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The Supply of Medicine to Developing Nations: Bridging the Incentive Gap

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Introduction

Improving access to essential medicines in developing countries is a fundamental development concern. Neglected diseases disproportionately affect developing countries¹ and account for more than 11% of the global disease burden², yet only a minor proportion of newly approved drugs specifically target this market. Essential medicines are defined as 'those that satisfy the health care needs of the majority of the population at a price they and the community can afford'³, and are intended to be available in health systems at all times in adequate amounts.

There has been a shift towards better provision in the last decade through several initiatives such as the Drugs for Neglected Diseases initiative (DNDi) and product development partnerships (PDP's). However, the high rate of neglected diseases in developing countries continues to stunt development⁴ due to the lack of sufficient investment undertaken by pharmaceutical companies to find and supply effective treatments to this base market.

This paper aims to evaluate the most effective means of ensuring pharmaceutical companies undertake the appropriate investment in Research & Development (R&D) by analysing policies that shift corporate incentives to align with this development priority. Supply fails to reach this demographic sector sufficiently due to a lack of commercial incentive as no viable profitable market exists⁵. The incentive for commercial investment in pharmaceutical R&D is tied to potential profitability due to the high rate of risk involved, as recognised by chief executive of GSK, 'if there is significant uncertainty about returns being available for value-adding products at the end of the R&D period, investors and therefore companies would be much less willing to invest'⁶. Evidently, in a situation where the public good, medicine, is under-supplied in the market, it is generally the role of governments⁷ to bridge the gap between the basic human need for medicine and economic incentive for market-driven companies.

Focus Area

The World Health Organization's (WHO) Consultative Expert Working Group (CEWG) on R&D stressed the need for a 'coherent global framework'⁸, combining a range of tools, partnerships and policies. Primarily, high-priority R&D focus areas need to be identified. Policies with the greatest potential impact are those that target these gaps; if these gaps in R&D can be effectively identified, we can avoid costly duplication of research and can channel future resources into neglected areas, effectively aligning research with need. The Access to Medicine Index⁹ champions the

use of G-Finder, a data source created by Policy Cures, which comprehensively tracks trends and investment patterns in 35 neglected diseases¹⁰. This tool provides open access to data, revealing gaps in R&D into which future investment can plug into.

If the viability of an R&D project is determined by its potential level of impact, we can identify which neglected diseases to tackle with the highest priority. Modelling the relevant variables, eg. *% of sufferers, ease of distribution, effectiveness of treatment*, will

1 WHO (2011), 'Financing & incentives for neglected disease R&D: opportunities and challenges' http://www.who.int/phi/news/phi_3_DNDi_submission_CEWG_190611_en.pdf DNDi

2 P. Chirac, E. Torreele (2006), Lancet, 'Global framework on essential health R&D'

3 WHO, 'Description of Essential Medicines'

4 US Census Bureau (2010), World Population Profile

5 IAVI (2010), Insights, Policy Brief

6 A. Witty (2016), UN High-Level Panel on Access to Medicines

7 EU Horizon 2020 Research Strategy

8 WHO CEWG (2012), 'Research and Development: Financing & Coordination'

9 Access to Medicine Index (2016), <http://accesstomedicineindex.org/>

10 <http://polycures.org/gfinder.html>

result in a numerical output that ranks projects, revealing which R&D projects should be tackled with most urgency to ensure productive and allocative efficiency is maximised. No weight should be placed on commercial validity (to disassociate investment from profitability), only on the projects impact on disease reduction. The models findings coupled with G-Finder data can compile potential investment projects into a priority list, reducing information failure by improving the transparency of pharmaceutical companies' market knowledge.

A major hurdle that needs tackling is the registration of new products, as data reveals new products are not being registered where they are most needed post-development (78% of recently developed products

are registered in less than half of the corresponding priority countries¹¹). Governmental intervention, in the form of additional regulations, should be required to link up the high-priority index of treatments to regions with the highest need, obligating companies to register their products in neglected areas. It would be compulsory to publish registration records of products to increase the ease of monitoring companies and further transparency. There is also a need for disease-specific time-bound registration targets¹² to systematically ensure that products developed are quickly accessible to the regions that have the greatest need, with a pay-for-delay penalty such as fines applicable for delayed registration in high priority countries.

Providing the Incentive

Incentive mechanisms are essential to ensure that a proportion of companies' resources are invested in these high priority projects. At the highest level, governments can ensure this by enforcing legally binding requirements. They can regulate the percentage of companies total R&D that has to be committed to projects that are on the high priority list, with higher corporate taxes on other profitable pipelines the price to pay for those that don't comply with regulations.

