

Global Health Policy Forum
28 JUNE 2012,
DG DEVCO

**Report of the Consultative Expert Working Group on Research and
Development: Financing and Coordination**

**The articulation with existing models such as the
Framework Programmes and EDCTP and the many
existing and very diverse initiatives to support
developing countries' health needs**

Albrecht Jahn
University of Heidelberg

The problem

- «... lack of research into diseases that disproportionately affect developing countries. ... the financial returns are often limited. ... a wide range of tools, partnerships and approaches will be needed.».

Andrew Witty, GSK

Witty A. New strategies for innovation in global health: a pharmaceutical industry perspective. Health Aff (Millwood). 2011 Jan;30(1):118-26.

Some basic underlying ideas

- Health is a global public good and thus a global responsibility
- Affordable and accessible medicines require ***delinking*** of R&D costs and prices of products
- Requires ***upfront public financing*** of the R&D
- R&D is reestablished as a ***global public good*** where there is need for global collective action and agreed financing contributions
- This global action needs to be based on a fair,

European Council Conclusions on Global Health 2010

- Promote effective and *fair financing* of research that benefits the health of all
- Ensure that innovations and interventions produce products and services that are *accessible and affordable*.
- *Working towards a global framework* for research and development that addresses the priority health needs of developing countries and prioritizes pertinent research actions to tackle global health challenges
- *Exploring models that dissociate the cost* of Research and Development and the prices of medicines in relation to the Global Strategy and Plan of Action on Public Health, innovation and intellectual property
- Ensuring ... public investments in health research secure access to the knowledge and tools generated as a *global public good* and help generate socially essential medical products at affordable prices, to be used through rational use
- *Promote dialogue and joint action* with key global players and stakeholders, including UN agencies concerned with global health, International Financing Institutions, regional organizations, regional health networks, and countries, in order to identify synergies, coordinate actions, advance in the achievement of commitments, and avoid duplication and fragmentation to increase effectiveness.

Council conclusions on the EU role in global health. 3011th Foreign Affairs Council meeting. Brussels, Council of the European Union, 2010

Antibacterials - delinking

- «A variety of incentives probably have to be applied, but having all in common that the *financial return has to be separated from the use* of the product”

