Accelerating access to medicines:

Policy recommendations for achieving the health-related Sustainable Development Goals

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Introduction

Improving access to quality healthcare remains a key area of action for the member states of the United Nations. As they gather in New York for the 74th UN General Assembly, focus is upon the health-related Sustainable Development Goals (SDGs), in particular SDG 3.4 relating to preventable non communicable disease (NCD) mortality[1] and SDG 3.8 relating to Universal Health Coverage.[2] It is expected that UN member states will agree a political declaration to be adopted at the UN General Assembly's high-level meeting on UHC in September 2019.[3]

The political declaration comes against a backdrop of slow progress towards the health-related SGDs goals:

- 35 high-income countries with an already low rate of NCD mortality are projected to meet SDG 3.4 by 2030, but the majority of countries are making slow progress and will not meet the target by 2030, particularly among men.[4]
- High out-of-pocket costs continue to limit access to health care in many parts of the world.

Increasing public and private financing of healthcare and improving the capacity of public and private sector delivery systems is essential to reversing this situation and achieving the health-related SGDs.

Fortunately, there are several low-cost steps governments could take immediately to improve and accelerate access to care and reduce NCD mortality, including cutting red-tape, slashing taxes and facilitating open trade. If governments are serious about meeting their commitments under the health-related SDGs, these practical solutions should be at the centre of discussions.

Reduce unnecessary medicine costs by:

- ✔ Reducing taxes
- ✔ Abolishing tariffs
- ✔ Eradicating other trade barriers

Accelerate access to medicines by:

- ✔ Speeding up patent examination
- ✔ Simplifying the drug approval process
- ✔ Modernising government medicine reimbursement decision-making
- ✔ Promoting open trade in medicines

Reduce unnecessary medicine costs

In the majority of Low- and Middle-Income Countries (LMICS), most healthcare costs are met directly out of pocket due an absence of functioning healthcare insurance and provision. Anything that needlessly adds to the end price of a medicine constitutes a major impediment to access, and with it the realisation of the health-related SDGs.

Abolish tariffs on medicines

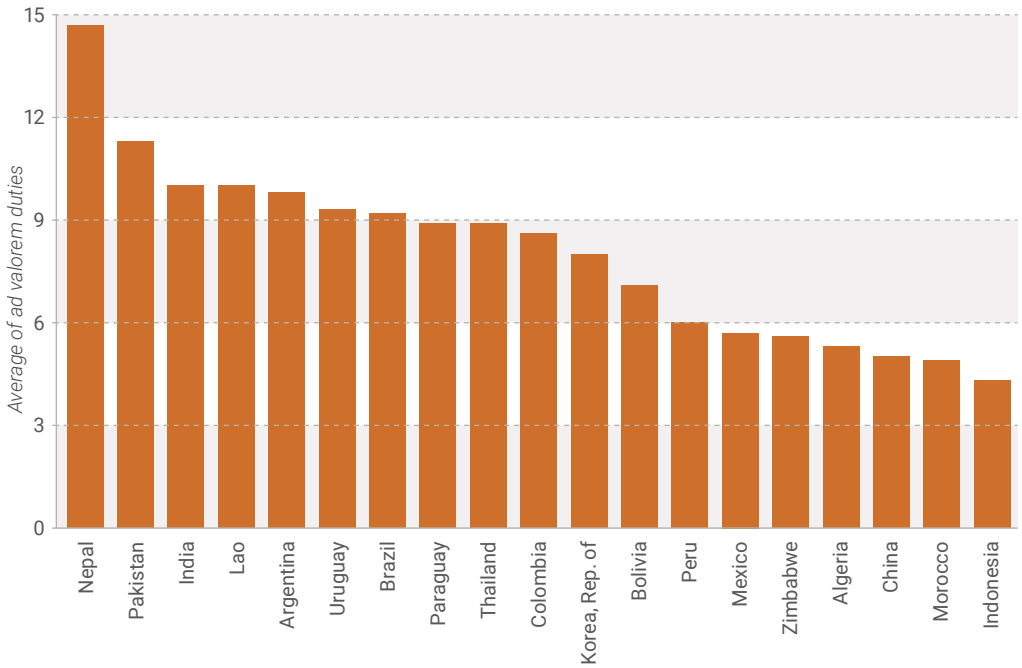
Although overall global average tariffs have been falling in recent years, many countries still apply tariffs to imported medicines. The highest average rates are found in South Asia and Latin America (Figure 1).