Most policy proposals in current literature are centred on 'Push' and 'Pull' incentive mechanisms. 'Push' funding policies help to initiate the early stages of product development such as preliminary research, by providing critical funding for capital-constrained organisations so that R&D for essential treatments can take place¹³. Pull mechanisms critically enhance the dedication to a product development by providing a monetary incentive for the end results of R&D¹⁴, compensating for the minimal market reimbursement available in low-income markets.

Product development partnerships (PDP's) are one of the major 'push' incentives motivating organisations to conduct necessary R&D into neglected diseases. They are a form of public-private partnership that

pools funds and employs these in multiple product developments, which reduces the industry and donor risk of investment through leveraging partner funding¹⁵. Having multiple donor partners provides the critical funding required by smaller pharmaceutical companies to support R&D projects and consequently results in more projects being undertaken, increasing the likelihood of suitable treatments being developed. One critical conclusion drawn from current partnerships is the need for local context. Specifically, organisations with suitable knowledge of key areas of drug distribution should be included in R&D knowledge pool to ensure that the products developed are suitable for the locality. This ensures that treatments, once developed, can be efficiently distributed and administered in key areas to effectively tackle the level of disease.

Transparency is essential for ensuring effective collaboration between multiple organisations. Information asymmetries between donors and companies should be minimised to avoid monitoring challenges and ensure funds are being directed to suitable pipelines and not being discretely absorbed into those with more commercial incentive. With legal requirements forcing companies to publish clinical

11 Access to Medicine Index (2016), <http://accesstomedicineindex.org/>

12 WHO (2012), http://www.who.int/nmh/events/2012/discussion_paper2_20120322.pdf

13 UNITAID (2016), 'An economic perspective on delinking the cost of R&D from the price of medicines.' [http://nopr.niscair.res.in/bitstream/123456789/21532/1/JIPR%2018\(5\)%20491-498.pdf](http://nopr.niscair.res.in/bitstream/123456789/21532/1/JIPR%2018(5)%20491-498.pdf)

14 C. Grace & M. Kyle (2009), Global Forum Update on Research for Health pp. 147-152, 'Comparative Advantages of Push and Pull Incentives for Technology Development: Lessons for Neglected Diseases', <http://www.margaretkyle.net/PushPull.pdf>

15 <http://devpolicy.org/product-development-partnerships-an-innovative-approach-to-tackling-neglected-diseases-20140528/>

data and specific R&D results relating to neglected disease treatments, the market avoids duplication of research. This sharing of knowledge improves efficiency and speeds up the innovation process, insuring that progression in healthcare availability is not suffocated by competition, resulting in faster results.

In ensuring open access to relevant knowledge, we encounter the issue of intellectual property protection. The existence of compulsory and voluntary licenses included in the World Trade Organization's (WTO) Trade Related Intellectual Property Rights (TRIPS) framework¹⁶, already undermines the value of Intellectual Property (IP) protection. This social policy tool is intended to encourage innovation and enable generic versions of trademarked drugs to enter the market¹⁷, however increased invalidation of patents significantly undermines the value of patents for pharmaceutical companies and deters the private sector from further investment into treatments for neglected diseases. Further legal requirements on the sharing of costly research findings will reduce incentives further.

Research subsidies are another push funding policy that can be employed, assuming the willingness of central governments to support critical R&D projects. Given that projects are in alignment with high priority market gaps, governments could commit to a 5-year-plan of funding support to subsidise preliminary research into possible products. This funding ensures projects are consistently undertaken and compensates for the risk of a lack of commercial revenues available at the end of the pipeline. The 5-year commitment could be set at a decreasing rate, creating a large incentive initially when the risk of R&D is highest and then lowered once a project gains more traction.

While push mechanisms are seen to be biased towards a handful of select organisations due to the limited amount of funding available for potential projects, pull mechanisms are technically available to any producer in the industry and thus expertise of researchers is maximised and all organisations are engaged. Advanced Market Commitments (AMC's)

are one such policy, of which any firm can tap into, permitting their product meets some pre-defined specification¹⁸ on what is required of the treatment in hand. The commitment takes the form of a legally binding financial commitment up to a pre-agreed total market value. This financial incentive acts as a reward for the first company to design and produce a suitable treatment for a target disease, thus attracting the expertise of a diffused set of researchers and increasing the rate of innovation. Other pull mechanisms that act in the same way as the AMC are the Medical Innovation Prize Fund¹⁹, which links the size of the monetary reward to the social value of the treatment, and the Health Impact Fund, which rewards companies who register their products in proportion to the impact (measured in quality-adjusted life years).