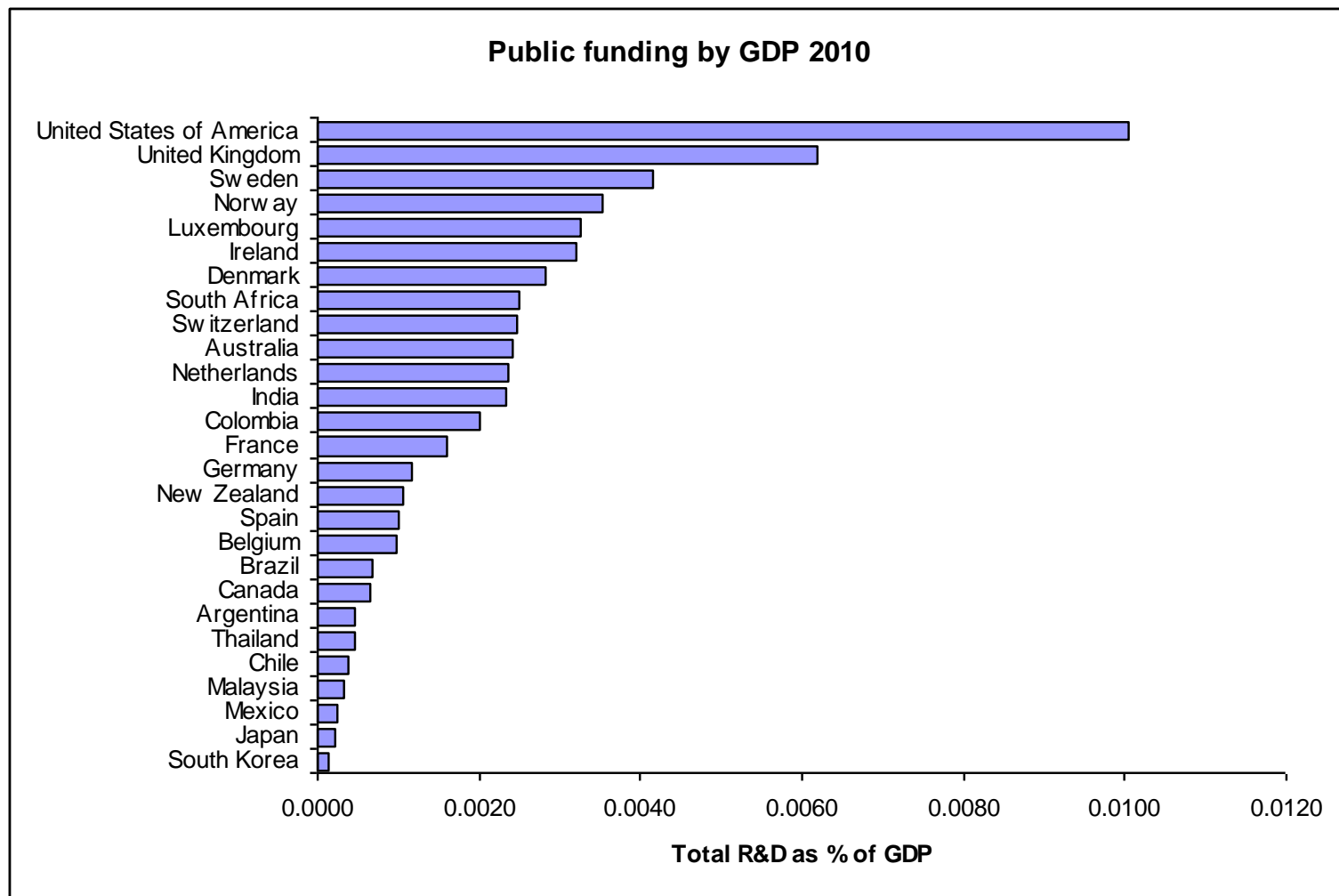
Richard Bergström, EFPIA

Bergström R. *The role of the pharmaceutical industry in meeting the public health threat of antibacterial resistance*. Drug Resist Updat. 2011 Apr;14(2):77-8. Epub 2011 Apr 13.