Many countries have long recognised the regressive nature of pharmaceutical tariffs and the obstacle they pose to improving access to medicines and fulfilling the right to health, and have unilaterally abolished them. Meanwhile, 22 WTO members have agreed to the reciprocal elimination of import duties on approximately 7,000 pharmaceutical products under the WTO Pharmaceutical Tariff Elimination Agreement (also known as the "Zero for Zero Initiative").

Although many countries outside this agreement do not impose tariffs on pharmaceuticals, a large number do. In fact, the value of worldwide biopharmaceutical trade in countries that are not parties to that Agreement increased at a compound annual growth rate of more than 20 percent between 2006 and 2013.[5]

Figure 1: The world's highest medicine tariffs

Source: WTO Tariff database



Policy recommendations

- ✔ **Non-members should join the WTO Pharmaceutical Tariff Elimination Agreement ("Zero for Zero" initiative).**
- ✔ **If this is not possible, countries that still levy tariffs should unilaterally abolish them.**

Eliminate other taxes on medicines

Domestic taxes and levies also contribute to the end price of medicines. Globally, VAT on medicine can reach up to 20%. Other taxes include state excise duty, stamp duty, community tax and other fees.[6] These mark-ups can inflate the end price of a medicine significantly: in Kenya, for example, mark-ups along the chain can add 300% to the manufacturer-selling price of a medicine, and 200% in Brazil (IMS Institute, 2014).[7]

Policy recommendations

- ✔ **Governments should review taxes imposed on medicines with a view to rationalisation, or preferably, abolition as long as such rationalisation or abolition doesn't create new or further distortions.**

Eradicate trade barriers at and behind the border

In addition to tariffs, there are still major obstacles to free trade, particularly at the border and behind borders. These so-called Non-Tariff Measures (NTMs) include inefficient customs procedures, cumbersome export/import procedures, administrative red-tape, hidden taxes, congestion fees and a generally sub-optimal trade infrastructure. For medicines, they also include burdensome labelling and packaging requirements, the need for importers to have multiple permits and licenses, and the requirement that imported medicines must pass through specific ports.[8] These barriers are often higher in LMICs.

- In India 3,958 instances of NTMs were reported in 2016, mainly labelling and packaging requirements.[9]
- A survey-based review of NTMs antimalarial drugs in developing countries found that 60% of interviewees faced burdensome NTMs, with the most commonly reported NTM relating to product registration and inspection requirements.[10]

The time and effort involved in navigating these procedures adds to the costs of trade in medicines, costs which are ultimately passed onto patients. For smaller markets, manufacturers might consider it unworthwhile to export, meaning that patients will enjoy fewer types of medicine and less competition.

Policy recommendations

- ✔ **Governments in LMICs should examine the existing stock of NTMs with a view to ensuring their consistency, utility and transparency. Superfluous regulations should be eliminated.**
- ✔ **Official forms and guidelines should be made available online.**
- ✔ **Countries that are supportive of open markets and free trade should push to include measures to reduce NTMs in Free Trade Agreements and Regional Trade Agreements.**
- ✔ **WTO members should continue to monitor the Trade Facilitation Agreement and ensure that all signatories abide by their commitments to reduce NTMs.**

Accelerate access to new medical technologies and medicines

Innovative treatments - both those recently and those yet to be developed – will be key to tackling the rising burden of non-communicable diseases in Low- and Middle-Income countries. In addition to completely new treatments, innovation in medicines is producing improvements of existing medicines that make them easier to use by patients and doctors, easier to store and transport, and more reliable.

