

THE LANCET

Essential Medicines for
Universal Health Coverage

**The Lancet Commission on
Essential Medicines Policies
Recommendations for ‘Delinkage’**

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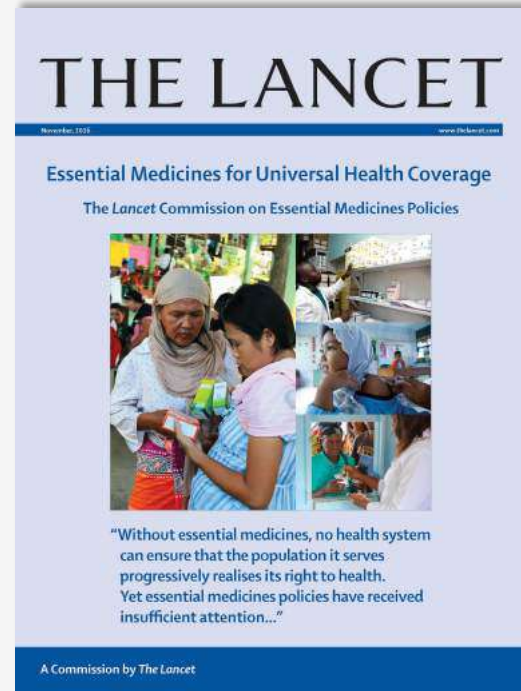
THE LANCET

Commission on Essential Medicines Policies



Report of the Lancet Commission on Essential Medicines Policies: *Essential Medicines for Universal Health Coverage*

- Paying for a basket of essential medicines
- Making essential medicines affordable
- Assuring the quality and safety of essential medicines
- Promoting quality use of essential medicines
- Developing missing essential medicines
- Measuring progress on essential medicines policies

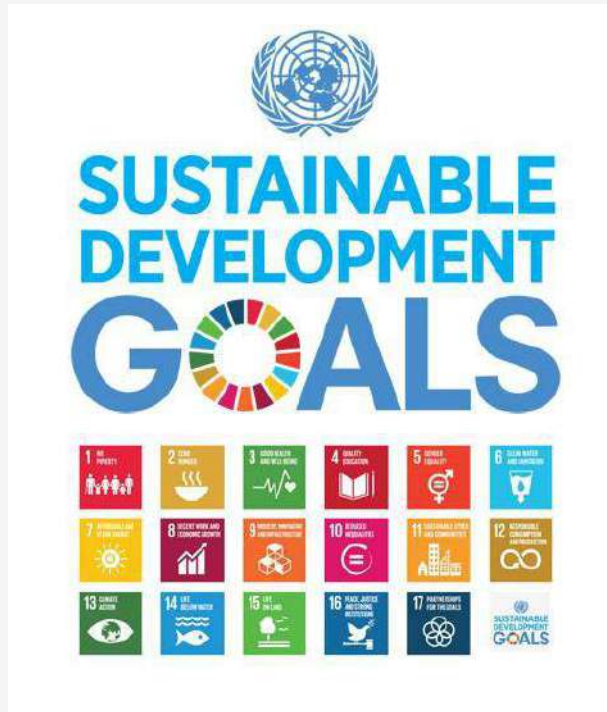


Key Problems: The Current Innovation System

- **R&D focus on modifying existing medicines**
Adds little therapeutic value
- **Essential medicines and diagnostics with insufficient profit potential are not developed**
E.g. antibiotics, neglected diseases (e.g. Ebola), paediatric formulations (e.g. HIV)
- **Essential medicines abandoned for lack of commercial potential**
E.g. Benzyl penicillin, anti-venoms for snake bites
- **New medicines are highly priced and widely patented**
E.g. oncology, hepatitis C, MDRTB, orphan drugs

Lack of access and innovation is now a global problem - no longer a developing country issue

Universal Health Coverage Demands Essential Medicines



Affordability questions everywhere, for everyone

Access to medicines—the status quo is no longer an option



Last week, the much anticipated report of the

rt's recommendations and block its release

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VIEWPOINT
VITAL DIRECTIONS
Improving
Efficiency

For the High-Level
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2016;386:1061-63

