

Policy Brief

# Transformative Policies to Realise Universal Access to Medicines

*Why We Need Knowledge Commons and Public Options  
for Pharmaceuticals to Realise the Right to Health*



## **Authors**

This policy brief was authored by Rossella De Falco, Programme Officer on the Right to Health at GI-ESCR. It was reviewed by Magdalena Sepúlveda Carmona, Executive Director at GI-ESCR and José Antonio Guevara Bermúdez, Deputy Director at GI-ESCR.

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## I. Introduction

This policy brief explores long-term, transformative solutions aimed at addressing the root causes of global inequalities in access to medicines. Framing universal access to medicines as a fundamental component of the rights to health and to science, it investigates innovative ways through which States might implement their obligations. The paper presents positive case studies where knowledge sharing and public ownership, rather than commercial incentives, made pharmaceutical innovation possible.

The policy brief begins by summarising the international human rights norms and standards related to access to medicines. It then examines the health equity implications of commercial approaches to pharmaceutical innovation, such as high prices of medicines and neglected diseases. In this context, the brief also explores the tension between intellectual property rights and international human rights law, as well as the challenges in monitoring and regulating private pharmaceutical companies.

Having discussed the limits of commercial approaches to pharmaceutical research and development, the paper reviews alternatives. It explores two feasible, rights-aligned policies that have the potential of realising universal access to medicines through a commons and public approach.



## II. Universal Access to Medicines Under International Human Rights Law

Medicines save lives and protect health by preventing and treating medical conditions. Hence, universal access to medicines is fundamental for the enjoyment of human rights,<sup>1</sup> including the right to the highest attainable standard of physical and mental health. The right to health is set out in several human rights instruments, most prominently in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).<sup>2</sup> The ICESCR imposes binding obligations in 171 States which have ratified it.<sup>3</sup>

The Committee on Economic, Social and Cultural Rights (CESCR), which supervises the implementation of the Covenant, has made multiple statements clarifying States' obligation to ensure universal access to medications. For example, in its General Comment 14, CESCR noted that 'the provision of essential drugs as defined in the World Health Organisation (WHO) Action Programme on Essential Drugs and Vaccines'<sup>4</sup> is a core obligation (i.e., has an immediate effect) with respect to health.<sup>5</sup>

Likewise, in 2013, the United Nations (UN) Human Rights Council (HRC), adopted a resolution emphasising that States have a duty to make sure that all persons, without discrimination, have access to medicines, especially essential medicines, and that medicines should be affordable, safe, effective and of good quality.<sup>6</sup>

During the COVID-19 pandemic, the HRC also adopted a resolution reaffirming that 'timely, equitable and unhindered access to safe, affordable, effective, and quality medicines, vaccines, diagnostics and therapeutics and other health related products and technologies' is a central element of the right to health.<sup>7</sup> In a separate resolution, the HRC declared that 'equitable, affordable, fair, safe, timely and universal access to vaccines is a determinant of the right to health and is essential to reversing the trajectory of any pandemic'.<sup>8</sup>

At the domestic level, some national courts have also determined that States have a duty to provide medication as part of their broader obligations under the right to health. For example, the Constitutional Court of South Africa, interpreting Article 12 of the ICESCR, ruled that the State was obliged to extend access to Nevirapine (which is used to treat HIV infection) from 18 pilot sites to all public health centres in the country in order to prevent mother-to-child transmission.<sup>9</sup> Similarly, the Constitutional Court of Colombia, has concluded that the State violated the right to life by denying antiretroviral treatment under the Colombian social security system.<sup>10</sup> In Argentina, the Supreme Court ordered the Ministry of Health to make available to a 63-year-old woman an anti-cancer drug that she needed to survive.<sup>11</sup>

If medicines are essential to meet the right to health, how can States ensure that all persons enjoy universal access to medicines without discrimination? To answer this question, we need to consider the right to benefit from advances in scientific understanding (right to science). To



## Understanding the Right to Science

International human rights law affirms the right to enjoy the benefits of scientific progress and its applications (the right to science). Article 27(1) of the **1948 Universal Declaration of Human Rights** states that 'everyone has a right in scientific advancement and its benefits'. Article 15(b) of the **1966 International Covenant on Economic, Social and Cultural Rights**, which has been ratified by 171 States, recognises that every person has the right 'to enjoy the benefits of scientific progress and its applications'.

