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Good practices on how everyone can:

A) get medicines, vaccines and other health products, and

B) get the best levels of physical and mental health[[1]](#endnote-2)

Report of the Office of the United Nations High Commissioner for Human Rights

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| *What is the aim of this document?* |
| This document, prepared under Human Rights Council resolution 50/13, presents an overview of good practices on how everyone can get access to medicines, vaccines and other health products, including policies and interventions that can help in this process. |
| *How can these good practices be achieved?*  Governments, pharmaceutical companies, health-care providers and international organizations must work together to ensure that medicines, vaccines and other health products are available, accessible, acceptable and of high quality.  To make this possible, we must learn from the good practices that are currently used which include managing intellectual property rights, following strong regulatory frameworks and investing in research and development of new medicines and vaccines.  This can happen through public-private partnerships, and policies and measures that encourage the production of generic medicines.  *Who might be interested in this document?*  People or agencies that:   * draft, design, or are interested in policy related to health and medicines, or * are interested in the area of health and medicines. |
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I. Setting and why we have this report

1. In Human Rights Council resolution 50/13, the Council requested the Office of the United Nations High Commissioner for Human Rights (OHCHR) to submit a compendium that identifies good practices about how everyone can access medicines, vaccines and other health products so that everyone can enjoy their right to receive the highest possible standard of physical and mental health, to the Council at its 53rd session. The compendium will be complemented by an analytical study on key challenges which will be submitted to the Council at its 56th session.

2. The OHCHR would like to thank all stakeholders for participating in the virtual expert workshop held on 14 February 2023, and for contributing in the preparation of this compendium. Submissions received are available on the OHCHR website.[[2]](#endnote-3) The submissions will help in preparing the comprehensive report on access to medicines, vaccines and other health products which will be submitted to the Human Rights Council at its 59th session.

II. Advice and Suggestions for action

3. Ensuring access to medicines, vaccines and other health products is an integral and fundamental part of the right to health. However, massive inequalities remain as one-third of the world’s population do not have access to essential medicines. The following groups’ needs are often underestimated, ignored and underserved:

* persons living in poverty,
* older persons,
* persons with disabilities,
* women,
* children, and
* persons who are vulnerable and marginalized.

4. The COVID-19 pandemic showed how access to medicine and vaccines could be helped or blocked. Some countries quickly received life-saving vaccines but factors, e.g. cost, patents and national stockpiling, determined which populations received them first. The challenges identified should encourage us to create an enabling global environment free of structural obstacles, in which everyone can:

* enjoy their right to health, and
* have universal and fair access to medicines, vaccines and other health products.

5. Governments, national and international actors, the private sector and civil society have a shared responsibility to provide everyone with access to medicines and vaccines. States must guarantee the right to health under their obligations stated in the economic, social and cultural rights framework, and that pharmaceutical companies meet their responsibility to respect their duty.[[3]](#endnote-4)

6. Identified practices that promote the availability, accessibility, acceptability and quality of essential medicines, vaccines and other health products include those that:

* are based on a human rights-based approach, and
* allow everyone to meaningfully participate, including civil society organizations, patients and consumer organizations.

These include:

(a) **Investing in research and developing new medicines and vaccines** by using:

(i) public-private partnerships, for example, innovative funding mechanisms and partnerships to improve the transfer of technology and investment in research and development, including in medicines and vaccines for non-communicable diseases, and

(ii) policies and measures to promote the fair pricing of medicines, vaccines and other health products to ensure they are affordable, putting the right to health considerations before profit, e.g.:

a. including essential medicines in social protection and reimbursement policies to ensure access to affordable medicines, vaccines and other health products without discrimination, particularly for persons and groups who are vulnerable or marginalized,

b. creating efficient and transparent procurement practices and procedures that are fair, competitive and require suppliers to meet strict rules,

c. creating policy frameworks that encourage the local production of medicines and vaccines to ensure they are available, accessible long-term and affordable, and

d. introducing measures that encourage generic medicines to be produced, and innovative models to buy and distribute medicines,

