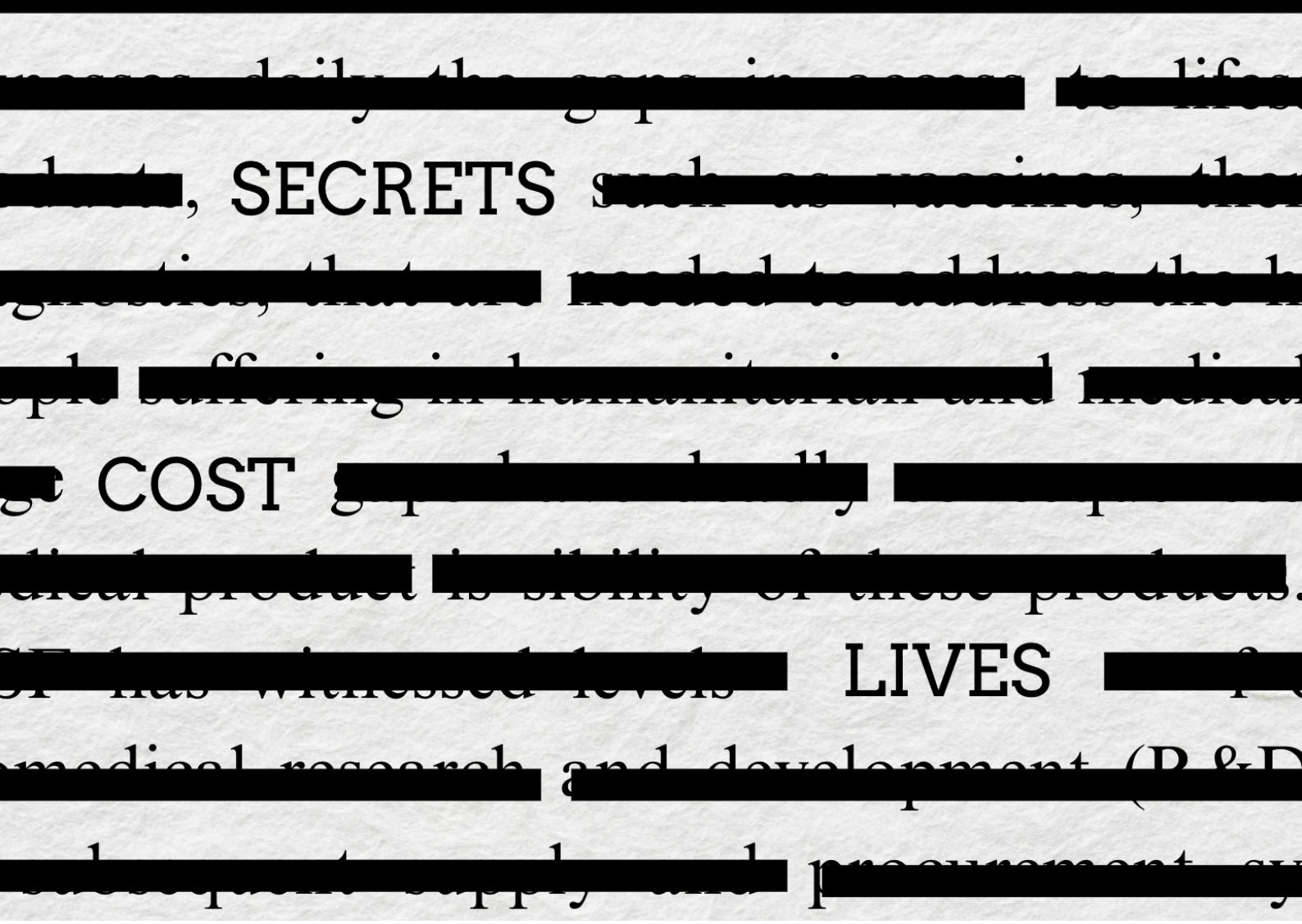


TRANSPARENCY AND ACCESS TO MEDICAL PRODUCTS

PROGRESS TOWARDS EQUITY IN ACCESS TO MEDICAL PRODUCTS CAN ONLY BE BUILT ON THE OPEN SHARING OF INFORMATION AND KNOWLEDGE, NOT ON SECRETS

JUNE 2024

ACCESS CAMPAIGN
MEDECINS SANS FRONTIERES

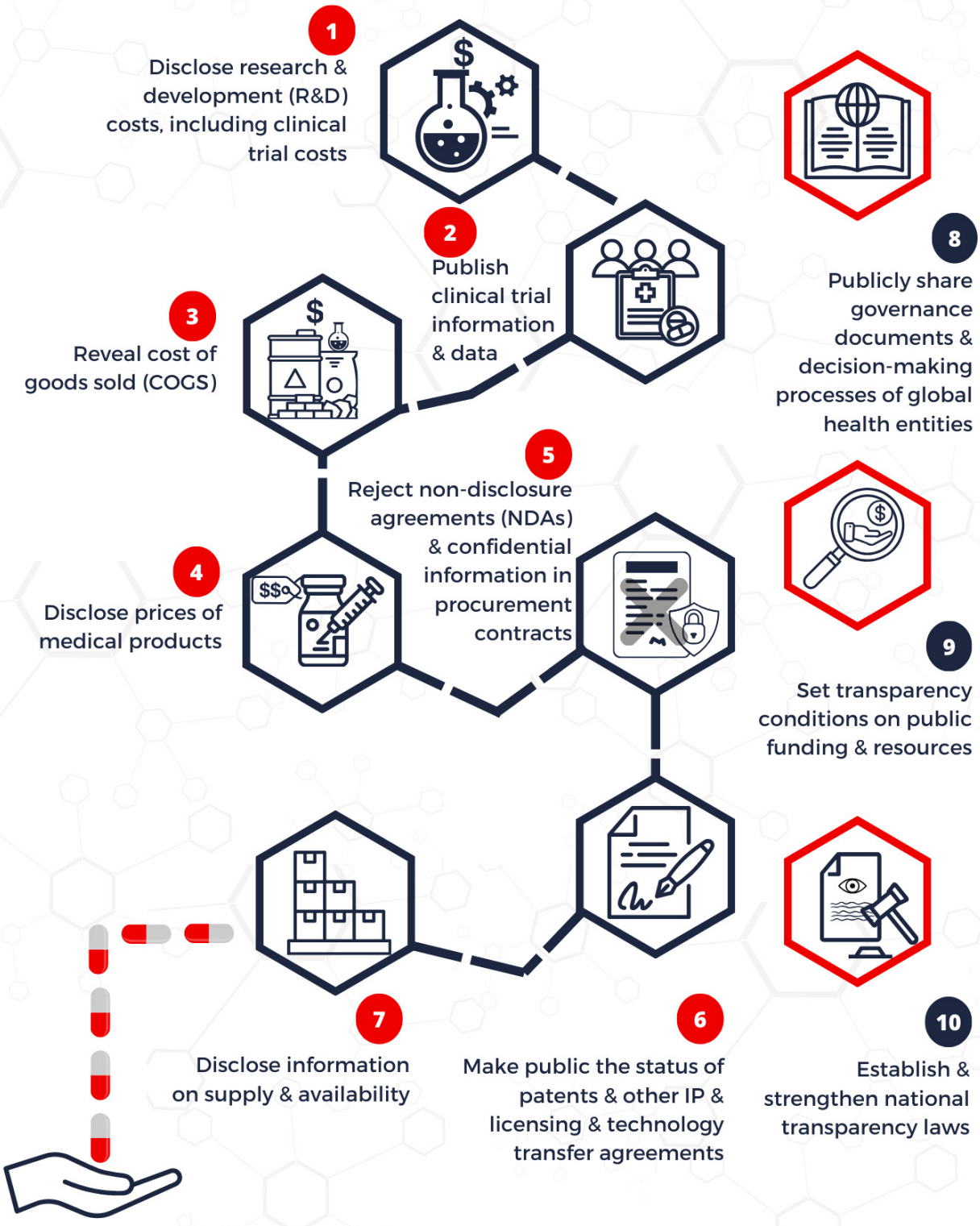
Médecins Sans Frontières/Doctors Without Borders (MSF) is an international, independent medical humanitarian organization that delivers medical care to people affected by conflict, disease outbreaks, natural and human-made disasters, and exclusion from health care. Founded in 1971, MSF has operations in over 70 countries today.
https://www.msf.org/

The MSF Access Campaign was launched in 1999, on the heels of MSF being awarded the Nobel Peace Prize. Rooted in MSF's medical operations, the MSF Access Campaign analyses and advocates for access to lifesaving medicines, diagnostic tests, and vaccines for people in MSF programes and beyond.
https://www.msfaccess.org/

Back cover photo:
MSF health promoter Lazare Bolepomi informing the people of Popokabaka, Democratic Republic of Congo, about an outbreak of typhoid fever, its symptoms, and how to prevent it. 2021.
Photo: Franck Ngonga/MSF

CONTENTS

TRANSPARENCY: 10 CRITICAL STEPS FOR ACCESS TO MEDICAL PRODUCTS



INTRODUCTION

As an international medical humanitarian organisation, Médecins Sans Frontières/Doctors Without Borders (MSF) witnesses daily the gaps in access to lifesaving medical products, such as vaccines, therapeutics, and diagnostics, that are needed to address the health needs of people suffering in humanitarian and medical crises. These gaps have deadly consequences.

Each time a medical product is out of reach, there are significant barriers in accessing critical information that determines the availability, affordability and accessibility of these products. For decades, MSF has witnessed astonishing levels of opacity in the biomedical research and development (R&D) system, and in subsequent supply and procurement processes. The lack of access to information has therefore itself become a barrier to equitable access to medical products.

The web of secrecy surrounding biomedical R&D, supply and procurement, has been systematically created and imposed by the biomedical industry, including pharmaceutical and diagnostics corporations. It is in their interest not to disclose this information as secrecy is the bedrock of monopolies they hold on medical products and the high prices they charge. This secrecy exists despite the majority of biomedical R&D initiatives receiving extensive amounts of public funding at one or more stages of their development, and despite multiple international reports, agreements and resolutions recognising the importance of transparency for sustainable access to medical products.[1,2,3,4] This information asymmetry between pharmaceutical corporations that hold this information, and everyone else that does not – including governments, treatment providers like MSF and patients – undermines efforts to ensure equitable access to lifesaving medical products, and ultimately costs lives.