Most patients in LMICs suffer significant delays before these innovations are available in their countries. Happily, there are several reforms which could address this problem.

Speed up the examination of medicine patents

A granted patent is a necessary precondition for launching a new drug in market. Too often, effective new medicines are held back from patients in LMICs due to delays and backlogs in patent examination at national patent offices.

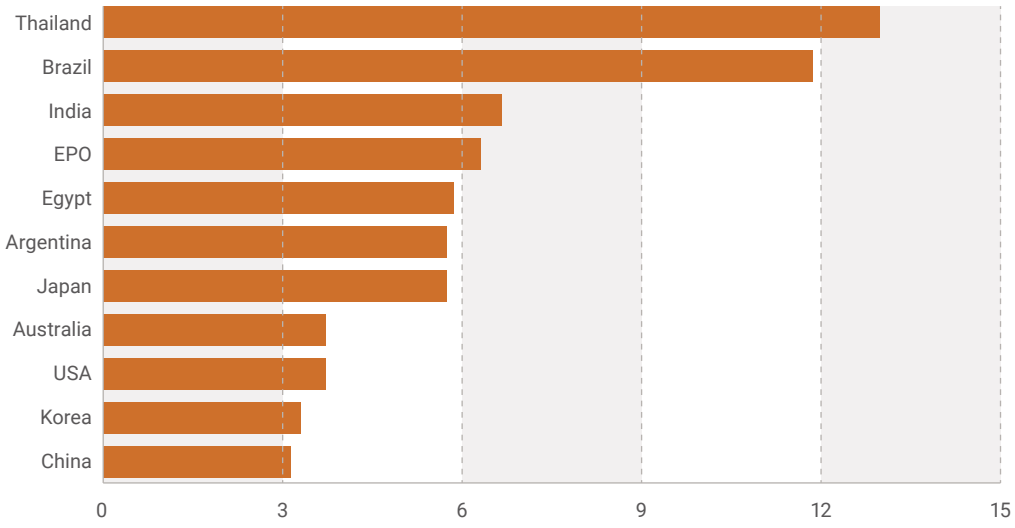
In some countries these backlogs can last almost the entire life of the patent. This means patients will not access that new medicine until many years after its first global launch. Studies have shown a link between weak patent protection and delayed market entry of drugs.[11]

Patent backlogs are particularly long for life sciences patents in LMICs:

- In Brazil, innovators face delays of up to 10 years for biopharmaceutical patents
- In Thailand it often takes more than 14 years on average to get a life sciences patent (Figure 2). In fact, Thailand regularly issues patents with only months or weeks of life left before expiration.

Figure 2: Average age of granted life sciences patents 2011-2015 (in years).

Source: Center for the Protection of Intellectual Property [12]



Policy recommendations

Reducing patent backlogs and increasing efficiency in patent offices is essential to accelerate access to the new medicines that will help achieve the health-related SDGs. Concrete steps have already been taken by several national patent offices to reduce patent backlogs, including India, Argentina, Brazil and Thailand.

- ✔ **National patent offices should hire more and better qualified examiners to tackle patent delay and backlog problems.**
- ✔ **Patents are increasingly filed in multiple jurisdictions, so to avoid duplication patent offices should share work or fast-track applications that have already been granted by recognised jurisdictions. One example is the Patent Prosecution Highway, in which different countries expedite patent examination if it has already been successfully submitted to a partner patent office in another country with similar patentability criteria.**

Speed up the process of drug regulatory approval

After a patent has been granted, patients face long waits for new treatments due to bottlenecks in national drug regulatory authorities.

Manufacturers wanting to export medicines to lower and middle-income countries must first receive marketing approval from the local drug regulatory authority, whose role is to ensure any new medicine is safe and efficacious before it can be made available on the market. This normally comes after and in addition to the product's initial regulatory approval by a stringent regulatory authority such as from the US food and Drug Administration (FDA) or European Medicines Agency (EMA).