The obvious risk of these financial rewards is that they may result in the wasteful duplication of resources if no regulation on the transparency of information sharing is present. Multiple companies may employ resources to find an efficient solution to the same high-priority product gap, when ultimately only one company can receive any financial reimbursement. The opportunity costs are therefore high and perhaps will disincentivise companies to conduct any R&D for the risk that another company will beat them to the finish line. The concept of companies battling for the end reward actively discourages information sharing and transparency in the market, which some argue is vital in the effort to reduce the level of neglected diseases.

There is also an opportunity cost of government funds that finances this reward system²⁰. Quantifying the size of the prize involves weighing the need to incentivise companies with a sufficient sum against the true monetary reflection of the treatment's impact on neglected diseases. This is both time-consuming and costly and also calls into question whether government funding is being used in the most effective way. Alternative uses of government funds that may result in higher investment from pharmaceutical companies involves setting a lower tax rate for companies who dedicate a pre-determined level of resources towards R&D into

16 https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

17 J. Law Med Ethics (2009), University of Connecticut School of Business, 'Developing nations and the compulsory license: maximizing access to essential medicines while minimizing investment side effects'.

18 C. Grace & M. Kyle (2009), Global Forum Update on Research for Health pp. 147-152, 'Comparative Advantages of Push and Pull Incentives for Technology Development: Lessons for Neglected Diseases', <http://www.margaretkyle.net/PushPull.pdf>

19 Medical Innovation Prize Fund Act, <http://www.cptech.org/ip/health/prizefund/hr417.html>, H.R. 417-

20 The Economist, 2006, 'Push and Pull', <http://www.economist.com/node/5655331>

neglected diseases. The appeal of tax rate exemption on more profitable product developments may be a large incentive for companies to focus part of their production in this sector.

Pricing

The accessibility of these pharmaceuticals is highly determined by the affordability for those in need, considering the target market in developing countries predominantly lie in the low-income band. The main theme throughout the current literature on accessibility is built around the idea of 'delinkage', which aims to transform the business model of the

pharmaceutical industry to expand access and reduce costs²¹. Delinkage is defined as the separation of R&D costs from product prices²², ultimately aiming to make investments more responsive to the needs of patients and society and products put on the market at lower and eventually affordable generic prices.

²¹ <http://delinkage.org/overview>

²² UNITAID (2016), 'An Economic Perspective: On Delinking the Cost of R&D from the Price of Medicines' http://www.unitaid.org/assets/Delinkage_Economic_Perspective_Feb2016.pdf

Conclusion

Some proposals include:

- Considering the purchasing of medicines for the public/charitable sector, a central global brokering facility would efficiently enforce a competitive tendering amongst suppliers²³, which fundamentally reduces prices. The market would benefit from the economies of scale effect, with discounts offered in bulk-purchase orders. Previous proof of this being successful in practice include the supply of TB drugs in developing countries near the marginal cost of production²⁴.
- Intra-country equitable pricing strategies suiting consumers from differing socio-economic segments²⁵. This will theoretically result in a needs-based tiered pricing structure that minimises the deadweight loss from a one-price-suits all structure. For example, for the lowest-income sector essential medicines would be freely available from charities or other NGO's, a highly subsidised price would be offered at local community run clinics, whereas at private clinics that attract wealthier customers, medicines are available at a marked-up price, to compensate for the loss of producer surplus in lower-income segments.

The risk of a tiered pricing structure is the arbitrage opportunities that it creates. Contractual agreements between companies and distributors would be necessary to counter any diversion across distribution channels²⁶, eg. free drugs supplied by charities to be consumed on site to avoid any risk of resale.

- The mobilisation of more Community Health Financing schemes (CHF)²⁷ so communities are given more responsibility in controlling their specific health-care needs to provide for more localised treatment. Volunteer groups are responsible for pooling funds and given predominant control of resources. This ensures that prices are being set accordingly to suit the affordability of the region.
- Ask companies to tender for specific projects, with the winner being solely responsible for the research. The tender process should ensure least cost production. Earmarking a percentage of the aid budget per country would provide the initial funding and Governments could also take out equity in any successful patent.

23 A. Attaran, JAMA (2001), 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa', <http://www.cptech.org/ip/health/africa/attaran-white.html>

24R. Gupta et al (2000), Science, , 'Responding to market failures in tuberculosis control'

25 http://pdpaccess.org/downloads/resources/pricing/Differential%20Pricing_Yadav.pdf

26 S. Moon, E. Jambert, M. Childs, and T. von Schoen-Angerer (2011), Globalization and Health, 'A win-win solution?: A critical analysis of tiered pricing to improve access to medicines in developing countries.'

27 http://www.afro.who.int/index.php?option=com_content&id=2233:community-based-health-financing&catid=1881

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