This report focuses on the need for transparency in 10 areas: seven specific areas in the product development, supply and procurement processes, and **three cross-cutting areas** where decisive action can ensure transparency and access to information more broadly:

1. Cost of R&D, including clinical trial costs;
2. Clinical trial information and data;
3. Cost of goods sold;
4. Prices;
5. Non-disclosure agreements and confidential information in procurement contracts;
6. Status of patents, other IP, licensing and technology transfer agreements;
7. Registration and supply information;
8. **Governance and decision-making processes of global health entities;**
9. **Transparency conditions on public funding and resources; and**
10. **National transparency laws**

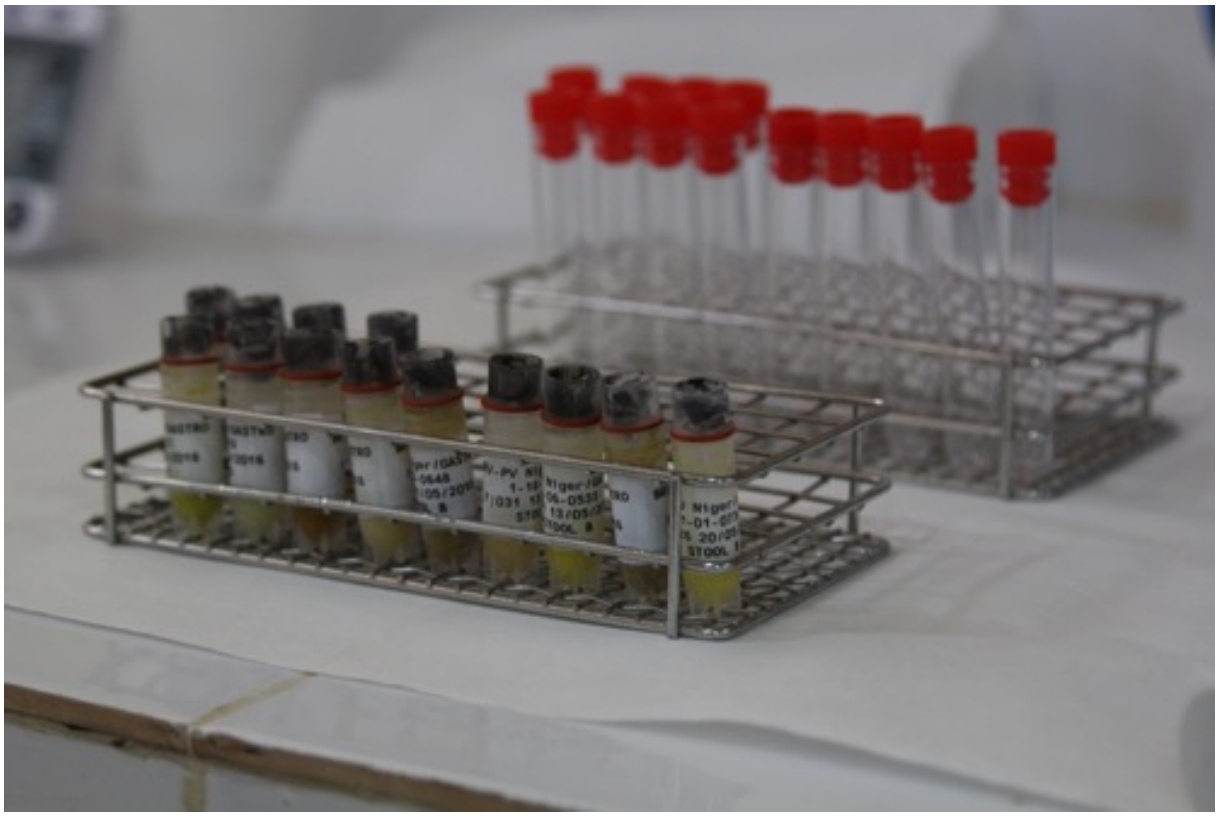
This is not an exhaustive list, but it aims to capture the information that, in MSF's experience of responding to multiple outbreaks, epidemics and pandemics, is most critical for access. These areas span across the lifecycle of medical products, from the early development stages to when they are supplied. The report also recommends actions for governments, pharmaceutical corporations and other stakeholders, and includes the steps MSF is taking, to reject secrecy as the status quo and ensure timely, equitable access. These actions are needed urgently if we are to overcome the overwhelming information asymmetry in the biomedical R&D processes that undermines efforts to save lives.

1. COST OF RESEARCH AND DEVELOPMENT (R&D), INCLUDING CLINICAL TRIAL COSTS

MSF has witnessed time and time again the impact of high prices on access to lifesaving medical products.[5,6] The pharmaceutical industry has created and perpetuated the narrative that high prices are needed to recoup R&D costs and sustain future innovation. However, research has shown that there is no link between high drug prices and industry's spending on R&D.[7,8] Despite this, industry R&D estimates are still used to inform R&D policy and drug pricing debates. This raises fundamental questions about how much it actually costs to develop a medical product, and how much it would cost – and how this would change the R&D landscape and access to these products – if it were to be financed and incentivised differently.

Estimates for the R&D of new drugs range widely, from US$43.4 million to $4.2 billion, based on what is included as an R&D expenditure.[4] Industry estimates include elements that go beyond out-of-pocket R&D costs. These include:

- Cost of capital: also known as cost of borrowing, this represents the returns that the investor



Samples to be analysed in a lab in Maradi, Niger, during a clinical trial of a rotavirus vaccine. 2016. Photo: Séverine Bonnet

could have gained if they had spent money on an alternative investment with equal risk. Accounting for cost of capital alone is enough to double the overall R&D cost estimate. For example, for the widely cited industry R&D cost estimate of $2.6 billion, nearly half the amount ($1.2 billion) was ascribed to the cost of capital.[9]

- Risk adjustments: this refers to the cost of failures, or the money spent by a corporation on other drug candidates that they cannot recoup through sales, as these products could not be brought to market for various reasons. Accounting for the risk of failures varies substantially across different types of R&D projects.

Research has shown that there is no link between high drug prices and industry's spending on R&D. Despite this, industry R&D estimates are still used to inform R&D policy and drug pricing debates.

Drugs for Neglected Diseases initiative (DNDi), a non-profit organisation that develops new treatments for neglected diseases, is one of the only entities to have previously published information on their R&D costs.[10] For the full R&D process for new formulations or new combinations of existing drugs, it cost DNDi between $4.3-10.7 million (raw figure)/$4.3-12.9 million (with attrition); for a new chemical entity, it cost between $48.3-75.1 million (raw figure)/$64.4-203.9 million (with attrition). While these figures cannot be considered a direct comparison with industry estimates because there are many methodological and other technical differences—including in-kind drug donations, for example—they do show an *"order of magnitude difference when comparing this real-life costing data with some of the industry estimates."*[i]

Ultimately, the huge variation in R&D cost estimates, and speculation around what is or is not included in these estimates, only serves to highlight the urgent need for fully transparent and publicly available information on disaggregated R&D costs.

CLINICAL TRIAL COST TRANSPARENCY

Since clinical trials are widely accepted as the most expensive part of the R&D process, information about the true costs of clinical trials would contribute substantially to public understanding of the key out-of-pocket cost drivers of the overall R&D process. A systematic review conducted in 2017 on the costs of randomised controlled trials (RCTs) found 56 articles, none of which provided empirical cost data for all aspects of a trial. It found that overall costs ranged from $0.2–$611.5 million per RCT. However, the authors highlighted that the studies use different methodologies, and concluded that there was a lack of transparency and comprehensive data.[11] As part of the literature review for the TB-PRACTECAL costing analysis outlined below, cost estimates for pharmaceutical phase 2 and phase 3 clinical trials ranged between $5-142 million (€4.7-133 million).[14]

[i] Rachel Cohen, then Executive Director, DNDi North America, speaking at a webinar on clinical trial cost transparency in 2022. See: https://msfaccess.org/transparency-matters-clinical-trial-costs

CASE STUDY: MSF's efforts to operationalise and promote greater transparency of clinical trial costs

Dr Louisa Dunn, a sub-investigator for the TB-PRACTECAL clinical trial, consults with a patient. 2018. Photo: Oliver Petrie/MSF

Recognising the need for more publicly available information about clinical trial costs, MSF is taking steps to publish the costs of clinical trials we carry out. In October 2022, MSF approved and published its first Clinical Trial Transparency Policy (CTTP).[12] This policy is a commitment to publishing research protocols, registering clinical trials on appropriate registries, and subsequently publishing clinical trial data in open access formats, in line with the WHO joint statement on public disclosure of results from clinical trials, to which MSF is a signatory.[13] Critically, it also includes commitments to publishing a minimum set of cost items for clinical trial costs.

As a first step to implementation of the CTTP, MSF published the costs of the TB-PRACTECAL clinical trial in April 2024.[14] MSF led the TB-PRACTECAL phase 2b-3 trial, which identified a new treatment regimen for DR-TB in 2022.[15] The results of this landmark trial led to WHO recommending a 6-month, all-oral regimen of bedaquiline, pretomanid, linezolid, and moxifloxacin [BPaLM] as the preferred treatment for rifampicin-resistant TB.[16] This regimen has been adopted for use in 40 countries until now.[17]

MSF found that TB-PRACTECAL cost a total of $36.4 million (EUR33.9 million). While the topline results were presented at the WHO Pharmaceutical Pricing and Reimbursement Information (PPRI) conference in April 2024, the detailed costs of the clinical trial have been submitted for a peer-reviewed publication to a journal. At the time of writing, this paper is still under consideration by the journal. In the full publication, the costs are broken down into 27 cost

categories, by year, and by trial site, in order to offer a high level of transparency. This study will be, to our knowledge, the first time the detailed costs of an individual clinical trial will have been shared publicly, challenging the lack of transparency around drug development, and the prevailing public and policy narrative that high prices are needed to recoup high R&D costs.

Building on this costing exercise, MSF developed "Transparency CORE", a clinical trial cost reporting toolkit, to encourage and support other public and non-profit actors to publish their clinical trial costs.[18] The cost categories suggested aim to be sufficiently granular to identify key cost drivers, while being broad enough to provide an overview and allow comparison across different trials. In addition to supporting other actors, we hope Transparency CORE can support the development of national policy and international standards for clinical trial cost reporting through demonstrating practical feasibility – since most actors capture some costs, but not all in the same cost categories, and none make them publicly available. A standard for clinical trial cost reporting (in a STROBE-like manner[ii]) would be a transformative step towards greater transparency, in line with the 2019 WHA transparency resolution 72.8, which urges member states to improve transparency of clinical trial costs.[2]

Overall, transparency of R&D costs is critical for four interrelated reasons related to access to medical products:

1. **Challenging high prices:** Only when there is full transparency of disaggregated R&D costs can evidence-based, sensible conversations be had, and decisions made, about R&D policy to ensure fair prices and equitable access. Access to disaggregated information about the true costs of R&D would increase the ability of governments, treatment providers, patients and access groups to challenge high prices. This was the case for bedaquiline, a lifesaving DR-TB medicine, whose high prices hampered much-needed access for a decade.[19] Academic research on bedaquiline revealed that the public sector invested up to five times more than private investors in the R&D of the medicine. This information formed a central component of global activism led by TB survivors demanding that Johnson & Johnson lower the price of bedaquiline, which led to significant price reductions.[21, 22]

2. **Informing alternative innovation incentives:** Beyond pricing, granular data on R&D costs can inform the design of future R&D initiatives, including innovative R&D financing mechanisms – particularly for areas where there is a lack of commercial interest due to lack of profitability, such as TB and antimicrobial resistance (AMR). For example, the role of clinical trial cost transparency has been explored extensively in informing the development of appropriate financial incentives to stimulate R&D to tackle AMR.[23]

[ii] STROBE stands for an international, collaborative initiative of epidemiologists, methodologists, statisticians, researchers and journal editors involved in the conduct and dissemination of observational studies, with the common aim of **STrengthening the Reporting of OBservational studies in Epidemiology**. See: https://www.strobe-statement.org/

3. **Support R&D initiatives in low-resource settings:** One of the challenges MSF faced while planning the TB-PRACTECAL trial was the lack of publicly available disaggregated data on clinical trial costs.[24] Access to disaggregated data on R&D and clinical trial costs would support trial budgeting, grant applications and allocation, and fundraising, especially for non-profit or publicly financed R&D initiatives in low-resources settings.