In its **General Comment 25** (2020), the CESCR noted that the terms 'scientific advancement' and 'scientific progress' underline the capacity of science to improve human wellbeing, implying that States should use science to advance human rights. It further observed that the 'benefits' of science may include material outputs, such as vaccinations and other pharmaceuticals, as well as immaterial ones, such as knowledge and information; and that the term 'applications' refers to technology, such as health software, appliances, or materials. State parties have an obligation to respect, protect and fulfil the right to benefit from scientific progress.

If medicines are essential to meet the right to health, how can States ensure that all persons enjoy universal access to medicines without discrimination? To answer this question, we need to consider the right to benefit from advances in scientific understanding (right to science). To fulfil the right to science (Article 15(1)(b) of the ICESCR), States must take steps 'necessary for the conservation, the development and the diffusion of science and culture' as well as for 'the encouragement and development of international contacts and cooperation in the scientific and cultural fields'.<sup>12</sup>

As exemplified by stark inequalities in accessing the COVID-19 vaccine, however, progress towards the realisation of the right to science is still staggering. While the first COVID-19 vaccines were administered in December 2020, at early stages of the pandemic, access to these essential drugs has been deeply unequal. As of November 2023, 80% of people living in high-income countries received at least one dose of the COVID-19 vaccine, against 33% in low- and middle-income countries.<sup>13</sup>

As developing countries were left behind in the vaccination route, UN Human Rights Treaty Bodies (the bodies that supervise compliance with UN human rights treaties) called for universal access to medicines based on the rights to science and to health. The CESCR underlined that access to a COVID-19 vaccine that is 'safe, effective and based on the best scientific developments' is an essential component of the right to health and an expression of scientific progress; that the production and distribution of vaccines must be supported by international cooperation and assistance, thereby sharing the benefits of scientific progress and its applications; and that States should develop strategies and mechanisms to ensure equitable distribution of vaccines.<sup>14</sup> The CESCR also noted with concern the 'unhealthy race among States for COVID-19 vaccines, which has created a sort of temporary monopoly by some developed States of the first vaccines to be produced',<sup>15</sup> and that 'vaccine nationalism'<sup>16</sup> violated States' extra-territorial obligations to avoid taking decisions that limit the ability of other States to make vaccines available to their population.<sup>17</sup>

In a similar vein, the HRC noted that, while the pandemic 'generated extraordinary gains' for the pharmaceutical sector, 'access to lifesaving COVID-19 vaccines has remained disturbingly unequal'.<sup>18</sup> Furthermore, in 2023, in the context of a decision adopted in the context of its 'early warning and urgent action procedures',<sup>19</sup> the Committee on the Elimination of Racial Discrimination (CERD) observed that:

*'the current challenges of inequality can be significantly mitigated by sharing access to intellectual property rights to life-preserving patents to vaccines, treatments and related technologies which are currently reserved by a few countries in the global North'.<sup>20</sup>*

The CERD further urged States 'in the global North to provide resources to enable poorer States to satisfy the core medical capacities that they are expected to have in place (...) and to enable vaccines, relevant medicines and other necessary equipment and supplies to be available to all in a non-discriminatory manner'.<sup>21</sup>

### III. The Limits of Commercial Approaches to Pharmaceutical Innovation and Delivery

The commercialisation of science is a relatively new phenomenon. In the 1970s it was normal to define science as ‘a public enterprise advancing fundamental knowledge about the world’.<sup>22</sup> Increasingly, however, commercial motives have dominated the development of new medicines, at the expenses of human rights priorities.<sup>23</sup> The mismatch between profit considerations and public health goals is well exemplified in the Venice Statement on the Rights to Enjoy the Benefits of Scientific Progress and its Applications,<sup>24</sup> signed by prominent human rights scholars and experts at a meeting coordinated by UNESCO:

*‘Scientific advances in medicine have helped to cure more diseases and enhance the quality of life. However, these advances are driven primarily by market considerations that often do not correspond to the health needs of the world’s population as a whole, thus affecting the right to health.’<sup>25</sup>*