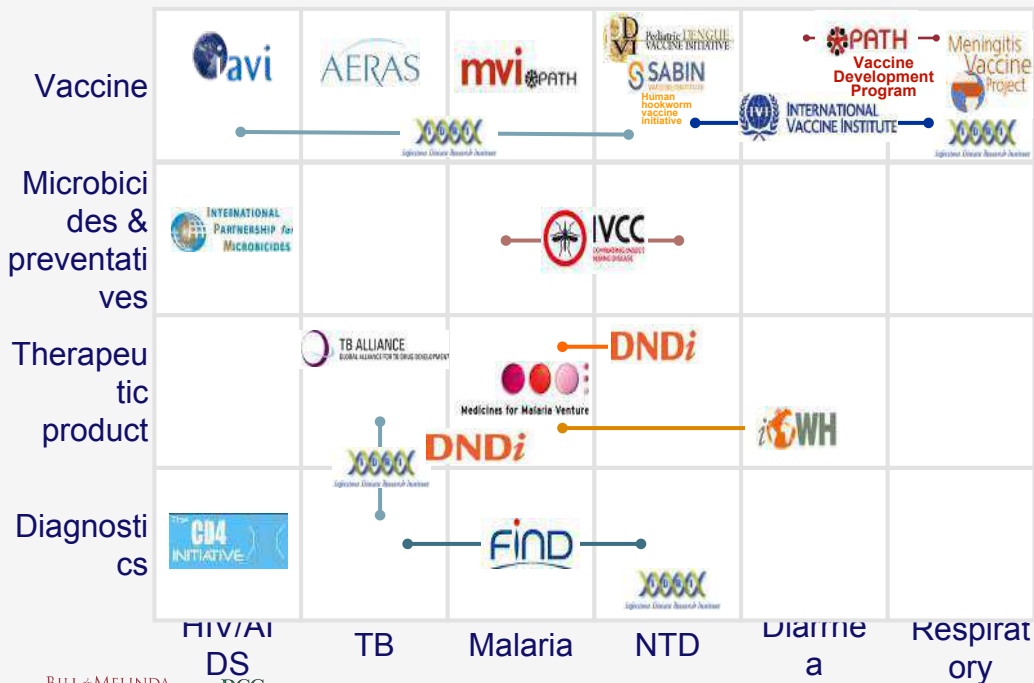
Campaigners protest outside the National Institute for Health and Care Excellence over
The report was o
the pharmaceutical

The challenges
medicines as a keystone of the global
development agenda. ■ The Lancet

Australian Prescriber
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Drugs
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Lessons learned: R&D initiatives



Source:

Lessons learned

- **New alternative incentives: push and pull**
E.g. UNITAID, GHIT Fund, Longitude Prize
- **Regulatory incentives: mixed results**
PRVs, paediatric formulations
- **Public funding**
Often initial R&D publically funded but final steps by for-profit companies who control IP rights
- **Patent pooling**
Medicines Patent Pool (HIV, Hep C, TB)
- **TRIPS flexibilities**
Compulsory licensing, government use, LDC waiver on patents
- **Pharmaceutical companies' social responsibility**
Investor needs versus public health needs

Blockbuster drugs with orphan status

Drug †	Global sales 2015 (\$B) †	Maker †	Therapy area †
Humira	14.1	AbbVie	Antirheumatic
Rituxan	7.6	Roche	Cancer antibody
Avastin	7.2	Roche	Cancer antibody
Herceptin	6.6	Roche	Cancer antibody
Remicade	6	Johnson & Johnson	Antirheumatic
Revlimid	5.7	Celgene	Blood cancers
Crestor	5.2	AstraZeneca	Statin

Seven of the 10 top drugs in global sales have received an orphan indication or designation from the FDA
<http://www.cnbc.com/2015/12/01/an-obscure-fda-rule-adding-to-drug-company-profits.html>

Costs Of Developing A New Medicine – Need For Transparency

Publication Year	R&D Cost Estimate	Source
1991	US\$ 231 million (<i>expressed in 1987 dollars</i>)	DiMasi
1993	US\$ 140-194 million (<i>expressed in 1990 dollars</i>)	OTA
2003	US\$ 802 million	DiMasi
2012	US\$ 1.5 billion	OHE
2014	US\$ 2.5 billion	DiMasi

- 2001 TB Alliance R&D cost estimate for a new chemical entity for TB (*including costs of failure*):
US\$ 76-115 million
- 2013 DNDi R&D cost estimate for a new chemical entity for a neglected tropical disease (*including costs of failure*):
US\$ 100-150 million

Towards A Global R&D Framework

Lancet Commission:

‘With the current patent-based innovation system, the feasibility of achieving or maintaining Universal Health Coverage is seriously at risk. ... “business as usual” will not resolve the current problems with R&D, ... concerted global action is the only way forward.’