4. **Accountability and maximising impact of public funding:** Where public funds are invested in R&D and clinical trials, the disaggregated costs of these initiatives should routinely be made publicly available in the public interest. In addition, this would allow the public and independent experts to compare clinical trial expenditures and identify inefficiencies.

There is increasing recognition by policymakers that the lack of transparency around R&D costs is undermining efforts to ensure equitable access to medical products. The Report of the UN Secretary-General's High-Level Panel on Access to Medicines in 2016 concluded that access to information on R&D costs was critical to "realize a fair public return for public investment".[1] The report called for "timely, comprehensive and user-friendly databases on costs and prices." The Pan American Health Organisation (PAHO) Resolution of 2016 on "Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies" calls for more transparency and access to timely and comprehensive information including on R&D costs, in order to "improve decision-making, avoid waste, and improve affordability of medicines and other health technologies". In addition, the World Health Assembly (WHA) transparency resolution in 2019 called for Member States to improve access to information on the costs of clinical trials.[2] There is an increasing number of domestic and regional initiatives that require disclosure of the costs of R&D, including in Brazil, the EU, France and Italy.[26,27,28, 29, 30, 31]

In the US, the proposed Pharmaceutical Research and Transparency Act would mandate clinical trial cost transparency.[32, 33] This Act has been informed by a New York University (NYU) report titled "Clinical Trial Cost Transparency at the National Institutes of Health (NIH): Law and Policy Recommendations".[34] This groundbreaking report examines the need for cost transparency into pharmaceutical R&D and, specifically, into the costs of clinical trials funded by the US NIH, and proposes a set of legislative, administrative, and other reforms to achieve this goal. The US NIH is the largest public funder of biomedical research in the world, with an annual budget of $48 billion.[35,36] In addition to making the case for clinical trial cost transparency at the NIH, the NYU report proposes a set of clinical trial cost reporting items, to make this proposal both effective and implementable. These reporting items formed the basis of the recommended cost items to include in the MSF CTTP, and went on to inform the development of the MSF Transparency CORE toolkit as outlined in the case study box.

RECOMMENDATIONS

Governments should enact legislation to mandate disclosure of disaggregated R&D costs, including clinical trial costs, particularly but not limited to when the R&D initiatives have received public funding.

Governments should require timely disclosure of clinical trial information and data, as above, as a condition when committing public money for clinical trials or other rewards such as PRVs or tax credits, and as part of licensing agreements.[iii,iv,v]

Other actors that fund or conduct R&D, including pharmaceutical and biomedical corporations, public institutions, philanthropic organisations, and product development partnerships (PDPs), should disclose disaggregated R&D costs and investments in entirety, particularly but not limited to when they have received public funding.

Governments, stakeholders and civil society organisations (CSOs) should advocate for the inclusion of clinical trial cost transparency in the implementation work of the WHA 75.8 Clinical Trial Resolution.

Other actors involved in the delivery of R&D and clinical trials should take steps to proactively publish the full, disaggregated costs of clinical trials. Guidance for the disclosure of clinical trial costs can be drawn from the Transparency CORE toolkit.

WHO should lead the development of international reporting standards for clinical trial costs, building on the MSF Transparency CORE toolkit, as part of efforts to implement the 2019 WHA transparency resolution 72.8.

2. CLINICAL TRIAL INFORMATION AND DATA

A frontline worker being vaccinated during a clinical trial for the rVSV-ZEBOV vaccine against Ebola virus disease in Conakry, Guinea. 2015. Photo: Yann Libessart/MSF

Clinical trial transparency refers to the degree to which the design and outcomes of a trial are publicly accessible. This includes registration of the trial on an appropriate trial registry, publication of the trial protocol, and timely publication of the results in sufficient detail.[37] Transparent publication and reporting of such clinical trial information and data is necessary from an ethical perspective, in order to respect the contribution and rights of patients, but also to prevent wasteful duplication of research and to enhance innovation and development. Drug regulators rely on data from clinical trials to decide which medical products to approve, while public health bodies rely on trial data to make decisions regarding access to products and in developing public health guidelines. Medical professionals rely on trial data to recommend treatment choices to their patients. Therefore, ensuring the transparent reporting of clinical trials and the data they generate is paramount.[xxxiii] Greater transparency in this regard is fully implementable while protecting medical ethics, patient privacy and data protection regulations.

Recognising the urgent need for, and benefits of, transparent and timely information and data from clinical trials, in 2017 MSF signed the WHO joint statement on public disclosure of results from clinical trials alongside 22 other signatories involved in conducting or funding clinical trials, such as the Coalition for Epidemic Preparedness Innovations (CEPI), DNDi, the Wellcome Trust, Bill and Melinda Gates Foundation (BMGF), FIND, and a number of governments.[13] Signatories to this statement committed to registering clinical trials on appropriate registries, publishing research protocols, and subsequently publishing clinical trial data within 12 months of trial completion, in open access formats wherever possible. The joint statement recalls the 2013 amendment to

the Declaration of Helsinki, which states that "*Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject*" and that "*Researchers have a duty to make publicly available the results of their research .... Negative and inconclusive as well as positive results must be published or otherwise made publicly available.*"[38]

In addition to voluntary actions by funders and implementers of clinical trials to improve transparency of clinical trials, there is an urgent need for domestic legislation to mandate disclosure of all clinical trial protocols and results in a timely manner.

CASE STUDY: COVID and the WHA Clinical Trial Resolution

A lack of sufficient transparency and information on clinical trials, at best, wastes time and resources, and at worst, can cause harm to patients. Notable examples were outlined in a 2022 report on COVID clinical trial integrity by TranspariMED and Health Action International (HAI).[39] The report shows that by October 2020, nearly a third of the 526 trials registered during the first 100 days of the COVID pandemic had not recruited a single patient, and only 10% had made their results public. The vastly different design of these small trials and the lack of outcome data meant that many of these efforts ended up as research waste. Research exploring the use of hydroxychloroquine (HCQ) as a COVID treatment is a stark example. Early research indicated that HCQ might be an effective COVID treatment, and as a result, HCQ began being administered to patients. 84 separate HCQ trials were registered worldwide in 100 days. But before most of those small trials had been completed or reported results, strong evidence from two large high-quality trials, the RECOVERY and SOLIDARITY trials, showed that HCQ provided no benefit to COVID patients.[40, 41, 42, 43] Following the results of these trials, WHO did not recommend HCQ for the treatment of COVID, and has since stated that "Taking hydroxychloroquine to treat COVID-19 may increase the risk of heart rhythm problems, blood and lymph disorders, kidney injury, liver problems and failure."[44] These examples highlight the importance not only of trial design, size and coordination, but also, critically, of the timely publication of trial protocols and results.

Following many of the challenges around clinical trial research wastage during the COVID pandemic, and recognising the huge importance of high quality well-coordinated clinical trials, the UK and Argentina led the adoption of a resolution on clinical trials at the WHA in 2022. The resolution urges member states and research funding agencies to improve transparency of clinical trials through "timely reporting of both positive and negative interpretable clinical trial results... including through registering the results on a publicly available clinical trial registry... and encouraging timely publication of the trial results preferably in an open-access publication."[45]

While this resolution is a significant step forward, it misses the opportunity to enshrine equity and access to the end products in clinical trial policy and governance, and also fails to recognise the importance of clinical trial cost transparency, as outlined above. These omissions highlight the importance of considering the bigger picture and the role of clinical trials within the broader R&D ecosystem, rather than as vertical stand-alone initiatives, and how getting clinical trial governance right can ensure equitable access to health products at large.

RECOMMENDATIONS

Governments should enact legislation to mandate disclosure of clinical trials results data within 12 months of trial completion, including failed, withdrawn, and successful trials, and of trial data for medicines already on the market. In addition, the legislation should mandate that all clinical trials be registered on appropriate registries, and research protocols be published no later than when trial results are disclosed.

Governments should require timely disclosure of clinical trial information and data, as above, as a condition when committing public money for clinical trials or other rewards such as PRVs or tax credits, and as part of licensing agreements.

Philanthropic organisations, private funders, PDPs and other actors that fund or conduct clinical trials should take steps to ensure proactive and full disclosure of clinical trial information and data.

National regulatory agencies should ensure enforcement of relevant clinical trial results reporting legislation to ensure compliance and impose sanctions for non-compliance when necessary.

[iii] The FDA's PRV programme grants clinical trial sponsors that successfully register an eligible medicine or vaccine a 'voucher' for priority review of another product that would not qualify for an accelerated review on its own merit.

[iv] Licensing agreements allow materials or technologies under intellectual property rights (IPR) to be used or made by another company (licensee). In this context, license agreements enable medical products under IPR to be made by companies beyond the originator, such as generics, under certain conditions.

[v] Tax credits are an incentive for R&D, whereby the government reduces the amount of tax a company has to pay in order to reduce R&D costs to companies and increase the public share of these costs.

3. COST OF GOODS SOLD

Siwar, 6, holds up an insulin pen used in her treatment for type 1 diabetes by MSF in Arsal, Lebanon. 2023. Photo: Carmen Yahchouchi/MSF

Similar to R&D costs, there is routinely little to no publicly available information regarding the cost of goods sold (COGS) of medical products, unless independently commissioned or investigated. COGS refers to the direct costs of producing the goods sold (in this context, a medical product), including the cost of the materials and labour directly used to create the good. The costs of larger investments in manufacturing infrastructure – for example, building a manufacturing plant – are also important, and can be included in COGS as amortised capital expenditures (capital expenditures attributed across the number of years that represent the expected lifespan of the relevant manufacturing infrastructure).