(b) **Using** **access-oriented management of intellectual property rights** by using:

(i) mechanisms that mitigate the impact of intellectual property rights and promote access to medicines, vaccines and health products under the right to health framework,

(ii) approaches that increase access to intellectual property management, including patent pooling and using non-exclusive voluntary licensing, and

(iii) the use of flexibilities under the TRIPS Agreement to promote regional collaboration to pool resources and increase competitiveness of local production,

(c) **Using** **strong regulatory frameworks**, including:

(i) streamlined review and approval processes to help the production of generic medicines, while maintaining the highest standards of quality and safety of medicines and vaccines,

(ii) procedures for increased transparency and accountability to address corrupt practices, especially in how medicines are selected, bought and registered,

(iii) competition laws and policies that prevent pharmaceutical companies from using anticompetitive practices and promote the competitive pricing of medicines, together with strong enforcement, and

(iv) disclosure of information on medicine prices and quality, and sharing information on patents and investments in research and development,

(d) **Using measures promoting effective participation and acceptability**, e.g.:

(i) ensuring communities and affected populations effectively participate in the decision-making process to increase trust and acceptability of medicines and vaccines,

(ii) creating national essential medicines lists, determined through a transparent and participatory process, that adequately reflect the national health situation, particularly the needs of vulnerable groups, and that are regularly updated, and

(iii) introducing tailored interventions supported by behavioural, science-informed analysis to ensure medicines and vaccines are accepted.

III. The relationship between human rights and getting fair access to medicines, vaccines and other health products

1. Ensuring that everyone can use their human rights to get access to medicines, vaccines and other health products

7. The lack of access to medicines, vaccines and other health products[[4]](#endnote-5) is a complex issue and a major obstacle that prevents people from enjoying their right to health.[[5]](#endnote-6) Ensuring access to medicines and vaccines requires a functioning health system that is based on the key elements of the right to health. The Committee on Economic, Social and Cultural Rights outlined, in its interpretation of the normative content of the right to health, that this includes ensuring that everyone has access to medicines and vaccines that are available, accessible, acceptable and of good quality.[[6]](#endnote-7) Access also means that governments, pharmaceutical companies, health-care providers and international organizations work together. This compendium aims to provide an overview of practices, policies and interventions that may contribute to improving access to medicines, vaccines and other health products.

8. The coronavirus disease (COVID-19) pandemic showed how human health is interconnected, i.e. where an individual’s health in one country impacts a person’s health in another country. Efforts to implement the right to health at the national level must recognise that States’ and businesses’ decisions affect people’s rights in multiple jurisdictions. In the pharmaceutical sector, which has typically accounted for a large amount of health budgets globally,[[7]](#endnote-8) the pandemic generated and continues to generate extraordinary gains.[[8]](#endnote-9) However, access to life-saving COVID-19 vaccines has remained worryingly unequal.[[9]](#endnote-10)

9. While the pandemic has led to innovation and cooperation, it has also exposed problems in getting universal and fair access to medicines and vaccines.[[10]](#endnote-11) The pandemic has reconfirmed the significant impact that lack of access to medicine and vaccines has on human rights, e.g. the rights to health, to life, to non-discrimination and to development.[[11]](#endnote-12)

10. Approximately 2 billion people have no access to essential medicines and 80% of the world’s population lives in countries with little or no access to controlled medicines for pain relief.[[12]](#endnote-13) About 25 million children did not have life-saving vaccinations in 2021 because of the COVID-19 pandemic and associated problems that have challenged health systems.[[13]](#endnote-14)