Financing: Recommendations

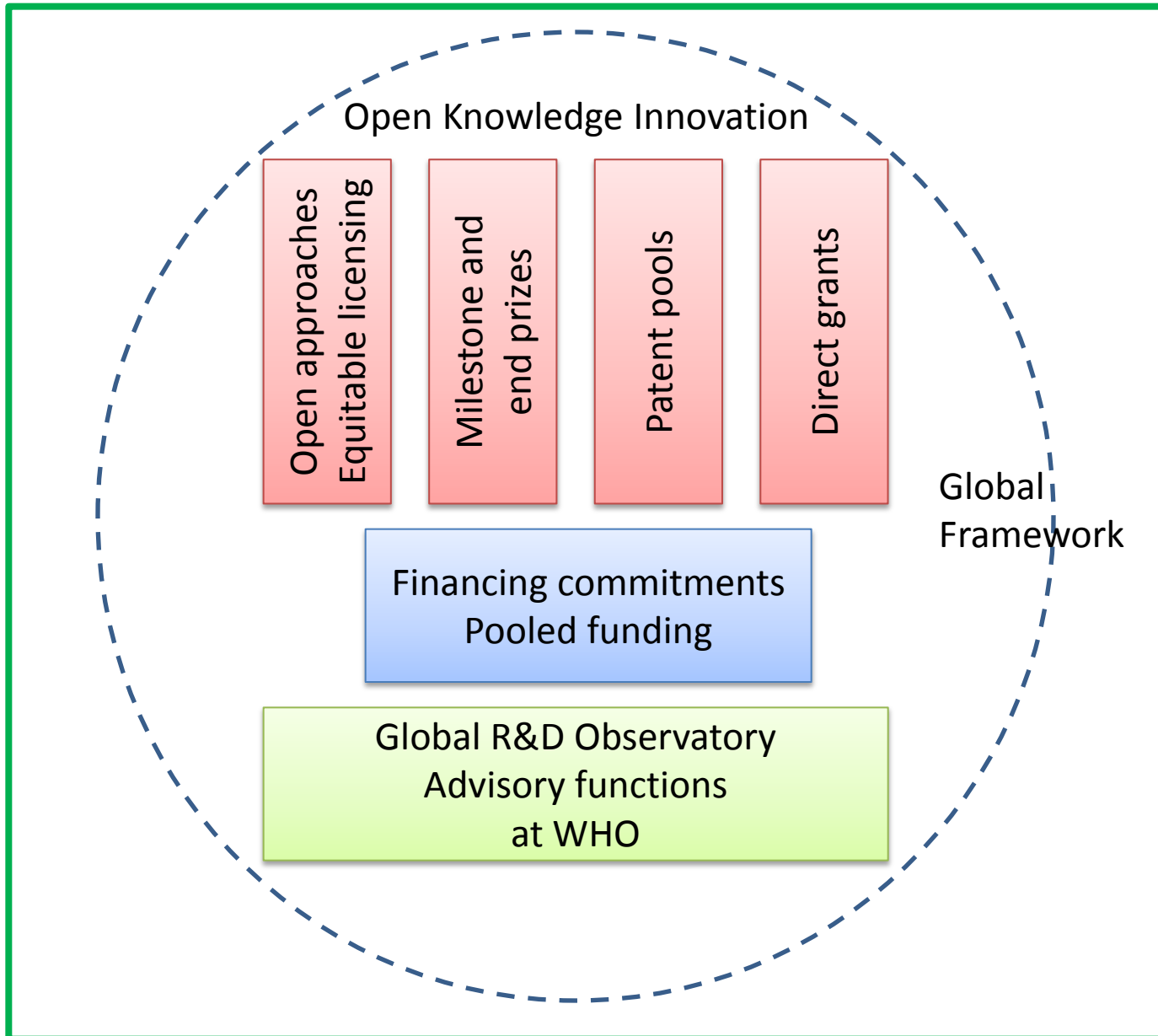
- All countries should commit to spend at least **0.01% of GDP** on government-funded R&D devoted to meeting the health needs of developing countries in relation to the types of R&D defined in our mandate.
- Most of this funding should be used within each individual country.
- **>20% of funds** raised for health R&D addressing the needs of developing countries should be channeled through a **pooled mechanism**.

Public Funding for R&D for Neglected Diseases



Key recommendations

Convention on Global Health R&D



EU funded or supported research initiatives

- **EDCTP**
- **Framework Programme**
- IMI
- AIDCO Actions initiated by the EP
 - Support to ANDI
 - The *Global Report for Research on Infectious Diseases of Poverty*

CEWG Recommendations and the EDCTP

- EDCTP is a model for a multi-country and multi-stakeholder pooled funding mechanism
- EDCTP pursues an open innovation policy
 - “all exploited results (products or services) must be made accessible and affordable, in developing countries, particularly in sub-Saharan Africa.”
- EDCTP invests in capacity building and technology transfer
- EDCTP has clear and empowering partnership guidelines
- EDCTP would benefit from better coordination
- EDCTP could be encouraged to review its scope and funding policy

CEWG Recommendations and Horizon 2020

- Low profile of research for the “priority health needs of developing countries”, e.g. no mention of
 - Global Health
 - Child Health
 - Maternal Health
 - Neglected diseases
- No reference to the Global Strategy and Plan of Action (different from the Council Conclusions and the Commission’s Global Health Communication 2010)
- Platforms or other models for joint priority setting with developing countries not yet specified

Horizon 2020 compared to FP7

The specific programme 'Cooperation' implementing the Seventh Framework Programme of the European Community (2007 to 2013):

“Specific cooperation actions will be implemented in the areas formulated through bi-regional dialogues in third Countries/Regions and international fora, as well as within the context of Millennium Development Goals.

***Such priority areas adapted to local needs and through partnerships may include: health policy research, health systems and healthcare service research, maternal and child health, reproductive health, control and surveillance of neglected communicable diseases*”**

Coordination: CEWG Recommendations

1) A Global Health R&D Observatory.

- Financial flows to R&D
- The R&D pipeline
- Learning lessons.

2) Advisory Mechanisms.