Knowing the COGS is a critical component of efforts to define a fair price for a medical product and to push for price reductions when high prices undermine access. This is key for planning procurement and treatment programmes. Information on COGS for TB, HIV and hepatitis C medicines have supported efforts to lower their prices.[46,47,48]

There is also precedent for using COGS data in regulatory and legal processes. Bangladesh, China, Iran, and Pakistan have implemented some form of "cost-plus" price regulation.[49] In South Africa, COGS data transparency is incentivised with additional payments in certain circumstances.[50] In jurisdictions with "excessive pricing" doctrines within their competition law, COGS data are vital. An OECD review noted that the lack of COGS data has been an impediment to states pursuing competition cases.[51] In the US, estimates of insulin COGS were

included in a suit alleging excessive pricing and unfair business practices by the 'Big 3' insulin manufacturers (Novo Nordisk, Eli Lilly, and Sanofi).[52]

Independent COGS analyses have consistently revealed that the sales price of medical products is not based on the COGS but on what the market can bear. For example, a recent analysis of the price of diabetes medicines found that a newer class of drug, glucagon-like peptide-1 receptor agonists (GLP-1s), could be sold at a profit for just $0.89 per month, but is sold at much higher prices globally, including at least $353 in the US, which represents a markup on COGS of 40,000%. Similarly, one pre-filled human insulin pen could be sold at a profit for $0.94, but is sold at much higher prices, including at least $90.69 in the US.[53] These products are out of reach for many people living with diabetes, including in many LMICs where MSF works, mainly due to the exorbitant prices. The case study below outlines an example of how transparency on COGS supported the push for a price reduction on GeneXpert diagnostic tests.

As COGS are not usually revealed by manufacturers, they are sometimes estimated through different methodologies to provide the public with some level of evidence about the production costs in the context of sales prices. However, in order to ensure COGS analyses for medical products are conducted in a consistent manner, it is important to develop standardised methodologies. Due to the fundamental differences between different types of medical products and what needs to be included in COGS for each, different methodologies are needed. For medicines, a standard methodology for COGS has been used for all medicines included in the WHO Model Lists of Essential Medicines (EML).[54,55] This methodology provides an estimated cost-based generic price including costs of formulation, packaging, taxes, and a profit. However, a COGS methodology has not been included in official guidance by WHO or other multilateral health organisations.

Knowing the cost of goods sold is a critical component of efforts to define a fair price for a medical product and to push for price reductions when high prices undermine access. This is key for planning procurement and treatment programmes.

For diagnostics, too, a standardised methodology for COGS has not been developed or published. FIND, a global health non-profit organisation, included transparency of COGS and COGS-based-pricing as a condition to disburse funding for the development of molecular diagnostic platforms for decentralised diagnosis of acute respiratory illness during the COVID pandemic.[56] As a result and given their expertise and experience in this area, FIND would be well placed to coordinate a process to develop a standardised methodology for estimating COGS for diagnostics.

In addition to developing standardised methodologies for calculating COGS, work also needs to be done to determine who would be best placed to conduct COGS analysis for medical products. The case study below highlights how COGS transparency supported the push for a price reduction of GeneXpert diagnostic tests and demonstrates the need not only for a standardised methodology for COGS analysis, but also for it to be conducted by an agreed independent third party and made publicly available in full.

CASE STUDY: MSF's "Time for $5" campaign for transparent pricing of diagnostics

GeneXpert, a rapid molecular diagnostic technology developed by the US-based corporation Cepheid, has revolutionised timely diagnosis for many diseases, including TB, HIV, hepatitis B and C, COVID, and various sexually transmitted diseases. Despite exponential growth in sales since 2012—when these tests became available in LMICs—the price of most tests remained unchanged at $10-20. National health programmes and non-governmental treatment providers like MSF have struggled with the high prices of the tests.

In 2018, faced with lack of transparency from Cepheid, MSF commissioned an independent COGS analysis to estimate the cost of production of these tests. The analysis estimated that the cost of producing a GeneXpert test cartridge, regardless of the disease for which it is used, is between $3.00 and $4.60.[57]

Therefore, while Cepheid and its parent corporation Danaher can sell GeneXpert tests for different diseases profitably at $5, they have charged LMICs 2-5 times what it costs them to make each test for more than a decade. Further, Cepheid received over $250 million in public funding, primarily from the US government, for the R&D of GeneXpert, which makes these high prices even more unjustified.[58] The "Time for $5" campaign – a coalition of 150+ CSOs coordinated by MSF, Partners in Health and Treatment Action Group – is a global campaigning and advocacy effort that calls for making GeneXpert tests accessible and affordable at $5.[59]

On 19 September 2023, under unprecedented pressure from the Time for $5 campaign, together with TB activists from around the world, including author and philanthropist John Green and the online community Nerdfighteria, Cepheid and Danaher reduced the price of the TB test by 20%, from $9.98 to $7.97.[59] In announcing the price reduction, Danaher stated that reducing the price to $7.97 meant "selling at its cost" with "no profit".[60] The difference between the independent MSF COGS analysis and this Danaher "at cost" price demonstrates the need for the development of a standardised COGS methodology, and for these analyses to be conducted by an agreed third party with full transparency.

Moreover, the price of all other GeneXpert tests remains unchanged, and the campaign continues to heap pressure on the corporations to extend the price reduction to all tests while calling for greater transparency.

To improve transparency and enable public scrutiny of prices set by manufacturers, MSF and CSOs have long advocated for COGS analysis and transparency of COGS to be attached as conditions to funding agreements with developers. As mentioned above, FIND has included such conditions for its funding for diagnostics. FIND also retains the right to require the manufacturer to transfer its technology, know-how and associated IP licenses to another manufacturer if transparency requirements are not met. This is an important step towards pro-transparency conditions in public funding agreements with implications for non-compliance, and an example of how this approach can become the standard when public investments are made in the R&D of any medical product.

RECOMMENDATIONS

WHO should lead on the development of a standardised COGS methodology for medicines, building on currently available methodologies, including the one used for the analysis of medicines on the EML.

WHO should develop criteria to identify medical products for which COGS analysis would most urgently be needed, and publish priority lists of such products. This could prioritise, for example - high-priced products, products with one supplier, originator products, or products where high prices are undermining access.

FIND should lead on development of a standardised COGS methodology for diagnostics, which should be supported by WHO.

Governments and buyers, including multilaterals conducting public procurement, should require publicly available COGS analysis for medical products as part of procurement negotiations with manufacturers. The COGS analysis should use a standard methodology, recommended above to be established by WHO. It should be conducted by an agreed independent third party.

Governments and other funders of R&D should require publicly available COGS analysis as a transparency condition when funding R&D of medical products, particularly for publicly funded R&D, or as a condition attached to rewards such as PRVs or tax credits. The COGS analysis should use the standard COGS methodology as defined by WHO, and it should be conducted by an agreed independent third party.

4. PRICES

Transparency of prices paid for medical products is critical to enable benchmarking for other buyers, and to negotiate lower prices; it is not possible to have a fair price negotiation without transparency. However, just as there are no obligations for pharmaceutical and diagnostics corporations to reveal disaggregated R&D costs for each product, there are often no obligations for them to reveal the prices they charge in procurement agreements. Indeed, final (net) prices agreed with procurers are shrouded in secrecy and increasingly protected through confidential terms as part of non-disclosure agreements (NDAs) (detailed in section 5). The lack of transparent pricing information leaves governments and treatment providers like MSF negotiating prices blindfolded, and often allows prices to go unscrutinised.

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While pharmaceutical corporations often claim that through tiered-pricing efforts they charge lower prices to lower-income countries, evidence has repeatedly shown that this is not always the case and, in some cases, the opposite is true. As a result, prices can vary for the same medicine depending on who is buying, and are not always correlated to the income status of countries.[61,62] For example, Pfizer's pneumococcal conjugate vaccine (PCV13) has been sold at higher prices in Tunisia and Morocco (both lower middle-income countries) than in France.[63] A WHO EU report concluded that "*some lower-income countries and small markets do not have access to high-priced medicines, even if they are willing to agree to a secret deal. If supplied, they tend to pay higher list prices and/or they are granted no discounts*". It went on to state "*Governments, even in high-income countries, feel pressured into accepting conditions and prices they consider unfavourable. With the loss of knowledge resulting from non-transparent deals, they are no longer on a level playing field with the industry*".[64]

Information about the list prices paid for medical products is available in many countries.[64,65] For example, a pharmaceutical pricing database in the US includes prices that have been negotiated by the US Federal Schedule Service with additional pricing concessions for the US Department of Veterans Affairs in return for a commitment to potential vendors.[66] The need for price transparency is entrenched in the South African constitution, and the South African Medicines Price Registry provides an Excel file with information on manufacturer prices.[67, 68] However, there is very limited transparency on the net prices (the actual prices paid after negotiations, rebates and discounts).[69] Discounts and rebates can vary between buyers, but are also often granted only on condition of confidentiality, further impairing transparency and leading to a distortion of medicines prices.[70,71] The pharmaceutical industry attempts to use confidentiality requirements to ensure the prices of medical products remain undisclosed, likely because there is substantial evidence to show that price transparency lowers prices and therefore impacts profit margins.

Since 2001, MSF has documented and published the prices of HIV antiretroviral (ARV) medicines in its Untangling the Web (UTW) report series (2001-2020) and subsequent publications.[72] These reports analyse access barriers to affordable, lifesaving diagnostics and treatments for HIV and opportunistic infections, and include updated drug pricing information from manufacturers. This report is consistently shared and used by ministries of health, CSOs, WHO and other stakeholders working to reduce prices and improve access to ARVs. MSF has also undertaken similar initiatives for hepatitis C (HCV) and TB medicines.[73, 74]

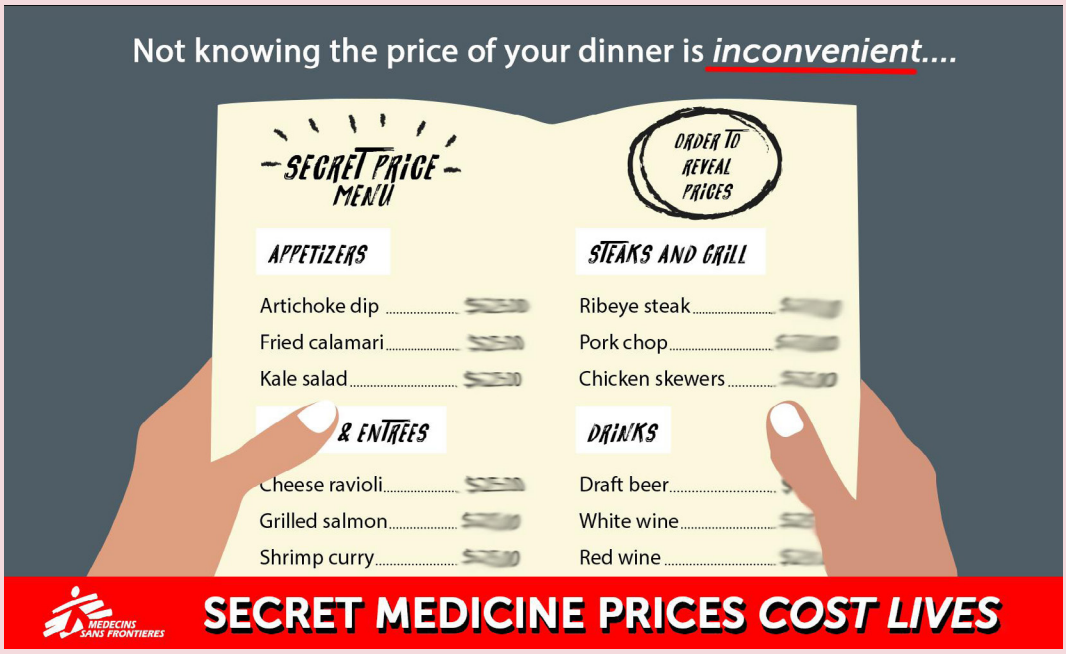
As part of the work related to the implementation of the WHA 72.8 transparency resolution (see explainer box for more details), WHO has noted the "high prices for some medical products, and inequitable access to such products within and among Member