11. The lack of fair access to medicines, vaccines and other health products disproportionately affects certain groups, e.g. persons living in poverty, older persons, persons with disabilities, persons living with chronic illnesses, women and children. Without access to health insurance or social protection, persons living in poverty, older persons and migrants cannot afford essential medications, including for managing chronic conditions. Women and children often have worse experiences when fighting disease than men, and may face additional challenges in accessing health care and medications.[[14]](#endnote-15) Almost 1 billion children, older persons and persons with disabilities do not have access to assistive technology, e.g. prosthetics, hearing aids and communication devices.[[15]](#endnote-16)

12. Stopping access to essential medicines, vaccines and other health products creates or makes discrimination and existing inequalities worse regarding how people enforce their right to health. Ensuring that the right to non-discrimination is upheld needs everyone to have access to essential medicines and vaccines. Governments have a primary responsibility to ensure that vaccines and medicines are available and affordable to everyone. Governments must also address the underlying social and economic factors that contribute to health inequities and discrimination.[[16]](#endnote-17)

13. While availability is a precondition for access, affordability is one of the dimensions of access. Up to 90% of the population in low- and middle-income countries buy medicines through out-of-pocket payments. A household that is forced to sell an asset, e.g. the family cow, or take children out of school to pay for medicines, may be pushed into intergenerational poverty.[[17]](#endnote-18) Other factors, e.g. gaps in local health systems and infrastructure, determine whether people have access to the medicines, vaccines and health products they need. Access also depends on procurement practices and the strength of national regulatory authorities. While access to essential medicines for non-communicable diseases is lower than for communicable diseases, many medicines for treating non-communicable diseases must be taken for life. Consequently, this has a severe impact on household expenditure, pushing many families below the level of poverty.[[18]](#endnote-19) Apart from being affordable and of good quality, medicines must also be safe. Secure supply chain management is needed to protect populations from substandard or falsified medical products.[[19]](#endnote-20)

B. Increasing the access and availability of medicines, vaccines and other health products

14. The call to make essential medicines, vaccines and other health products available and accessible to everyone everywhere is based on an approach of universal health coverage.[[20]](#endnote-21) Making medicines and vaccines as available, accessible and affordable as possible requires a varied approach that involves:

* increasing funding for research and development,
* encouraging generic drug manufacturing,
* implementing price regulation,
* increasing public awareness, and
* addressing intellectual property issues.

15. It also requires following the Guiding Principles on Business and Human Rights. These principles require companies to assess the main human rights risks throughout their value chain, both upstream and downstream. Lack of affordability and the resulting impact on how people enjoy their right to health must be included systematically in pricing discussions.

16. Medical devices are essential to prevent, diagnose and treat illness and disease, and for patient rehabilitation. Yet 13% of the world’s population accounts for 76% of the use of global medical devices.[[21]](#endnote-22) Even where they are made available, medical technologies are not typically designed for use in settings with hot temperatures, fluctuating electricity or lack of clean water. Installation, maintenance services and user training are often missing; this leads to the unsafe use of devices, with potentially harmful consequences, e.g. misdiagnosis.[[22]](#endnote-23)

1. Funding and partnerships for research and development

17. Public-private partnerships, bringing together governments, pharmaceutical companies and other stakeholders, can help develop and deliver medicines and vaccines to underserved populations when human rights considerations become the focus of these partnerships. These partnerships can help technology invention and the sharing of the costs and risks of research and development, and can help increase the availability of and access to health care. These partnerships can play an important role in improving access to medicines and vaccines in low- and middle-income countries by mobilizing additional resources, promoting collaboration, supporting innovation, improving efficiency and ensuring sustainability.[[23]](#endnote-24)

18. Several public-private partnerships have contributed to developing medicines and vaccines and helping low- and middle-income countries get access.