The main problem created by commercial approaches to medical innovation is the high prices of medicines. This is largely a consequence of patents, a form of intellectual property protected under the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>26</sup> Patents contribute to increasing the price of medicines because, from a legal point of view, only the pharmaceutical company that holds the patent is allowed to manufacture and sell the drug.<sup>27</sup> At the same time, from an economic point of view, patents grant certain companies a monopoly that allow them to increase the price of their medical products without competition from other firms. In other words, patents tend to increase prices of medicines because they delay the production of generic drugs,<sup>28</sup> a crucial step in expanding availability and accessibility of pharma.<sup>29</sup>

By contributing to high prices of medicines, thus, patents make life-saving treatments unaffordable, with marginalised populations being impacted the most.<sup>30</sup> This is why, in the late 1990s, several low- and middle-income countries, with support from international activists, contested the use of TRIPS to maintain high prices for on-patent medicines, particularly antiretrovirals (ARVs) for treating HIV.<sup>31</sup> Seeing intellectual property restrictions as embedded in a broader neo-colonial approach to development, these movements aimed to redistribute medicines as a matter of justice rather than charity.<sup>32</sup>

This global pressure led to international bargaining and the consequent adoption of the Doha Declaration on TRIPS and Public Health. The declaration was adopted by members of the WTO during the fourth WTO Ministerial Conference<sup>33</sup> The Doha Declaration recognised that WTO member states have the ‘right to protect public health and, in particular, to promote access to medicines for all.’<sup>34</sup> The statement importantly urges countries to use TRIPS flexibilities to meet public health goals, especially compulsory licenses,<sup>35</sup> allowing a State or a third party to produce a patented product or process without the consent of the patent owner.<sup>36</sup>

Several human rights monitoring bodies have recommended recourse to TRIPS flexibilities to achieve human rights purposes. In its General Comment 17, the CESCR underlined that:

*‘States parties should prevent the use of scientific and technical progress for purposes contrary to human rights and dignity, including the rights to life, health and privacy, e.g. by excluding inventions from the patentability whenever their commercialization would jeopardise the full realization of these rights’.<sup>37</sup>*

Consistently, in its General Comment 25, the CESCR emphasised that the intellectual property regime does not have to be implemented in a manner that is detrimental to the right to health. The Committee encouraged States to use the flexibilities of the TRIPS Agreement to provide universal access to essential medicines, including by the most disadvantaged groups.<sup>38</sup> In 2022, the HRC urged States to ‘promote the transfer of technology and know-how’ and ‘to encourage research, innovation and commitment, where possible, to voluntary licensing in all agreements in which public funding has been invested in research and development’.<sup>39</sup>

States have successfully used TRIPS flexibilities in a range of cases.<sup>40</sup> However, they are not always the solution to the limits of patents-based medical innovation, as shown by the COVID-19 pandemic. In October 2020, South Africa and India asked the WTO to waive intellectual property protections on all COVID-19 medical tools, including vaccines, diagnostics, therapeutics and other health technologies.<sup>41</sup> Concerningly, at a time when even days were critical, the WTO reached an agreement one year and a half later.<sup>42</sup>

Furthermore, negotiations considerably watered down the proposal. In June 2022, trade ministers agreed on a temporary 6-month waiver limited to COVID-19 vaccines, through a ministerial decision at the 12th WTO Ministerial Conference.<sup>43</sup> The waiver did not apply to the production and supply of COVID-19 therapeutics and diagnostics, which are however critical in detecting new cases and variants.<sup>44</sup>

Furthermore, from a human rights perspective, reducing high prices of medicines are not enough. In a system largely based on market incentives, there is also lack of interest in addressing public health concerns with low profitability prospects. This is why, for instance, there has been insufficient investment in tropical diseases in low-income countries.<sup>45</sup> For example, of the 1,393 new chemical entities marketed between 1975 and 1999, only 16 targeted tropical diseases or tuberculosis.<sup>46</sup>

Beyond using TRIPS flexibilities, therefore, there is a need for transformative, rights-aligned policy solutions for medical innovation in pharmaceutical research and development. Case studies on these policies are examined in the next section.



## IV. The Need for Transformative Policies

In this section, the briefing presents two innovative policy solutions that can revolutionise the current system and help States to implement their human rights obligations: open science; and public pharmaceutical institutions. These policies are already being successfully implemented in a few countries, and they can play a transformative role in tackling inequalities in accessing universal access to medicines by addressing their root causes.