The process of seeking subsequent approval from national regulatory authorities can add years of delay to the product's appearance on the market.

- In Latin America, overall regulatory approval times have increased over the last decade, with registration times of around two years in Brazil and Colombia (Figure 3)[13]
- Delays of an average 400-500 days exist in India, Taiwan, Singapore, South Korea and Malaysia.
- The medium review time for a new medicine is 1057 days in Indonesia and 800 days in China (Figure 4).
- In sub Saharan Africa there is a lag of four to seven years, on average, between initial submission of a drug or vaccine for regulatory approval (typically in a high-income country) and final approval in 20 sub-Saharan African countries.[14]

According to WHO, many of these delays are bureaucratic in nature, and are derived from overly complicated guidelines and assessment procedures; long timeframes for registration and administrative backlogs.[15] In addition, many national drug regulatory authorities are under-resourced. Further, registration requirements vary across countries and are unnecessarily duplicative, with national regulatory authorities typically failing to take advantage of prior reviews by external and potentially more mature regulatory authorities.

Figure 3: Average drug approval times in Latin America

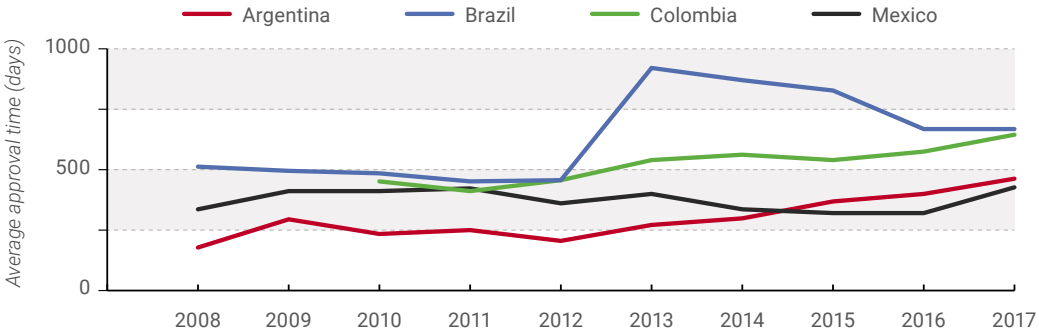
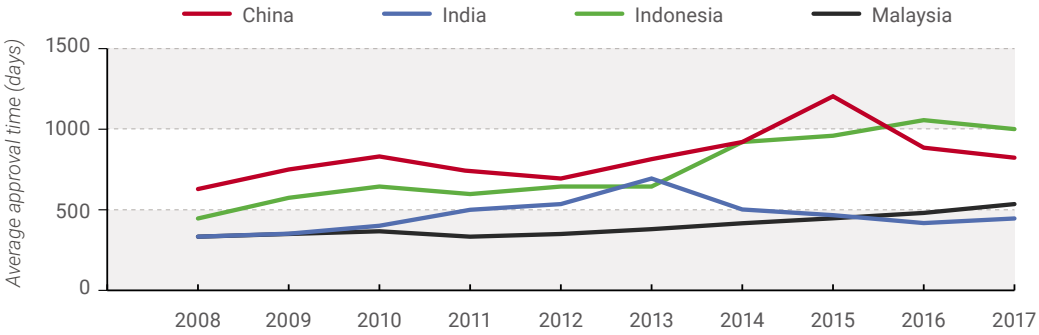


Figure 4: Average drug approval times in Asia



Some countries have taken steps to reduce drug registration backlogs. Mexico has reduced times by entering into cooperation agreements with other drug regulatory authorities.[16] Progress is expected in the Gulf states. Saudi Arabian, Jordanian and Egyptian regulators adopted in 2018 a system that bases new drug approvals on decisions already made by EU or US regulators. The objective is to reduce review times to 30 – 60 days compared to a year.[17]