Lancet Commission on Delinkage 1/3

‘A new global policy framework is needed to drastically adapt the current model and to reduce its reliance on market exclusivity as the main driver of innovation.

Governments need to define a list of missing essential medicines to be provided under UHC schemes, and governments, non-governmental organisations, and the industry need to make the necessary R&D financing mechanisms available for these identified needs.

The price of new essential medicines can then be delinked from development costs and the products can be made widely available and affordable through non-exclusive licensing agreements. The resultant decrease in price can provide the financial space to more directly finance the identified priority R&D.’

Lancet Commission on Delinkage 2/3

The concept of delinking costs from prices is based on the premise **that costs and risks associated with R&D should be rewarded, and incentives for R&D provided by means other than through the price of the product.** If the R&D cost of new medicines did not have to be recouped through high prices, those medicines would be free of market exclusivity and could be made more widely available and more affordably priced through better competition.

The Commission supports proposals to progressively delink the cost of R&D for priority medicines from the price of the products, and to develop new ways of sharing the cost burden of innovation internationally.

Lancet Commission on Delinkage 3/3

The talks about a new R&D framework are likely to be intensely political, as were the negotiations for the GSPA. It will be important for clear R&D priorities to inform this process. The necessary practical details of a new medical R&D framework will need to be negotiated.

These global discussions on R&D priorities provide opportunities for national governments, WHO, and the UN to fulfill their obligations to present a bold new global framework for achieving the dual objectives of health-need driven R&D and equitable access to its products.

NL Ministers E. Schippers (Health) and L. Ploumen (Foreign Trade and Development Cooperation) In response to the Lancet Commission:

“We cannot achieve any real progress without acknowledging that the current patent-based business model and the way we apply international patent rules need to change. The system is broken.

...

Patent and intellectual property exclusivities are the only cornerstone of the current model. Companies can ask the price they like. This will no longer do. We need to develop alternative business models. And if public money is used for the development of new medicines, agreement upfront is needed about what this public investment will mean for the final price. We believe that companies must provide full transparency regarding the costs of research and development (R&D).

...

Through upfront public and philanthropic contributions, R&D costs are delinked from final consumer prices, to the benefit of affordable and equitable access to patients. The public sector has shown its willingness to put money on the table. The time has come for the pharmaceutical industry to also come forward with more substantial financial contributions.”

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)31905-5/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31905-5/fulltext)

EU assessment of existing R&D incentives

The Council has outlined the following actions for the European Commission:

- Streamline implementation orphan regulation; ascertain proper application of the rules, incentives and rewards and revise them if necessary;
- Create an overview of EU pharmaceutical legislation in relation to IP related incentives and their intended purposes;
- Analyse effects of these incentives on innovation, accessibility, availability and affordability of medicines, as well as price strategies of the industry;
- Analyse functioning of the EU pharmaceutical market in terms of transparency, market behaviour, and competition, and strengthen market oversight
- Recommend possible remedies in the context of the agenda 2017-2020.

<http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/>

Recommendations

- Governments and WHO must take international **public leadership for priority setting for essential R&D** with due regard for the public health needs of low- and middle-income countries.
- Governments must lead the process towards a global research and development policy framework and agreements, which include **new financing mechanisms to ensure that missing essential medicines are developed and made affordable based on “delinkage” principles.**
- The international community must create a general **Essential Medicines Patent Pool** (hosted by the Medicines Patent Pool).
- Governments and national stakeholders must develop and implement comprehensive national action plans to **guarantee equitable access to new essential medicines**, including open knowledge innovation, fair licensing practices, support for a patent pool for essential medicines, full use of TRIPS flexibilities when needed, and reject TRIPS-plus.
- The **pharmaceutical industry** must better align its R&D priority setting with global health needs, and develop access strategies to make medically important innovations available to all in need.

Towards a global R&D framework

Market failure or public policy failure?

“We have to recognize that the free market, as good a servant as it is, is a bad master. We cannot take important global decisions on the basis of the free market alone.”

Nobel laureate Sir John Sulston

Thank you.

The Lancet Commission Report:

www.thelancet.com/commissions/essential-medicines

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