### 1. Open Science and the Knowledge Commons

Open science is an approach to scientific discovery that prioritises knowledge sharing and collaboration among researchers. It has been central to the dissemination of intangible information since the study of knowledge commons emerged in the mid-1990s.<sup>47</sup>

Scientific knowledge is built on the collective efforts of successive generations of scientists, who progressively take forward the work of others to secure new discoveries.<sup>48</sup> The rapid evolution of information technology has made it simpler to share knowledge, creating perfect conditions for the spread of open science.

Open science can contribute to the realisation of human rights, including the rights to health and science.<sup>49</sup> Open science initiatives are common in areas with comparatively lower profit prospects, like rare and tropical diseases,<sup>50</sup> including malaria.<sup>51</sup>

### What is Open Science?

UNESCO defined open science as:

*‘an inclusive construct that combines various movements and practices aiming to make multilingual scientific knowledge openly available, accessible and reusable for everyone, to increase scientific collaborations and sharing of information for the benefits of science*

*and society, and to open the processes of scientific knowledge creation, evaluation and communication to societal actors beyond the traditional scientific community.’*

According to UNESCO, the values underpinning open science research models are quality and integrity, collective benefit, equity and fairness, diversity, and inclusiveness.

The premise is that scientific discovery is a **social collaboration** and that its products belong to **the community**. The open science community has developed open data guidelines, which indicate that data should be findable, accessible, interoperable, and reusable (FAIR). Open science practices recommend open access, open source, open data and open peer-review. **Knowledge commons** refer to intangible information some of the properties of the traditional commons.

Human rights law also provides a basis for promoting open science. In its General Comment 25, CESCR has affirmed that ‘States should promote open science and open source publication of research’.

There are several examples of the benefits of open science in medical innovation. During the COVID-19 pandemic, researchers shared publications, data, and software widely and quickly. For example, the full genome of COVID-19 was published in an open-access publication one month after the first patient was admitted to Wuhan hospital.<sup>52</sup> Simultaneously, collaborative platforms such as Nextstrain,<sup>53</sup> and Gisaid,<sup>54</sup> made it possible to track the spread of genetic mutations, while the European Commission rapidly established a COVID-19 data portal in April 2020 to share research data on the disease.<sup>55</sup>

Furthermore, in 2022, a team of researchers at Texas Children Hospital and Baylor College of Medicine developed a patent-free COVID-19 vaccine (CORBEVAX).<sup>56</sup> This protein-based vaccine is comparatively cheaper to manufacture and easier to storage than mRNA vaccines.<sup>57</sup> It is currently being approved in 2 countries and is currently under additional trials.<sup>58</sup>

A good example on how open science works in practice is the WHO's Global Influenza Surveillance and Response System (GISRS).<sup>59</sup> Created in 1952, the GISRS is an international network comprising research institutions and laboratories in 129 WHO member States and is primarily funded by governments and non-profit foundations. GISRS functions as a global mechanism for surveillance, preparedness, and response for seasonal, pandemic, and zoonotic influenza.<sup>60</sup> In this context, the network also alerts for new influenza virus and other respiratory pathogens.<sup>61</sup>

The scientists in the network collaborate to routinely update the formula for the vaccine against influenza and make it publicly available to companies and States. Therefore, GISRS shows how medical innovation is possible without profit incentives.<sup>62</sup> Medical researchers in the network are motivated by immaterial benefits like reputational gains, which then translate in increased funding and higher salaries.<sup>63</sup>

## 2. Public Options for Pharmaceutical Research, Development, and Distribution

States' primary role is often to fund pharmaceutical research and development. For instance, the United States government invested USD 31.9bn to develop, produce, and purchase mRNA vaccinations for COVID-19.<sup>64</sup> However, public universities, public laboratories, official governmental agencies, and other public institutions can also lead research into medicines and their development and distribution. Below, there are examples of public institutions that have led pharmaceutical innovation, offering an alternative to market-based models.

While public institutes are traditionally associated with exploratory, initial stages of medical research, they play an increasing role in applied research as well. A peer-reviewed study in 2011 found that, in the last forty years, public research institutes discovered 153 approved new drugs or vaccines, or novel indications for existing drugs.<sup>65</sup> Half of these have been used to treat or prevent cancer or infectious diseases, with very high therapeutic benefit.