States", and the role that price transparency can play in addressing these challenges. As such, WHO recommends that countries improve the transparency of pricing and prices through sharing the net transaction prices of pharmaceutical products, disclosing prices along the supply and distribution chain, and publicly reporting the R&D contributions from all sources.[75]

Market Information for Access to Vaccines (MI4A) is a WHO initiative launched in 2018 for countries that are mostly excluded from international support mechanisms for vaccines, such as Gavi, the Vaccine Alliance (Gavi). As part of this effort, a range of information around vaccine procurement, including vaccine price per dose, volumes and manufacturers, is reported by over 150 countries through the WHO/UNICEF Joint Reporting Form.[76] This information is then used to inform global access strategies. According to WHO, as a result of this initiative, countries have saved millions of dollars in vaccine procurement: Eswatini achieved an 87% price reduction on hepatitis B vaccines, 65% price reduction for the combined diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenzae B vaccine (DTP-HepB-HiB) and a 17% reduction for PCV13; North Macedonia achieved a 77% price reduction on the price of human papillomavirus (HPV) vaccine; Iraq saved $70 million following a data-informed vaccine dosing schedule change in 2019.[76]

In addition to MI4A, other examples of using price transparency to lower prices of medical products include the Strategic Fund of PAHO - Strategic Fund of PAHO, the Global Fund's Price and Quality Reporting System,and the UNASUR database for sharing prices of medicines that are publicly procured.[77,78,79] These efforts have reaffirmed the role of price transparency in negotiating fair prices and ensuring equitable access to medical products. Governments must heed this evidence, build on these efforts and work together to tackle the information asymmetry in price negotiations with pharmaceutical corporations by ensuring that the prices they pay for medical products are transparent.

Activists protesting vaccine pricing policies in front of the headquarters of pharmaceutical corporation Pfizer in New York, USA. 2015. Photo: Victor J Blue.



EXPLAINER: WHA 72.8 Transparency Resolution

What is it? In response to the growing secrecy around the prices of medical products, member states adopted the WHA 72.8 resolution "Improving the transparency of markets for drugs, vaccines and other health-related technologies" in 2019.[2]

Why is it important? This resolution was the result of a historic mobilisation of governments and CSOs calling for greater transparency to improve equitable access to medical products. The adopted resolution included calls for improved transparency of net prices of medical products, clinical trial results and costs data, patent status information, as well as improved reporting of information by suppliers on registered medical products. By recognising the need for such information for governments and other buyers for fair price negotiations, this resolution attempted to address the information asymmetry and power imbalance that exists between sellers and buyers of medical products.

What is missing? While this resolution is an important step, many elements that are needed to ensure equitable access are missing. These include full R&D costs, including public funding contributions and production costs, terms and conditions of IP and technology licensing agreements, terms and conditions of public funding and public procurement agreements, and full IP status (not limited to patents) information. It is also important to note that the inclusion of clinical trial cost transparency in the resolution is only where this information is "already publicly available or voluntarily provided", which severely limits its potential impact. Furthermore, it is striking that the UK, Germany, the US and Japan chose not to support the resolution, making it unlikely that it will be implemented in these countries. Unsurprisingly, these countries are home to the largest multinational pharmaceutical corporations that lobbied against the resolution.[80]

Implementation efforts: Efforts to implement the resolution are beginning to emerge in different countries, including Italy and France.[81] Italy notably led the WHA transparency resolution initiative, and in August 2020 approved a decree that requires pharmaceutical corporations to provide information about R&D costs and the prices being charged in other countries before any major drugs purchase by the government.[30] In France, amendments to a social security budget adopted in November 2020 require companies to disclose the public funding contribution towards the R&D of new medical products during price negotiations for public procurement. Although a historic move, the final amendment was substantially watered down from earlier versions that aimed to incorporate more fully the requirements contained in the transparency resolution.[29]

After five years since the passage of this resolution, significantly more effort is needed by WHO and countries to begin and expand implementation of the resolution in order to start seeing the impact of increased transparency of the markets of medical products.

RECOMMENDATIONS

Governments, other funders of R&D and procurers should require upfront information on the net prices – both for the procurement agency and the public – as a condition of public R&D funding, to receive other rewards such as PRVs or tax credits, as part of licensing agreements, or as part of procurement negotiations with manufacturers.

Governments and procurers should individually and collectively publish the net prices, including the breakdown of rebates and discounts, they pay for medical products, as well as all relevant disaggregated information such as volumes, freight and taxes, in a publicly available platform or database. If this is implemented regionally or internationally, it could increase bargaining power and negotiation of fair prices through pooled procurement strategies.

WHO should continue and expand efforts to increase transparency of the net prices of medical products as part of the implementation of the WHA 72.8 transparency resolution.

Governments and procurers of medical products should individually and collectively adopt new transparency policies and principles that reject confidentiality and non-disclosure clauses in medical product procurement agreements. At the very least, price and supply information should not be confidential information.

5. NON-DISCLOSURE AGREEMENTS AND CONFIDENTIAL INFORMATION IN PROCUREMENT CONTRACTS

An MSF pharmacy assistant at the MSF office in Barbacoas, Nariño, Colombia. 2021. Photo: Santiago Valenzuela/MSF

Governments and other treatment providers routinely use public funds to procure medical products to treat people. As a treatment provider, MSF regularly procures medical products directly from pharmaceutical corporations.

Supply agreements for procurement of medical products are common practice and contain crucial information such as price per dose, supply terms and delivery schedules. There is public interest in the proactive disclosure of such information as it increases trust, competition and transparency. It enables other procurers to benefit from such disclosure by supporting price negotiations and efforts to find alternative suppliers. According to the Principles on Commercial Transparency in Public Contracts published by the Centre for Global Development, transparency should be the norm for government contracts, particularly regarding information on what is being procured and for what price.[82]

Transparency laws, often referred to as freedom of information (FOI) or right to information (RTI) laws, can ensure transparency in government contracts for procurement of medical products. One of the first

such laws was passed in India by the state of Tamil Nadu in India in 1998 to provide transparency to eliminate corrupt practices in public procurement.[83] This led the procurer of medical products for the state of Tamil Nadu to systematically publish prices and sources after completing tendering and procurement procedures on an annual basis.[84] In South Africa, public procurement prices are published by the National Department of Health. Information can also be obtained by filing RTI applications seeking prices per dose, quantities procured, suppliers and other key details. Specific pieces of information included in a public contract can be withheld if they are deemed to harm security or reveal personal information, but these reasons do not cover information on prices, supply terms and sources. Some other countries publish information on the prices paid for medical products, as do other procurement agencies, as outlined in the previous section.

However, NDAs required by the pharmaceutical industry as part of procurement contracts often require critical information, including price and supply terms, to be kept confidential. These confidentiality requirements prevent disclosure by governments and other procurers of the prices they have paid for medical products, as well as other terms such as supply conditions. Such confidentiality clauses are often justified by the industry through claims that this information is protected as "trade secrets" or on account of being "commercially sensitive". They are often only required by originator pharmaceutical corporations as it helps them maximise profits by keeping prices as high as the market will bear on their monopoly products.

Widespread use of confidentiality clauses on prices means that governments and other procurers often do not know the prices paid by others when entering procurement negotiations, which makes benchmarking and negotiating lower prices more difficult and therefore restricts access. In addition to their impact on access, confidentiality clauses undermine governmental accountability to their populations, and prevent governments and civil society from holding the private sector to account.

Widespread use of confidentiality clauses on prices means that governments and other procurers often do not know the prices paid by others when entering procurement negotiations, which makes benchmarking and negotiating lower prices more difficult and therefore restricts access.

The COVID pandemic saw an amplification of the challenges surrounding NDAs for the procurement of medical products. This practice was extended to many LMICs, preventing disclosure of price per dose and other supply terms in procurement contracts for COVID vaccines. The issue received attention during the pandemic as countries were left with no choice but to agree to NDAs from pharmaceutical corporations.[85] By conditioning desperately needed vaccines on the signing of NDAs or confidentiality clauses that preclude disclosure of the content of the agreement and contracting parties, pharmaceutical corporations pressured governments in Latin America, South Africa, Malaysia, Philippines and other MICs to violate both international standards of transparency and their domestic practices on proactive disclosure and right to information in public procurement.[86,87,88]

In addition to governments, other procurers receiving public funds also lacked transparency during the pandemic. In 2021, Amnesty International, Human Rights Watch and Public Citizen asked the COVAX vaccine initiative to publicly disclose the contracts and additional details related to country and industry participation, and pricing. However, COVAX responded that its contracts "contain commercially sensitive and proprietary information protected under confidentiality obligations" that cannot be disclosed.[vi,89] Experts have highlighted that this approach is flawed as withholding all information for reasons of commercial sensitivity is an overly broad use of this exemption. In fact, other agencies receiving public funds from governments like UNICEF, the Global Fund and the Global Drug Facility, have a longstanding practice of price transparency. Any exclusion from disclosure or

[vi] COVAX was the vaccines pillar of the Access to COVID-19 Tools Accelerator (ACT-A) co-led by Gavi, CEPI, WHO, and delivery partner UNICEF.

redaction requested should pass the public interest test – where a clear case has been made that it is in the public interest to redact more than the public interest to publish information.

Beyond prices, secrecy in supply contracts was also used to hide terms and conditions on indemnity and lack of supply guarantees on delivery timings and volume. Among the most egregious clauses inserted by multinational pharmaceutical corporations in purchase agreements for COVID vaccines with governments and COVAX was to pass on the legal liabilities for any potential severe injuries resulting from these new vaccines (indemnity clauses) to purchasers like governments and non-governmental organisations (NGOs) procuring vaccines.[88,90] This risks setting an extremely problematic precedent.

MSF is often asked to agree NDAs or terms in supply contracts that preclude disclosure with pharmaceutical corporations in order to procure medical products. MSF has long supported efforts towards price transparency – as outlined in the section above – and has tried to resist NDAs and the inclusion of pricing and other supply terms as part of confidentiality clauses in contracts with corporations.

During the COVID pandemic, MSF attempted to buy nirmatrelvir/ritonavir (marketed as Paxlovid by Pfizer). But Pfizer's demand for MSF to sign an NDA even before negotiations could be launched undermined MSF's ability to procure the medicine. There was no public information about available supplies and prices as purchasers at the time – including UNICEF[91] – had to sign NDAs with Pfizer that included confidentiality clauses on the price. MSF refused to comply, and looked for alternative generic suppliers, but eventually did not purchase a single dose. Since then, MSF has had some success in resisting confidentiality clauses in purchase agreements with pharmaceutical corporations.

