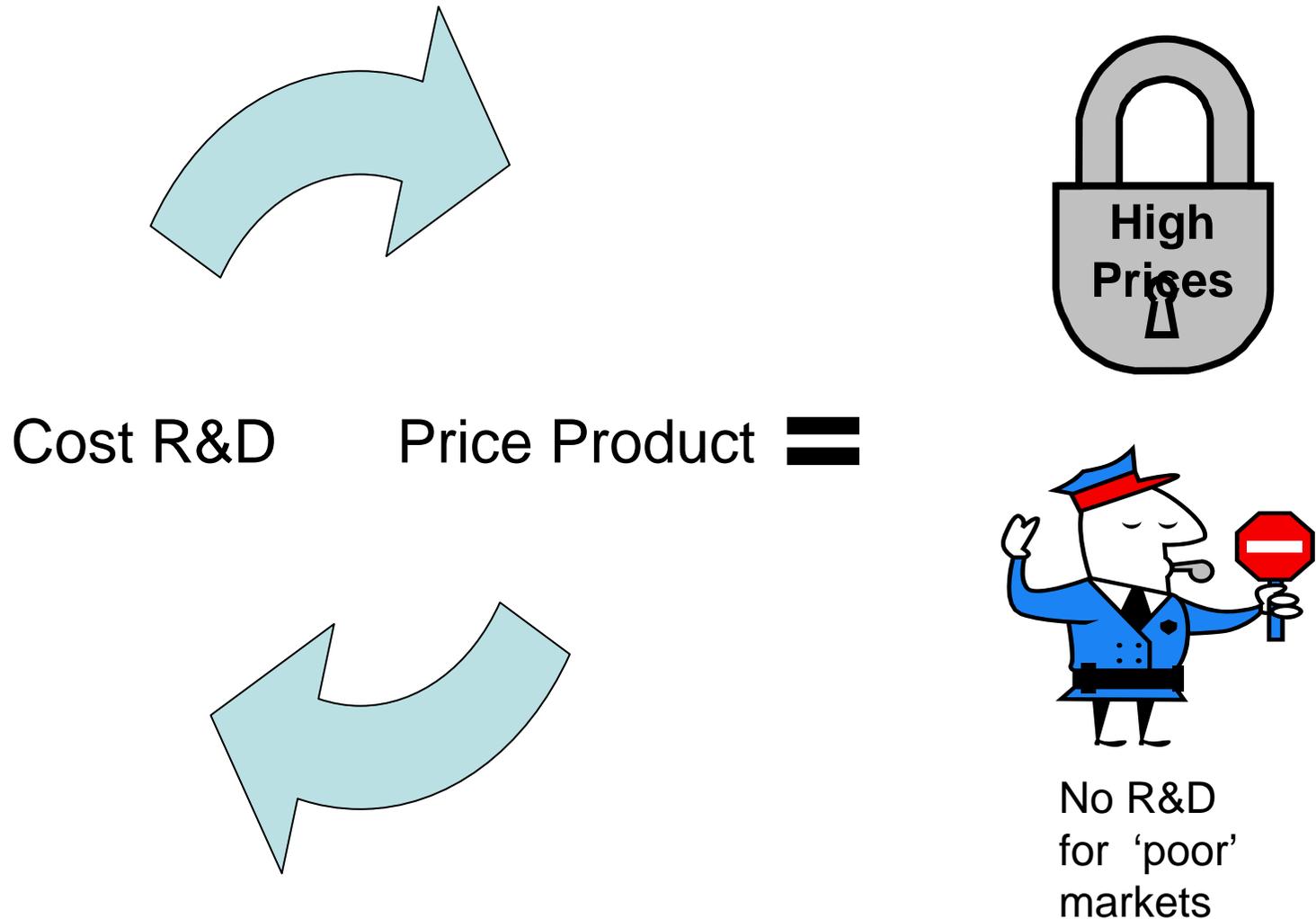
Unaffordable, Unavailable, Unsuitable

- **Unaffordable:** Existing medicines, vaccines and diagnostics are priced out of reach -too expensive for individuals and mass government treatment.
- **Unavailable:**
Certain diseases 'neglected' few or no drugs or diagnostics exist or are being developed. (ND, TB) Production of essential medicines and diagnostics that are needed but do not make profits are abandoned
- **Unsuitable:**
Not adapted for needs of developing countries e.g heat stable, child formulations, diagnostic tools