- A Network of Research Institutions and Funders
- An Advisory Committee
- A credible and sound priority setting mechanism
 - Example: The Consultative Group on International Agricultural Research (CGIAR)

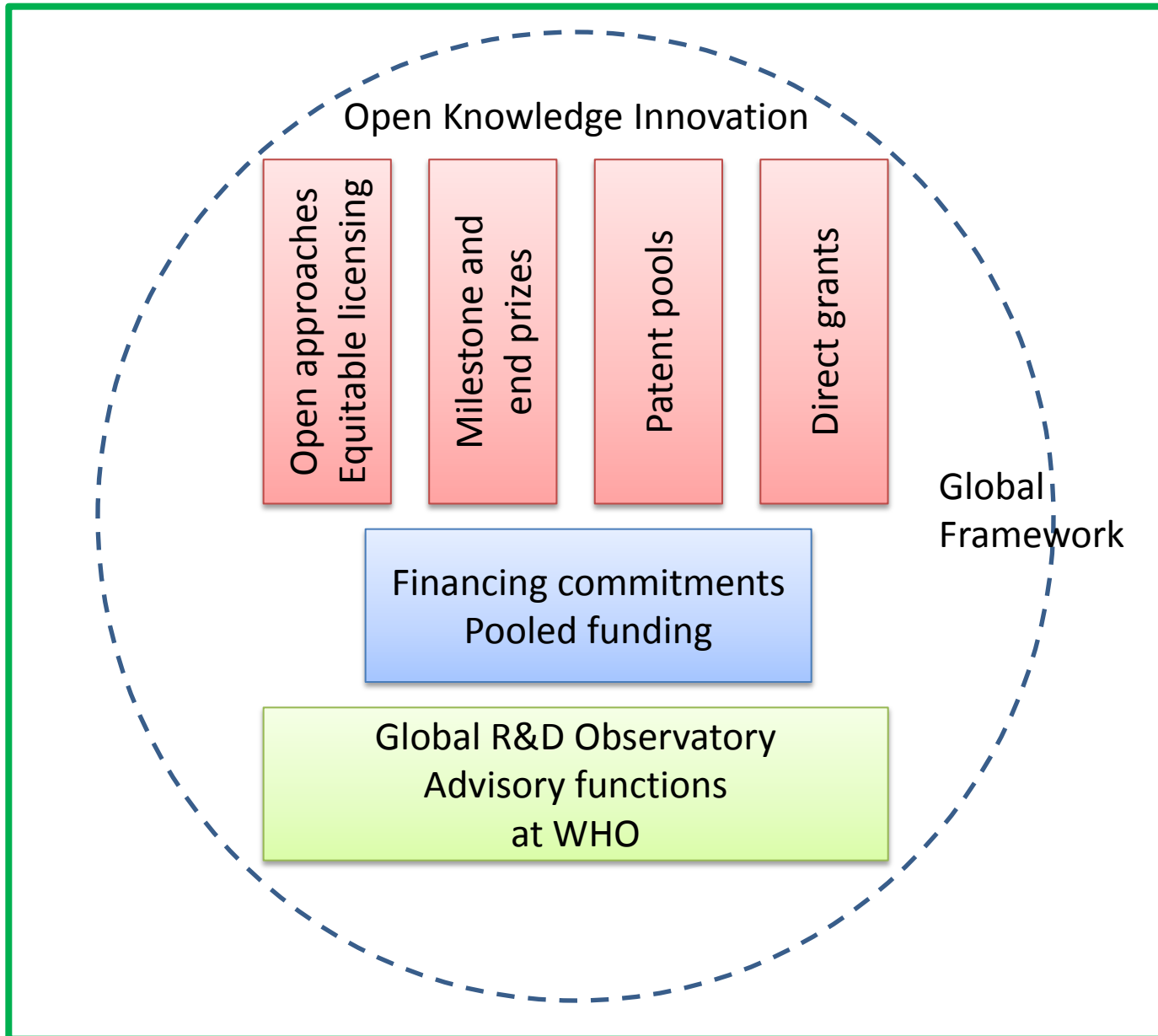
→ **WHO should play a central role in improving coordination and this should be considered as part of the WHO reform process.**

How can ongoing initiatives use the CEWG Report

- **The construction of a global framework will be an incremental process**
- **Many of the specific recommendations are already tested and can be used (patent pools, equitable licensing, taxes)**
- **The proposed observatory can help to avoid duplication, assist priority setting and rationalise R&D processes**
- **However, in the long run, a global framework, will need to be backed up by a reliable collective financing mechanism**

Key recommendations

Convention on Global Health R&D



Thank you for your attention!