CASE STUDY: Confidentiality clauses on the price of CAB-LA in MSF's contract negotiations with ViiV Healthcare

MSF recently resisted efforts by ViiV Healthcare, a joint venture of GlaxoSmithKline, Pfizer and Shionogi, to conceal the access price paid for long-acting cabotegravir (CAB-LA), an injectable medicine that is recommended by WHO as a new option to prevent HIV infection. It is worth noting that three of the four clinical studies the WHO reviewed in recommending the drug were publicly funded by the US.[93,94, 95]

MSF had been in negotiations with ViiV for over 18 months when the corporation inserted last-minute terms in August 2023 that undermined supply security – ViiV tried to retain the power to terminate the contract or refuse the purchase order without just reasons – and a confidentiality clause on the drug's access price for the countries where it applies. MSF refused to sign the agreement with these terms as it would undermine drug pricing transparency, limit civil society activism for lower drug prices and restrict supply to LMICs.[96]

ViiV dropped the confidentiality clauses on the price of CAB-LA in October 2023 following an open letter by MSF, and the two parties were able to relaunch negotiations to move forward in the procurement of CAB-LA.[97, 98]

CSOs have been successful in demanding disclosure of COVID vaccine contracts. In South Africa, the Department of Health declined Access to Information requests to make the COVID vaccine purchase contracts public on the grounds that it is bound by confidentiality clauses that preclude disclosure. This was legally challenged by a public health and law organisation, Health Justice Initiative (HJI). The High Court in Pretoria, South Africa, ruled that COVID vaccine contracts and related documents had to be made public and that there is public interest in the disclosure of the records. This led to the disclosure of contracts for COVID vaccines between the South African Department of Health and Johnson & Johnson, Pfizer, Serum Institute, and the COVAX initiative.[99] In recent FOI/RTI cases, access to medicines and transparency activists in Colombia and Spain have achieved some success in establishing the principle that drug prices are not protected as trade secrets.[100,101] Following these cases, civil society groups have begun pushing back against the use of confidentiality conditions and NDAs, and recently wrote to the leaders of the world's largest medical product procurement agencies urging them to reject such demands on NDAs or confidentiality clauses in supply agreements[102,103]

RECOMMENDATIONS

Governments and all procurers using public funds or resources should institute and clarify transparency requirements for procurement contracts from the outset of the procurement process. Information on price, performance obligations, and supply terms should be published proactively. Any exclusion from disclosure or any redaction requested should pass the public interest test. Ideally, contract information should be published in an open data, machine-readable format with a clear data scheme to facilitate sharing and use.

Governments and all procurers of medical products should review definitions of "confidential information" in purchase agreements for medical products, especially in emergencies. At the very least, existence of the contract, price and supply terms should not be confidential information and should not be considered trade secrets or withheld for reasons of commercial sensitivity.

Governments should strengthen their FOI/RTI laws and drug procurement rules to ensure that supply terms, pricing, volumes purchased and delivery schedules are routinely made publicly available.

6. STATUS OF PATENTS AND OTHER IP, AND LICENSING AND TECHNOLOGY TRANSFER AGREEMENTS

A woman dances at a meeting of the Stop Stock Outs Project, a coalition of civil society organisations that mobilises activists and people living with HIV or TB to record and report occurrences of drug shortages, in Pretoria, South Africa. 2015. Photo: Stefan Heunis

Since the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in 1995, patents and other intellectual property (IP) rights have increasingly played a role in determining where and at what price medical products are made available to people who need them. The TRIPS Agreement laid the groundwork for many access barriers we face – be it high prices of medical products, or monopolies restricting generic production and availability of global supply. MSF has witnessed these challenges repeatedly, including during the HIV epidemic in sub-Saharan Africa in the early 2000s, shortly after the TRIPS Agreement came into force.

To tackle the barriers that IP rights pose for accessing lifesaving medical products, several tools and strategies are available for use by governments, competitor corporations, CSOs and patient groups. These include voluntary licenses, compulsory licenses and patent oppositions. For these tools and strategies to be truly effective, it is critical to ensure full transparency in the IP landscape. Transparency of patents and other IP, including identification of their holders and relevant related information (e.g., expiry dates, related applications etc.) and the products to which they pertain, can facilitate comprehensive analysis of how patents affect access and inform strategies for more equitable access.

IP LANDSCAPE, COMPULSORY LICENSES AND PATENT OPPOSITIONS

Access to timely, accurate and complete information on the legal status of patents is critical to overcoming the access challenges they pose. Currently, it is very difficult to access information regarding what patents are held on a medical product. This includes information on what patents are filed, where and when, their expiration date, international non-proprietary names (INN) and active pharmaceutical ingredient (API) information, as well as any existing licensing agreements, changes in legal status of patents and patent applications, including rejections, nullifications or revocations. Patent landscapes of medical products can be highly complex, with multiple – often hundreds – patents filed by pharmaceutical corporations on a single product, including unjustifiable patent claims covering an overly broad scope of the concerned product.[104] These patents may cover aspects ranging from specific molecules (primary patents) to processes, formulations, combinations, new uses and derivatives (secondary patents) of the same products. Identifying these patents is even more challenging when INNs are not disclosed in similar patent applications.

The legal status of patents and patent applications can change over time, so up to date or real-time data is crucial. Patent applications can be rejected, withdrawn or opposed. Granted patents can also be revoked, invalidated or can lapse in different jurisdictions. For primary patents on pharmaceutical products, a major change in the legal status could enable production of generic or biosimilar products, and therefore the legal status of patents and applications is crucial information that can ensure timely access to affordable generic versions of medical products. To achieve an accurate patent landscape for a specific medicine, identification and scrutiny of each patent application related to a drug is required. However, identification of patents is a laborious and costly process, making it difficult for third parties to file oppositions, request licenses, conduct R&D, consider investing in producing generic versions of patented products or conduct analysis for academic and research purposes.

In order to address some of the challenges around lack of publicly available information on patent landscapes associated with essential medicines, MSF Access Campaign published a report unpacking the complexity of navigating and understanding patent information on medicines in 2004.[105] In 2015, the UN Development Programme (UNDP) published a methodology for patent searches on essential medicines to increase patent information and transparency.[106] Subsequently, the Medicines Patent Pool (MPP) established the MedsPal, VaxPal, and LAPaL databases that allow patents to be searched by product names, as well as offer information on patent expiry dates, withdrawals, and relevant voluntary licenses and compulsory licenses.[107,108] Despite these positive steps and initiatives, in general, it is still difficult to identify patents on specific medicines in the absence of routine disclosure of INN names in patent applications. While there is a growing number of patent offices providing searchable databases with patent information, it is critical that this is done routinely and they make all relevant information freely available to the public. The World Intellectual Property Organisation (WIPO) and member states should address the lack of transparency in patent information on medical products, and establish disclosure requirements for INN in patent applications. INN-based patent databases should also be managed and maintained independently, and be subject to public review and verification based on official information from national patent offices, in order to avoid conflict of interest involving patent holders and to ensure accuracy of the information.[109] In addition, national patent laws should explicitly include an INN disclosure requirement. For example, Chile's Patent Office, under Article 32 of Decree 82 of 2022, adopted a regulation that mandates the inclusion of INN in the summary of patent applications for pharmaceutical compounds.[110]

Access to information on patents and patent landscapes is critical for the effective use of patent oppositions.[vii] The patent opposition in India that led to the Indian Patent Office's March 2023 rejection of secondary patent applications on bedaquiline is a

[vii] Compulsory licenses are a legal measure enabling a government to grant a permit allowing alternative production or importation of a generic version of a patented medical product without the prior consent of the patent holder.

case in point. This victory initiated a snowball effect leading to secondary patents on bedaquiline being questioned the world over, and the corporation holding these patents, Johnson & Johnson, eventually announcing in September 2023 that it will not enforce any secondary patents on the medicine in LMICs.[111] In order for the pre-grant patent opposition to be filed, numerous lawyers and IP experts had to conduct extensive analysis of the patent landscape of bedaquiline. More routinely available and up-to-date information on patents and IP landscapes would facilitate these efforts more broadly.

WATCH OUT FOR: Free trade agreements

Demonstrations against the India-European Union free-trade agreement in Delhi, India. 2011. Photo: Rico Gustav/APN+

Free trade agreements (FTAs), such as the EU-India FTA and UK-India FTA – both currently under negotiation – can contain hugely problematic IP provisions that can undermine access to affordable medical products.[112,113] MSF, other global health organisations, and LMICs rely heavily on affordable, quality-assured generic medicines produced in India to treat many people including those with TB, malaria and HIV, among other conditions. For decades, MSF Access Campaign has monitored, analysed, advocated and campaigned against such provisions, which include patent-term extension, data exclusivity, prohibiting patent oppositions, lowering the bar of patentability and other clauses that aim to artificially prolong monopolies on lifesaving medical products and delay generic entry.[114]

Despite FTAs being long-standing and largely irreversible commitments, there are unprecedented levels of secrecy surrounding their negotiations. Often, the only publicly available access to FTA negotiating texts is through leaks.[115] Some jurisdictions publish their negotiation strategies or opening positions, such as the EU, but most enable little to no transparency on negotiating texts.[116] FTA negotiations that affect public health and the right to health must be conducted with adequate levels of transparency and public scrutiny, and access to the negotiating texts and positions must be increased in advance of negotiating rounds. We call on all parties involved in FTA negotiations to publish updated versions of their negotiating positions, and allow sufficient time for parliamentary and public scrutiny of the negotiation text at each stage of the negotiation.

VOLUNTARY LICENSES

Voluntary licenses are contractual agreements through which patent-holding entities (licensors) set out the terms under which a generic version of a patented medicine can be used, produced or marketed by other entities (licensees). Through license terms and conditions, pharmaceutical corporations can set limitations on where and to whom a product can be sold, control the supply of API and impose other restrictions on licensees. As such, the scope and impact of a voluntary license is determined by the pharmaceutical corporation that holds the patents, in contrast to the scope and impact of compulsory licenses, which is determined by governments. Voluntary licenses can be agreed directly between the licensor and licensee, such as a generic corporation, or can be mediated by a third party, such as the MPP.

An analysis by MSF found that while voluntary licenses may promote more affordable access to medicines for some people in some countries, they often come with negative terms and practices that needlessly undermine access to medicines for others.[117] Since the terms and conditions in voluntary licenses essentially determine who will get access to the medical product in question and when, it is critical that voluntary licenses and their terms are publicly available in full.