Problems trying to solve

- Lack of needs-driven **Innovation**
- Lack of affordable **Access**
 - Innovation is pointless in the absence of favourable conditions for people to access existing, as well as new, products

Funding model barrier to low cost



IP barrier to innovation

- IP a barrier to innovation itself- block further research - may lead to fewer products for improving public health
- Survey 103 Indian firms 'among 13 variables that could determine the abandonment of R&D projects by the Indian pharmaceutical industry, restricted access to patented upstream technologies because of contractual difficulties was likely have the biggest impact on a firm's decision to abandon such projects.
- Sampath,G "breaking the fence: can patent rights deter biomedical innovation in 'technology followers'

De-linkage – key issues 1

- TRIPS Agreement: IP laws justified as required to enforce monopoly to recover cost of R&D development through high prices = linkage
- **But**
- separating the payment for the cost of R&D development for health technologies from price of the product - delinkage provides a path way to focus R&D towards health needs
- R&D priorities driven by health needs not marketing opportunities
- Aim: innovation and access
- Does not mean that IP will never used but not to enforce high prices

De-linkage – key issues 2

- Reconciling innovation and access: affordability and accessibility need to be considered up front when funding/ creating incentives for R&D
- Must be included at all stages of research from the basic research through to product development and delivery
- As de-linkage provides pathway to orient R&D towards health needs
- Delinkage can and should apply across the full range ways of funding R&D
- grants , PDPS (push) and rewards at the end prizes (pull)

De linkage on governments agenda

- WHO Member States have agreed a new Global Strategy on Public health , innovation and intellectual property .
 - 5.3.a “explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the cost of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries”
 - Key issue when and how to implement it.

Principle options to ensure affordability and accessibility

- **Third party competition**
 - highly efficient to reduce price (more efficient than tiered pricing)
 - Requires dealing with patents, i.e. no patent, no enforcement or appropriate licensing strategy (voluntary/compulsory, patent pooling)
 - Additional benefit: allows for further adaption and innovation by third parties
 - **But Under threat by ACTA & Free Trade Agreements: EU-India FTA**
 - **Where quick competition not feasible, e.g. vaccines, complex diagnostics**
 - Needs short term strategy: possibly tiered pricing (but who decides on price level and when?),
 - Pathway to accelerate time to competition: technology transfer- meningitis A vaccine produced by Serum Institute of India to be sold at \$ 0.40 /dose.