Policy Recommendations

- **LMIC governments should strengthen regional agreements relating to mutual recognition procedures for regulatory approvals in order to accelerate access to both innovator and generic medicines (e.g., the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, the European Union Mutual Recognition Procedure, and the African Medicines Regulatory Harmonization Program)**
- **National regulatory authorities should accept clinical trials data generated overseas except where there is a compelling public health justification.**

Get new medicines onto public formularies more quickly

Once a medicine has received regulatory approval, it cannot be adopted by the public health system until the government decides whether it can be included on the National Formulary List and if so at what rate it will be reimbursed. Unfortunately, these decisions can take a very long time in certain countries, further delaying access to medicine and undermining patient choice:

- Turkey takes an average of one year to make reimbursement decisions, despite commitments by regulators there to deliver more timely decisions.[18]
- In Mexico, reimbursement delays add more than two years to the time taken for new drugs to gain market access.[19]

A major cause of this problem is that national formulary lists can be updated infrequently, meaning many years may pass before a new medicine can be included and made available to patients. For example, prior to 2017, China had only undertaken two substantive updates (2004 and 2009) to the National Reimbursement Drug List which delayed reimbursement by up to seven years.[20]

Policy recommendation

Patients are denied access to life saving medicines while government agencies decide whether or not they can be provided by the public sector.

- ✔ **In order to accelerate decision-making around whether to include a new medicine on public sector reimbursement lists, governments should update them constantly, instead of publishing new lists annually or less frequently. This would take better account of constantly changing technology and changing needs of patients.**

Promote open trade in medicines

New medicines will get to patients quickly if manufacturers are allowed to allocate resources and locate their operations in the way they deem most efficient. Many governments of LMICs interrupt these market processes through "localization barriers to trade." (LBTs) which require companies to locate specific parts of their value chain within their borders in return for license to operate. LBTs have grown significantly in recent years in the medicines sector[21] and include measures such as:

- Requiring multinational manufacturers to locate R&D activities or manufacturing facilities in the country (Russia).
- Banning the importation of drugs that have a locally-manufactured equivalent (Algeria).
- Explicitly favouring local companies in state procurement tenders, or prioritising locally-manufactured medicines in public-sector reimbursement formularies (Turkey).[22]

Many of these policies are protectionist in intent, and aim to promote industrialisation and economic development. But such protectionist policies balkanise value-chains and drive up the end price of medicines by requiring firms to create multiple and duplicative local manufacturing plants. They also reduce numbers of medicine suppliers, leading to higher prices, fewer choices and shortages, undermining progress towards public health and development goals:

- Algeria maintains import bans on over 300 medicines, which combined with insufficient local manufacturing capability have resulted in shortages of 320 mainly chronic disease treatments (including cardiovascular and cancer drugs as well as insulin).
- Indonesia has extremely poor availability of medicines despite its comprehensive localisation framework: only half of the drugs on the WHO's list of essential medicines are supplied in the local market, and a survey of 9,000 health centres found that 85% had less than 80% of the medicines on the country's essential medicines list are in stock.
- In Turkey, only 30% of drugs approved in the US and EU between 2011 and 2014 were available in Turkey during the same period, with this figure dropping to 4% between 2013 and 2014.

Policy recommendations

Medicines choice and access will improve more rapidly under conditions of market competition:

- ✔ **WTO members should work towards a stronger role for the WTO in enforcing existing laws regarding local content requirements and establish a comprehensive database to track LBTs worldwide.**
- ✔ **Instead of trying to promote industrialisation through protectionism, LMIC governments should look to make their economies more attractive to foreign investment by for example investing in human capital and physical infrastructure.**
- ✔ **Public procurement of medicines should be conducted transparently and in the best interests of the taxpayer.**