For additional information see:

<http://www.who.int/phi/en/>

http://www.who.int/phi/news/cewg_2011/en/index.html

Backup Slides

Four types of recommendations

- **Principles:**
 - Affordable products can best be achieved through free open market competition.
 - Requires delinking of R&D costs and prices of products.
 - R&D is a global public good where there is need for collective action and agreed financing contributions to avoid free riding.
- **Functions/operational:**
 - Need to increase public investments to at least \$6 billion annually (the double of current total investments).
 - All countries should commit to spend at least 0.01% of GDP on government-funded R&D.
 - 20–50% of funds should be channeled through international pooled mechanisms to improve efficiency and coordination
 - More efficient and collaborative R&D processes through sharing of results: *Open Knowledge Innovation*: precompetitive research and development platforms, open source and open access schemes, and the utilization of prizes, in particular milestone prizes, equitable licensing and patent pools.
 - Strengthening research and development capacity in and technology transfer to developing countries.
 - Establish a Global Health R&D Observatory and relevant advisory mechanisms under the auspices of WHO.

Strengthening R&D capacity in Dev. countries

- Promotion of partnerships and collaborations based on joint agendas and priority setting related to developing country health needs and national plans for essential health research.
- The development and retention of human resources and expertise..
- Sustainable medium/long-term collaborations.

Four types of recommendations

- **Implementation instrument:**
 - Need for an agreed upon *global framework*
 - A global legally binding instrument would be most effective
 - Propose an international Convention on Global Health R&D (utilizing Article 19 of WHO constitution)
 - First global regulatory instrument for a global public good within health
- **Process/next step:**
 - Resolution at 65thWHA
 - Establishing a working group or technical committee composed of two Member States from each WHO region to undertake preparatory work on the elements of a draft agreement.
 - Provide for the establishment of an intergovernmental negotiating body open to all Member States, to be established under Rule 40 to draft and negotiate the proposed R&D convention following on from the report of the proposed working group

Principles of a global binding instrument

- **Under the Auspices of WHO (Article 19).**
- **Delinking of the cost of R&D and the price of the product.**
- **Involvement of all governments in setting priorities, coordinating and funding R&D efforts.**
- **A funding mechanism to ensure the sustainable financing of all activities under the convention.**
- **A supplementary instrument to the IPR based incentive system (Not a replacement).**
- **WHO Member States to decide on the institutional mechanism and *modus operandi* of the instrument.**

Objectives of a global binding instrument

- **Implementing States' obligations and commitments.**
- **Promoting R&D for developing new health technologies.**
- **Securing sustainable funding.**
- **Improving the coordination of public and private R&D.**
- **Enhancing the innovative capacity in developing countries and technology transfer to these countries.**
- **Generating R&D outcomes as public goods, freely available for further research and production.**
- **Improving priority setting based on the public health needs of developing countries.**
- **Focus on development of health technologies for Type II and Type III diseases as well as the specific needs of developing countries related to Type I diseases.**

Financing mechanisms

- **All countries should aim to achieve specified levels of public funding on health R&D relevant to the needs of developing countries.**
- **A financing mechanism should be established under the convention based on contributions by governments.**
- **Financing mechanisms need to be supportive to the broader context of overall allocation of public financing to health research.**
- **The convention should define which research entities should be eligible for funding.**
- **Funding should be directed so as to promote cost-effective R&D.**
- **Funding should promote capacity building and technology transfer to the public and private sectors in developing countries.**

Coordination mechanisms

- **A coordination mechanism to promote the objectives in Element 2.3 of the GSPA-PHI - “improving cooperation, participation and coordination of health and biomedical research and development”.**
- **It should improve the measurement of the volume, type and distribution of relevant R&D and the evaluation of R&D outcomes, in particular so that progress against commitments and compliance could be measured.**
- **Compliance mechanisms, including through cooperation of the parties to the convention.**