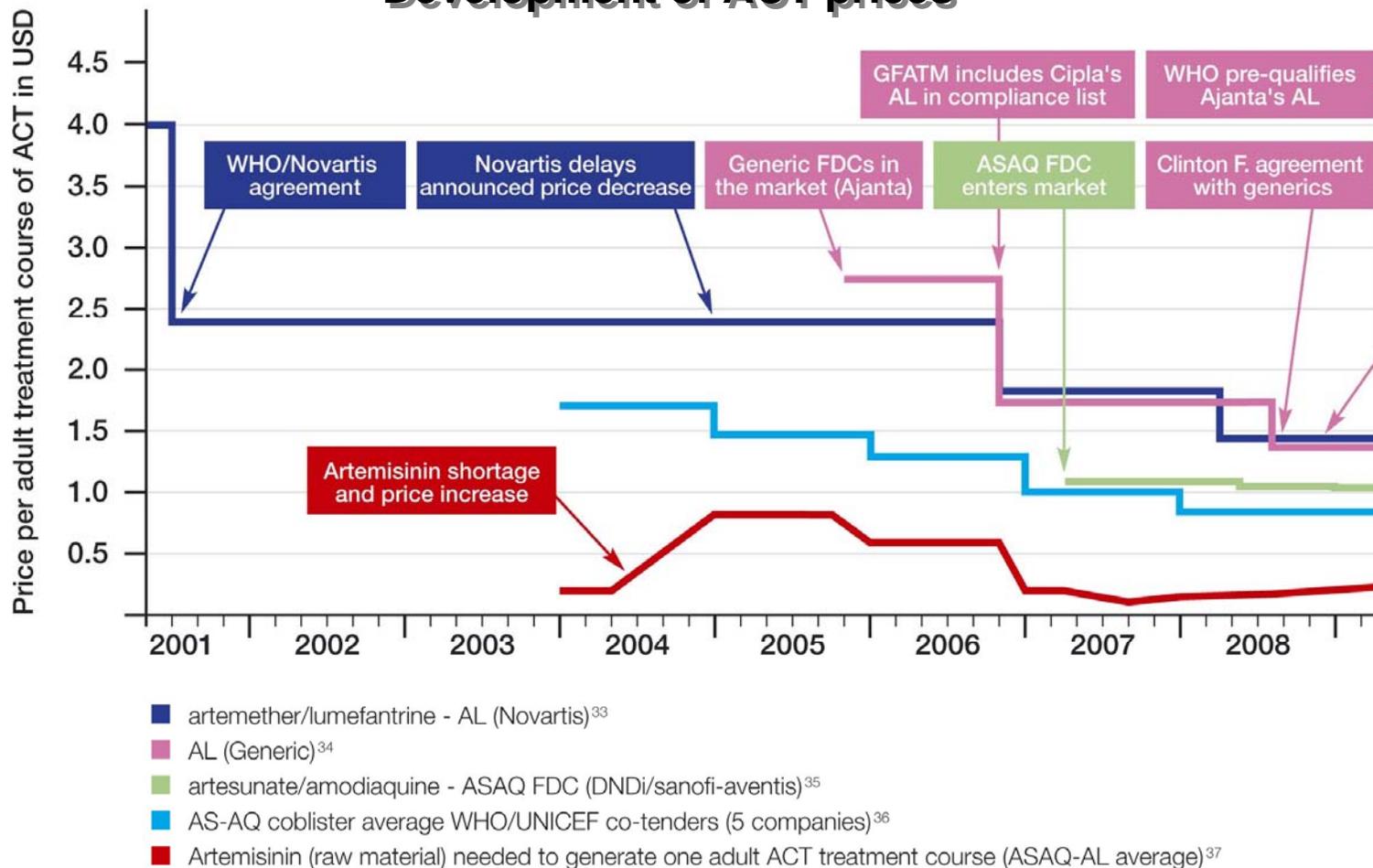
De-linkage and R&D push and pull funding

- PDP
 - De-linkage possible
 - Donors can/do request global access policies
 - Too early to assess: most products still in pipeline and IP and access agreements kept confidential
 - Example: DNDi-sanofi malaria ASAQ: patentfree
 - But if no producer?
- Direct grants to small companies
 - De-linkage only realistic if grant covers full R&D cost
 - Access provisions should be a minimum requirement – access not discussed in EWG report
- Government grants in general
 - Need to ensure public access to the results of government funded research. This is not always the case, e.g. rBCG Δ ureC:Hly (VPM1002) – TB vaccine candidate

Prizes

- Pay for results (pull) reward that provides de-linkage , provided designed appropriately and includes access and cost provisions.

Development of ACT prices



Prices exclude main carriage/freight and insurance costs

Moon et al. PLoS Medicine 2009; 6(7)

Conclusions

- De-linkage is a key concept that enables reconciliation of innovation and access
- De-linkage is a key criteria to assess proposals for stimulation of R&D related needs of developing countries in relation
- Put delinkage into practice: Attach explicit conditions to the R&D funding that will ensure public investments in health secure access to the knowledge and tools generated
Access provision should apply to both push and pull funding .
- Implementation of de-linkage is uneven among push mechanisms and not yet implemented for pull financing
- De-linkage should be included as one of the principles in the design of a needs driven R&D global framework

Thank you!

**For more information:
www.msfaccess.org**