Secrecy of voluntary licenses is often justified by the industry through claims of confidential commercial information or trade secrets. In cases where national laws maintain broad definitions of trade secrets, it enables corporations to claim any type of business-related information as confidential, including licensing terms and conditions. Claiming licensing terms as trade secrets or classified security information is problematic. However, in many countries, legal mechanisms to ensure transparency of licenses are weak or insufficient. While a number of countries, including Brazil and Thailand, have included requirements for voluntary licenses to be registered or approved by competent public authorities, the requirements stop short of publishing licensing terms, and in practice countries exercise no oversight of the terms of voluntary licenses.[118, 119] Increasing transparency is extremely important to enable government scrutiny of licenses and prevent anti-competitive practices that may negatively impact both local and global markets. In contrast, all license agreements signed by MPP are published in full. Despite industry claims, publication of the terms of MPP licenses has caused no competitive or commercial harm.

CASE STUDY: The case of the Oxford/AstraZeneca license on COVID vaccine

The Oxford-AstraZeneca COVID vaccine received over $2 billion in public funding to support its development and as part of advance purchase agreements.[120,121,122] Despite early assurances from researchers and published guidance at University of Oxford that they were committed to maximising access to their vaccine through non-exclusive IP licensing on the vaccine technology to enable production and supply, they later signed an exclusive IP license with the UK-based pharmaceutical corporation AstraZeneca.[123,124,125] This exclusive license was not made public, so the terms that were agreed with AstraZeneca were not known. While AstraZeneca claimed that they would not make a profit from the vaccine during the pandemic period, there was no evidence to substantiate these claims, and there were no assurances given about the price after the pandemic was to be declared "over" - or, indeed, which entity should determine when the pandemic is "over", and on what basis.[126] Following the exclusive license agreement with Oxford, AstraZeneca went on to enter multiple sublicense technology transfer agreements with other vaccine manufacturers, including the Serum Institute of India (SII) and Fiocruz in Brazil. The terms of these sub-licenses were also unknown. This made it impossible to understand the global supply landscape for this vaccine, sustainability of supply, technology transfer arrangements, which countries were included in the license agreements, and what the price of the vaccine would be.

Following multiple FOI requests, and a subsequent formal complaint in the public interest, University of Oxford published a redacted version of their license with AstraZeneca.[127] Most of the critical information needed to determine global supply, prices and access was redacted. It wasn't until a later leak of the unredacted AstraZeneca-Fiocruz sub-license that it became clear that commitments to no-profit prices were not upheld in sub-license agreements, and the "pandemic period" during which they had committed to making no profits, was pre-defined by AstraZeneca. The leak also exposed other limitations related to technology transfer and exportation.[128] The full terms of the sub-license agreement with SII are still not publicly known. An initial vaccine supply agreement between the UK and AstraZeneca was also published with critical information redacted, despite the UK committing over $100 million for the research, development and manufacture of this vaccine.[129] Despite assurances from AstraZeneca that they would sell the vaccine at no profit, it later transpired that South Africa was paying more than double the EU price for the vaccine.[130]

While the Oxford-AstraZeneca vaccine was more affordable than other vaccines for COVID, it took MSF and other CSOs months to try and uncover the terms in these agreements, and what the price and available supply would be. Information on the terms of licenses and agreements was mostly gathered through FOI requests, investigative journalists and leaks, which is inappropriate and unsustainable. These experiences show the need for a clear obligation for governments to ensure disclosure of information and to uphold public health interests against commercial confidentiality claims over lifesaving medical products.

RECOMMENDATIONS

IP landscapes, compulsory licenses and patent oppositions

- **Governments** should address the lack of transparency in key patent information concerning medicines, vaccines and diagnostics, and establish disclosure requirements for INNs in patent applications in their national laws.

- **National patent offices** should create free-to-access, publicly available and searchable databases that contain all relevant patent information associated with medical products. Information should include what patents are filed, where and when, their expiration date, INN and API information, as well as any existing licensing agreements, changes in legal status of patents or patent applications, including rejections, nullifications or revocations.

Voluntary licenses and their terms

- **Governments** should ensure information on voluntary licenses and technology transfer agreements and their terms are put in the public domain in the following manner:

  – In countries where no legal requirements for registration and publication of licenses exist: establish voluntary license registration and mandatory publication requirements under national laws. Both patent offices and competition authorities should be given the authority to require registration of voluntary licenses and publication of licensing terms as early as possible to encourage transparency and accountability.

  – In countries where registration or submission of voluntary licenses to authorities is a legal requirement: make licenses a part of the public record by developing a publicly accessible database to make information on all registered license agreements available.

  – In all countries: establish and strengthen public interest doctrine in legal decisions, laws and policies on right to/freedom of information, confidential information and trade secrets. This would allow the public interest to override claims of confidentiality for voluntary licensing terms concerning essential medicines, vaccines and other medical products, in order to allow their publication or inspection.

At a minimum, governments should require corporations to publish the main terms of their bilateral licenses and any additional or updated agreements related to a medicine. This should include the territorial scope of the license, formulations of the medicine covered, terms on API sourcing, the patent landscape, and royalty rates.

Free trade agreements

- **Governments** involved in FTA negotiations should publish updated versions of their negotiating positions, and allow sufficient time for parliamentary and public scrutiny of the negotiation text at each stage of the negotiation.

7. REGISTRATION AND SUPPLY INFORMATION

A woman holds a sign at a meeting of the Stop Stock Outs Project in Pretoria, South Africa. 2015. Photo: Stefan Heunis

Following the R&D process, a medical product goes through regulatory processes before it is made available on the market. Information about a number of elements in these processes, including registration status in countries and supply capacities and timelines, is not known, collated or disclosed publicly, which makes it difficult to ensure access, particularly when the product is in short supply.

Regulatory aspects:

It is critical to have publicly available information on what medical products are registered in countries and approved for use. Only with this information can gaps be identified and addressed to ensure equitable access. As such, the following information should be made publicly available at the national level through an official online database managed and updated by national regulatory authorities:

- Assessment reports for new products with a benefit/risk analysis that led to the regulatory decision.
- The address and affiliation of the manufacturing site for the finished product and for API.
- In certain circumstances, such as national or international emergencies, in the context of scarcity, a monopoly, high prices, or when a trial sponsor refuses to co-operate voluntarily, sharing of data that can help accelerate the development of generic or biosimilar products by government agencies with third parties should be allowed.

A global, publicly available database that compiles the above information from regulatory authorities would be extremely beneficial for providing a

snapshot of the regulatory status of medical products in each country in order to help identify gaps in registration, particularly in LMICs.

Supply capacities:

In order to prevent stockouts and shortages wherever possible, there should be publicly available information regarding supply capacities of medical products. This information should be provided both by manufacturers of medical products and governments to help understand the supply available within each country at any given moment. It should include what stocks are currently available; current and projected manufacturing capacities of the API, raw materials and final products; supply schedules, prices and full copies of purchase agreements without confidentiality clauses, as well as licensing and technology transfer agreements, as outlined above. Access to this information is particularly pertinent during an outbreak or pandemic, when demand may be higher than available supplies.

Stockpiling:

Building and maintaining stocks of medical products is an important strategy to help prepare for and respond to health emergencies. They can also be established and managed at an international level for outbreak response, to ensure rapid activation and delivery to countries when an emergency occurs. International stockpiles are especially critical when there is an anticipated shortage of supply globally, and they have proven effective at ensuring equitable access during multiple outbreaks.

However, some national stockpiling efforts could compete with needs internationally. Stockpiled treatments for Ebola virus disease are a case in point. While there are now two approved treatments for Ebola, almost all of the global supply sits unused in the national biosecurity stockpile of the US.[131] As a result, people most affected by Ebola in countries where the disease is endemic are left relying only on ad hoc donations in order to be treated. To date, no international stockpiling and allocation mechanism is available to secure and ensure supply for possible new outbreaks.[132]

In order to ensure stockpiling efforts are fit for purpose, information about what stockpiles are being developed both nationally and internationally, their size, expiration dates, allocation plans, and purchase agreements, including prices paid, needs to be public. This information needs to be shared by countries that are planning a national stockpile, as well as at the international levels by agencies involved in coordinating and managing international stockpiles.

Allocation:

The equitable allocation of medical products in short supply is only possible when the information outlined above on regulatory aspects, supply capacities and stockpiling efforts is shared. It is critical to have both a global and national picture of what is available and where, so that allocation plans can be coordinated based on need and not ability to pay the most. In most outbreaks we have witnessed to date, and particularly starkly during the 2014-16 West Africa Ebola outbreak and the COVID pandemic, allocation was primarily based on which governments could pay the most for the relevant medical products, and not on public health need. Despite international efforts during the COVID pandemic to prevent this through the Access to COVID-19 Tools-Accelerator (ACT-A), high-income countries and the pharmaceutical industry rendered these efforts useless by agreeing largely secret purchase and supply agreements bilaterally. The lack of transparency requirements by ACT-A, and by governments themselves in purchase and supply agreements, meant these actions were able to go unchallenged until it was too late. Transparency across the whole network of supply and allocation demands accountability from all actors, which can in turn support a more just public health response.

In order to ensure stockpiling efforts are fit for purpose, information about what stockpiles are being developed both nationally and internationally, their size, expiration dates, allocation plans, and purchase agreements, including prices paid, needs to be public.

RECOMMENDATIONS

Governments should:

- Through national regulatory authorities, develop or amend official public online databases containing the relevant regulatory information outlined above;
- Make publicly available the information outlined above regarding supply capacities of medical products;
- Publicly share information regarding national stockpile plans, as outlined above;
- Make purchase and supply agreements publicly available in full, with no confidentiality clauses; and
- Publicly share allocation plans for medical products, particularly during outbreaks or public health emergencies.

Manufacturers should:

- Provide information on manufacturing and production schedules, including supply to individual countries, regions and other global health entities, to enable proper global and national-level programmatic planning.

Global health entities should:

- Make publicly available plans and governance arrangements for any international strategic stockpile, including decision-making processes, stockpile size, prices paid and allocation plans; and
- Ensure LMICs and humanitarian organisations are adequately included in the design and coordination of such efforts.

REMEDIES FOR BROADER TRANSPARENCY AND ACCESS TO INFORMATION

While acting on the recommendations for the distinct areas discussed above individually is critical, it is also important to maintain a holistic view of the challenges related to lack of transparency and the interconnections between different transparency issues. For example, even when COGS are available, it may be necessary to have access to price information or R&D cost information in order to effectively negotiate lower prices. With this interconnectedness in mind, it is worth considering transformational remedies that would support access to information in a more comprehensive, cross-cutting manner and bring about systemic changes needed for more equitable R&D models. In this section, we discuss such remedies in three areas: governance and decision-making processes of global health entities; transparency conditions on public funding and resources; and national transparency laws.

Kassaye Sisay, a clinical officer and MSF's medical activity manager in Abdurafi, Ethiopia, holds an antivenom vial. 2023. Photo: Amanuel Sileshi

8. GOVERNANCE AND DECISION-MAKING PROCESSES OF GLOBAL HEALTH ENTITIES

The global health landscape is becoming increasingly complex, with multiple new and existing players including governments, government agencies, UN agencies, multilateral organisations, philanthropic organisations, universities, industry, civil society and patient-led organisations. This was amplified during the COVID pandemic when a number of significant new entities were formed or expanded in a very short space of time – for example, ACT-A and related pillars and institutions – many of which continue to absorb key functions of the global health architecture well beyond their original mandate.[133] The growing complexity and fragmentation of the global health landscape has amplified the opacity of decision-making processes and governance arrangements and further shrunk accountability and opportunities for civil-society consultation.

