

CEWG Report

what are the most promising models that dissociate the cost of R&D and the prices of medicines and how do you think the models could articulate between themselves?

Role of the research-based industry in R&D

- Industry is the second largest funder of R&D for diseases of developing world, with a total amount of \$503m in 2010
- Industry is thinking creatively about how to conduct R&D. For example, companies are actively contributing to the WIPO Re:Search initiative, a new voluntary database for sharing know-how and intellectual property for R&D on medicines and vaccines for tuberculosis, malaria and neglected tropical diseases.
- We are also working with the Commission to see whether there are opportunities for improved collaboration

Problem statement

- Addressed by CEWG
 - lack of sustainable funding for type II/III diseases
 - sources of finance
 - legal and institutional incentive proposals
 - coordination of R&D
- Not addressed by CEWG
 - low levels of affordability in some countries and populations
 - absence of healthcare and regulatory infrastructure
 - prioritisation?

De-Linking

- proposals should be understood as ways of encouraging R&D. CEWG did not suggest there was one best model
- CEWG identified 9 criteria for assessing proposals, including "the extent to which product pricing and the financing of R&D are determined independently"
- Other criteria included public health impact, efficiency, technical feasibility, financial feasibility, intellectual property, access, governance and accountability, and contribution to capacity-building

What does de-linking achieve?

- it lowers the risk of R&D
- it reduces the price of medicines

When is de-linking likely to be beneficial?

- when it is part of an integrated strategy including all stages of the R&D process, including access to the end-product
- when it is targeted, geographically and therapeutically, to areas of market failure
- when it is linked to sustainable financing
- when it meets some or all of the following criteria
 - it addresses a "gap" in R&D
 - it builds on existing processes
 - it leverages available capabilities

Integration of delinking mechanisms

Research & Development

pre-clinical and clinical R&D

Post-marketing 1 Delivery

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graph LR; A[open compound database & research grants] --> B[product development partnerships]; B --> C[advanced market commitments];
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open compound database
& research grants

product development
partnerships

advanced market
commitments

source : pugatch consilium, 2012

CEWG - Next Steps

- As a key provider of R&D, the industry is interested in contributing to the reflection process following the WHA
- We agree, in line with the CEWG philosophy, that governments should focus on the balance and coordination of their own activities
- The financing gap is key - it must not be lost in technical debates
- Any new mechanism should
 - able to be implemented in short to medium term
 - sufficiently credible to engage key funding sources
 - endorsed by R&D providers
 - non-erosive of existing efforts

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Report of Pugatch Consilium available at
http://www.ifpma.org/fileadmin/content/Publication/2012/Assembling_the_RD_puzzle_FINAL.pdf