In addition to research and development, publicly owned pharmaceutical institutions also manufacture, distribute, and deliver medicines. In Sweden, the *Apotek Produktion & Laboratorium*,<sup>66</sup> for example, is one of the largest manufacturers of medicines in

Europe. In Cuba, the biotechnology and pharmaceutical organisation *BioCubaFarma*<sup>67</sup> undertakes research, development, manufacturing and distribution of medicines. In Brazil, public pharmaceutical laboratories have historically played a central role in the large-scale production of essential medicines and drug,<sup>68</sup> including anti-retroviral drugs.<sup>69</sup> In all these cases, the crucial advantage of publicly owned pharmaceutical institutions is that, because they are not owned by shareholders or driven by commercial motives, they can prioritise public health, human rights, and scientific innovation.<sup>70</sup>

Above national level, some experts and civil society movements are calling for further expansion of public pharmaceutical bodies.<sup>71</sup> In an expert report to the European Parliament, for instance, Massimo Florio has proposed a Europe-wide public infrastructure for medical research and development.<sup>72</sup> After analysing the failure of the current business model to deliver on public health goals, Florio's report explains how a public infrastructure could meet Europe's long-term drugs research, development, production, and distribution needs.<sup>73</sup> In the United States, a range of civil society organisations are campaigning for a nationwide public pharmaceutical industry that would retain the patents on new medicines it develops.<sup>74</sup>



## V. Final Observations

Commodification of pharmaceuticals increases economic inequalities within countries and pushes poorer countries into debt, reinforcing colonial legacies in global health.<sup>75</sup> Commercial models for researching, developing, manufacturing, and delivering medicines have failed to meet human rights goals. While TRIPS flexibilities can be useful to address some problems, they alone cannot achieve the long-term project of realising the rights to health and science. States need to comply with their human rights obligations through transformative and progressive policy solutions.

This policy brief has described two policy solutions that have the potential to revolutionise how medicines are developed and delivered. They are mutually reinforcing and should be implemented in parallel. First, States can invest in rights-aligned open science initiatives that research and develop new medicines without patent incentives. This model envisions scientific advancements as global commons, whose collective benefits must be shared society. The paper has shown that knowledge commons initiatives have already been effective, for instance in addressing the research gaps on neglected tropical diseases and monitoring endemic viruses.

Second, public institutions of different kinds are well-equipped to realise universal access to medicines. They are not constrained by the need to make profits, therefore, they are able to prioritise public health goals and human rights. The paper has reported successful examples of public options for pharmaceutical research, development, manufacturing, and delivery in both high- and middle-income countries.

Finally, along such policy commitments, States can also improve access to medicines by monitoring and regulating private pharmaceutical companies,<sup>76</sup> including research, generic and biotechnology companies.<sup>77</sup> The United Nations Guiding Principles on Business and Human Rights, unanimously endorsed by the Human Rights Council in 2011, clarify States' duties to respect, protect, and fulfil human rights, including when third parties are involved in health care, as well as the corporate responsibility to respect human rights.<sup>78</sup> The CERD has also recognised (in its General Recommendation 37) that 'States should adopt regulation ensuring that (...) pharmaceutical companies, manufacturers of health-related goods (...) comply with the principle of equality and non-discrimination in the right to health, in line with the 2011 Guiding Principles on Business and Human Rights'.<sup>79</sup>

To realise the right to health, societies need to remove the root causes of inequality in accessing medicines. Inequality is ingrained in current commercial approaches to medical innovation, which privilege wealthy States and consumers and powerful pharmaceutical companies. However, an alternative system is possible. This brief has shown that some alternatives are already working effectively to achieve public health goals. States can reconceptualise the products of medical innovation as knowledge commons, and reclaim public ownership of pharmaceutical research and delivery. By doing so, they could transform the health sector, meet more fully their right-to-health obligations, and realise universal access to medicines. The examples of success in this brief show that another way is possible.

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## **Transformative Policies to Realise the Right to Health: Why we Need Knowledge Commons and Public Options for Pharmaceuticals to Realise the Right to Health.**

December 2023

### Authors

This policy brief was authored by Rossella De Falco, Programme Officer on the Right to Health at GI-ESCR. It was reviewed by Magdalena Sepúlveda Carmona, Executive Director at GI-ESCR and José Antonio Guevara Bermúdez, Deputy Director at GI-ESCR.

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