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During the COVID pandemic, it was an almost daily occurrence for civil society representatives to hear government officials, industry and key decision-makers in multilateral organisations describe how they were "*building a plane as we are flying*", indicating how the response to the pandemic was being developed and implemented at the same time. In addition to exposing how unprepared the global health landscape was for a pandemic, this phrase also aimed to bat away criticism of a lack of transparency around key decisions, accountability and an opportunity for adequate civil society consultation.

It was within this context that the world witnessed one of the most inequitable global health responses in a generation. High-income countries worked alongside industry to buy up the majority of available global supplies of critical health products, including PPE, oxygen, vaccines, treatments and diagnostics, particularly in the early stages of the pandemic. At one stage, some high-income countries hoarded more than five times the number of vaccine doses that they needed for their population, while the majority of LMICs were left with little or no supply. This was despite the promise of the COVAX initiative, which spectacularly failed in its attempt to ensure equitable access to COVID vaccines during the pandemic.[90] COVAX later became a key example of a new global health entity designed and governed with little to no transparency or avenues for accountability regarding the design of the facility, governance arrangements, policies or the day-to-day functioning of the entity. Policies outlining how the initiative would approach access considerations, and agreements with governments, companies and manufacturers were not shared, making it impossible to understand how commitments to equitable access were going to be upheld. The combination of this opacity with the influence of global health players and governments that champion the status quo – namely, a group of high-income countries, BMGF, Gavi, the Wellcome Trust and CEPI, led to a response that was not able to ensure equitable access to the world's poorest by failing to put in adequate conditions to ensure equity would be achieved.[134]

The WHO Pandemic Accord aims to create and improve global systems for pandemic prevention, preparedness and response (PPR) and other global health emergencies. Negotiations for the accord between member states, which were recently extended for up to a year, are a key opportunity to mandate transparency and accountability from global health actors, including private and philanthropic funders, public and private PDPs, other global health institutions and relevant bodies involved in PPR.[135]

Beyond pandemics and emergencies, global health entities should be mandated to ensure adequate levels of transparency, both as a principle, particularly when receiving public funding, to ensure trust and accountability in global health systems and medical products, as well as for designing and ensuring a successful, equitable and effective response. Drawing on years of established practices across the majority of the largest global health multilaterals, a number of "Principles of Meaningful Involvement of Communities and Civil Society in Global Health Governance" have been developed by civil society and community organisations, demanding adequate levels of ownership, involvement and transparency in global health governance.[136]

RECOMMENDATIONS

Governments should:

- Ensure that the governance and decision-making process of global health entities has adequate representation and meaningful inclusion of LMICs, regional bodies, and CSOs.
- Publish full contractual terms of R&D funding, supply and purchase agreements (without confidentiality provisions which limit disclosure of terms and conditions).
- Include transparency requirements as conditions attached to R&D funding, procurement and supply agreements, as outlined in detail in the next section.

Global health entities should:

- Commit to publishing contracts with governments, industry and manufacturers in full, both for purchase and supply agreements, and contracts for R&D funding.
- Include transparency requirements as conditions attached to R&D funding, procurement and supply agreements with companies, as outlined in detail in the next section.
- Commit to public disclosure of governance documents, including the full text of access policies or conditions.

9. TRANSPARENCY CONDITIONS ON PUBLIC FUNDING AND RESOURCES

Protestors picketing outside the offices of Johnson & Johnson in Midrand, South Africa. J&J's anti-TB drug bedaquiline was developed with considerable taxpayer support, yet high prices hampered much-needed access for more than a decade. 2019. Photo: Boitumelo Zwane/MSF

Governments make substantial contributions to the R&D of medical products. In addition to providing public funding for R&D, or directly carrying out research/clinical trials, governments make indirect contributions such as through grants, subsidies and tax credits to private entities. Following these contributions to their development, governments also often pay high prices to procure medical products once they are on the market, effectively paying twice for the same products.

> Public funding, resources and incentives towards R&D should come with conditions attached in order to ensure a fairer, more effective, efficient and equitable biomedical R&D system.

In the current context, where models of innovation in the biomedical R&D system lead to high prices, restrict access to essential medical products and fuel global inequity, public funding, resources and incentives towards R&D should come with conditions attached in order to ensure a fairer, more effective, efficient and equitable biomedical R&D system. However laudable their intentions, many publicly funded R&D initiatives and incentive mechanisms do not achieve this goal, and therefore need revisiting.

If other R&D funders, such as private philanthropies, PDPs and global health actors, do not commit to including these provisions in their funding agreements as indicated in section 8, governments should also require them to do so, particularly if they host these entities in their territories, have a representative sitting in their governing body, or provide funding to them. In addition to ensuring equity, it is also a matter of ensuring accountability of public funds.

Conditions on public funding should include a range of requirements to ensure equitable access. These include:

- Affordable pricing requirements for end products (such as the "cost of goods plus reasonable margin" or "no profit-no loss" models);
- Non-exclusive licensing/technology transfer requirement to ensure diversity of manufacturing and supply;
- Retention of rights by funders linked to the research, in the event that the manufacturers' supply does not meet demand in a timely manner or is not reasonably priced (so-called "march-in rights");
- Access plans and specific, transparent and disaggregated indicators that include registering and making available the drugs, vaccines or diagnostics, particularly where clinical trials were hosted; and
- Timely access to comparator drugs, tests, assays and vaccines needed for comparison studies, regulatory approvals and/or R&D.

In addition, they should also include the following transparency requirements:

- **Full disaggregated R&D costs, including disaggregated clinical trial costs – including but not limited to public funding contributions;**
- **Clinical trial protocols and disaggregated preclinical and clinical trial results data;**
- **COGS;**
- **Prices;**
- **Subsequent IP licensing, sub-licensing and technology transfer agreements;**
- **Information on supply capacities, forecasts and delivery schedules;**
- **Information on stock management, allocation and coordination; and**

Critically, the contractual terms of the R&D funding agreement itself should also be published in their entirety.

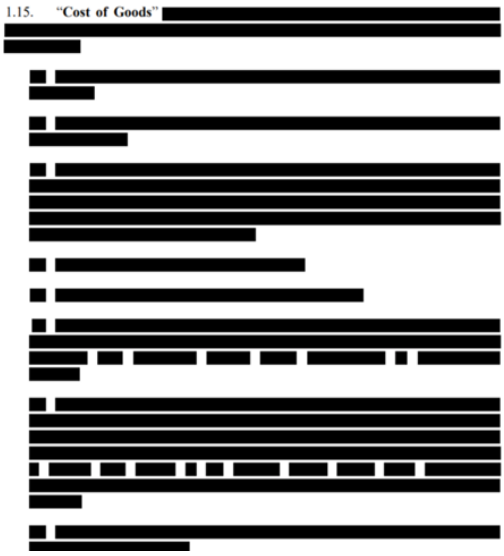
By including transparency requirements as part of a broader range of conditions on public R&D funding, governments can go a long way to better understanding the failures of the biomedical innovation system in ensuring equity, and use the information gained to demand accountability from corporations and require them to do much more to ensure medical products are affordable and accessible for patients.

10. NATIONAL TRANSPARENCY LAWS

An MSF team driving through slums in Mumbai, India, in an auto-rickshaw to spread awareness about COVID. 2021. Photo: Premananda Hessenkamp

National transparency laws enable public access to information held by public authorities. They do this by requiring public authorities to publish certain information about their activities, or by enabling the public to request access to specific information. These mechanisms, where available, can be used to obtain information from relevant public authorities about public health-related contracts, documents and agreements. However, applications for information are often rejected, or granted with key information redacted, on grounds such as risk of undermining commercial interests, national security, trade secrets or ongoing negotiations. While the decision on the rejection or redactions of critical information can sometimes be challenged on public interest grounds, this avenue is often not pursued due to a lack of appropriate provisions in national laws or lack of support for public interest arguments from judicial or administrative appellant bodies.

During the COVID pandemic, it took months to access critical information in agreements between key stakeholders that determined who would get access to COVID medical products and when. In the UK, as recounted earlier, it became clear that AstraZeneca had not upheld its commitments to no-profit pricing only after multiple FOI requests and leaks. In the EU, a contract between AstraZeneca and the European Commission was made public in August 2020 with critical information redacted.[137]



1.15. "Cost of Goods"

A page from the contract between AstraZeneca and the European Commission.

A number of more successful FOI cases are outlined in section 5, including how access to medicines and transparency activists in Colombia and Spain have successfully fought for the principle that drug prices are not protected as trade secrets. HJI in South Africa also recently won a groundbreaking victory in an access to information case, requiring the full disclosure of onerous, one-sided procurement agreements for COVID vaccines between the South African Department of Health and Johnson & Johnson, Pfizer, Serum Institute, and COVAX.[99]

In order to protect the right to information, governments should establish and strengthen national laws and practices on the right to/freedom of information, and review and reform laws and practices concerning confidential information and trade secrets. This should incorporate requirements and procedures for public sector entities to:

- Proactively disclose information on agreements that have a bearing on public health, including those related to procurement, supply, distribution, cost, pricing and licensing of medical products. A comprehensive national transparency checklist has been developed by access to medicines activists to define what information should be made available at national level to support efforts to ensure sustainable and equitable access to medicines.

- Improve procedures for disclosure of information requested by the public. This should allow claims made in the public interest and for the purpose of protecting public health to override claims of confidentiality, business interests and trade secrets concerning certain information, licenses and agreements determining access to essential medicines, vaccines and other medical products. Confidentiality clauses, especially on pricing, cost, manufacturing capacity and supply schedules, IP and technology licensing terms, in public procurement and supply contracts, IP licensing and technology transfer agreements, should be restricted, and prohibited during public health emergencies and pandemics.

In order to protect the right to information, governments should establish and strengthen national laws and practices on the right to/freedom of information, and review and reform laws and practices concerning confidential information and trade secrets.

CONCLUSION

MSF has repeatedly witnessed how the world's most vulnerable people are left behind without access to the lifesaving medicines, diagnostics tests and vaccines they need. Ensuring access to these medical products requires access to information about them throughout their life cycle, from the R&D stages to when they are brought to market. But this information has been systematically hidden from public view by the biomedical industry.

It is urgent that we move from a biomedical R&D system for which the status quo is secrecy, to one built on the open sharing of information.

To this end, this report outlines challenges and makes recommendations related to access to information about medical products in 10 areas. Concerted action by governments and global health institutions in partnership with civil society organisations, healthcare workers, patients and affected communities to increase transparency would not only build trust and accountability, but also help ensure equitable access to medical products and ultimately save more lives. Progress towards equity in access to medical products can only be built on the open sharing of information and knowledge, not on secrets.

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