References

1. 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being.
2. Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.
3. UNGA to Begin Negotiating Declaration on Universal Health Coverage, IISD Knowledge Hub, https://sdg.iisd.org/news/unga-to-begin-negotiating-declaration-on-universal-health-coverage/
4. Bennett et al (2018) NCD Countdown 2030: worldwide trends in non-communicable disease mortality and progress towards Sustainable Development Goal target 3.4, The Lancet, 392: 10152, pp1072-1088
5. Banik, N. and P. Stevens (2015), "Pharmaceutical tariffs, trade flows and emerging economies," Geneva Network, available at http://geneva-network.com/wp-content/uploads/2015/09/GN-Tariffs-onmedicines.
6. The Global Use of Medicine in 2019 and Outlook to 2023." IQVIA Institute for Human Data Science, January 2019. https://www.iqvia.com/institute/reports/the-global-use-ofmedicine-in-2019-and-outlook-to-2023
7. IMS Institute for Healthcare Informatics (2014) "Understanding the pharmaceutical value chain"
8. Market Access Map (International Trade Centre), available at https://www.macmap.org/
9. Banik N and Singh S (2017) Demystifying the Role of 'Barriers at and behind the Borders 'in India: A Case Study of Pharmaceutical Products" CUTS International, available at http://www.cuts-citee.org/pdf/Discussion_Paper-Demystifying_the_Role_of_Barriers_at_and_behind_the_Borders_in_India.pdf
10. International Trade Centre, (2011) "Non-Tariff Measures and the Fight Against Malaria: Obstacles to trade in anti-malarial commodities", available at http://www.intracen.org/publications/ntm/Anti-Malaria/
11. Duggan et al, (2016) The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India, 106 Am. Econ. Rev. 99; Ernst R. Berndt and Iain M. Cockburn, (2014) The Hidden Cost of Low Prices: Limited Access to New Drugs in India 33 Health Affairs 1567; Iain M. Cockburn, Jean O. Lanjouw, and Mark Schankerman (2014, Patents and the Global Diffusion of New Drugs, NBER Working Paper 20492, http://www.nber.org/papers/w20492; Joan-Ramon Borrell (2005)., Patents and the Faster Introduction of New Drugs in Developing Countries, 12 Applied Econ. Letters 379
12. Schultz, Mark & Kevin Madigan (2016) "The Long Wait for Innovation: The Global Patent Pendency Problem": Center for the Protection of Intellectual Property; George Mason University (Fairfax, Virginia).
13. Patel P, McAuslane N, Liberti L. 2019. R&D Briefing 71: Trends in the Regulatory Landscape for the Approval of New Medicines in Latin America. Centre for Innovation in Regulatory Science. London, UK.
14. Ahonkhai et al (2016) Speeding Access to Vaccines and Medicines in Low- and Middle-Income Countries: A Case for Change and a Framework for Optimized Product Market Authorization. PLOS ONE 11(11): e0166515. https://doi.org/10.1371/journal.pone.0166515/
15. World Health Organization, "Assessment of Medicines Regulatory Systems in Sub-Saharan African Countries: An Overview of Findings from 26 Assessment Reports" (World Health Organization, 2010)
16. CIRSCI, 2019
17. Cortellis, "Steps taken to streamline regulatory processes in the Middle East", 22nd January 2018, available at https://clarivate.com/cortellis/blog/steps-taken-streamline-regulatory-processes-middle-east/
18. Datamonitor Healthcare (2016) "Health policy initiatives and funding issues drive rapid changes" available at https://pharmastore.informa.com/wp-content/uploads/2016/10/Key-Trends-in-BRICMIST-Market-Access_165412.pdf
19. Ibid
20. Ibid
21. Ezell S et al, 2013 "Localization Barriers to Trade: Threat to the Global Innovation Economy," Information Technology and Innovation Foundation, available at http://www2.itif.org/2013-localization-barriers-to-trade.pdf
22. Pugatch Consilium (2016), Separating Fact from Fiction – How Localization Barriers Fail Where Positive Non-discriminatory Incentives Succeed: A Global Assessment of Localization Policies and Incentivizing Life Science Investment and Innovation", available at https://www.pugatch-consilium.com/reports/Localization%20Paper_US_FINAL.pdf