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| **Examples of public-private partnerships:** | |
| **Advance Market Commitments** | This advance market commitment was a public-private partnership that made the development and production of the pneumococcal vaccine possible.  An innovative financing mechanism was used that provides guaranteed funding to develop and produce vaccines, at an affordable price, for diseases that disproportionately affect low- and middle-income countries.  Under the advance market commitment, in return for funding from donors, the manufacturers commit to supplying the medicine or vaccine at an affordable price to low- and middle-income countries.  This arrangement provides a market for vaccine manufacturers and an incentive for them to invest in research and development.[[24]](#endnote-25) |
| **The Gavi Alliance** | The Gavi Alliance is a public-private partnership that helped to immunize over 822 million children and helped to prevent over 14 million deaths by improving access to vaccines in low- and middle-income countries. The Alliance has served as co-lead of COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator.[[25]](#endnote-26) |
| **The Global Fund to Fight AIDS, Tuberculosis and Malaria** | This global fund finances and coordinates programmes to prevent and treat disease through public-private partnerships.[[26]](#endnote-27) |
| **The Medicines for Malaria Venture** | This public-private partnership scheme has contributed to developing new treatments for malaria.[[27]](#endnote-28) |
| **The Innovative Medicines Initiative** | This public-private partnership initiative was established in 2008 for the development of new treatments for diseases, e.g. Alzheimer’s, diabetes and cancer, building on how pharmaceutical companies, research institutions and patient groups work together.[[28]](#endnote-29) |
| **The Access to Oncology Medicines (ATOM) Coalition** | In the area of non-communicable diseases, this public-private partnership[[29]](#endnote-30) seeks to increase access to essential cancer medicines and the possibility to use them appropriately.[[30]](#endnote-31) |

2. Ensuring fair pricing

19. Essential medicines and vaccines should be treated as public goods; however, their current cost is a high financial burden for low-income countries and is an important obstacle to global medicine and vaccine fairness. Medicines and vaccines must be priced fairly and be affordable so as not to unfairly cause difficulty to persons living in poverty. It has been argued that the right to health means States must regulate private-sector production of essential medicines if the production puts medicine affordability and accessibility at risk.[[31]](#endnote-32)

20. Commercial interests may lead to greater unfairness in how people can get access to medicines and vaccines. At the same time, when prices are too low and this limits profits, companies leave the market which reduces the availability of quality products.[[32]](#endnote-33) Therefore, the price of new medicines and vaccines must ensure that they are affordable to all patients and health systems, while allowing for a reasonable profit margin for pharmaceutical companies and acting as a stimulus for further innovation.[[33]](#endnote-34)

21. Based on criteria, e.g. affordability, access and value for money, the World Health Organization (WHO) sets guidelines and makes recommendations for fair pricing of medicines and vaccines. By implementing those, pharmaceutical companies and other stakeholders can work together to ensure that medicines and vaccines are priced fairly and that there is fair access to health care nationally and globally.[[34]](#endnote-35)

22. Under the Guiding Principles on Business and Human Rights, pharmaceutical companies must respect human rights in how they run their businesses. They must avoid infringing others’ human rights and should take action to address any negative impacts on human rights resulting from their actions.[[35]](#endnote-36) This responsibility includes conducting appropriate human rights due diligence to identify, prevent, mitigate and address any risk or actual human rights impacts of their activities and operations.[[36]](#endnote-37) Also, businesses must consider the negative consequences that pricing and distribution decisions may have on equal access to medicines and vaccines, particularly for those in vulnerable and marginalized situations.[[37]](#endnote-38)

23. Pharmaceutical companies can play a key role in fair pricing by using transparent pricing strategies and differential pricing, and working with stakeholders. They should be transparent about the costs of research and development, manufacturing and distribution. Pharmaceutical companies must have a well-established governance structure, and health technology assessments, for value-based pricing, to ensure that processes are transparent. Assessment reports and decisions should be disseminated publicly. The governance structure of pharmaceutical companies should include enacting legislation, regulations or rules to mandate transparent pricing and reporting of prices, where appropriate.[[38]](#endnote-39)

24. Differential pricing allows pharmaceutical companies to price medicines and vaccines based on the country’s or region’s purchasing power where they are sold. This helps to ensure that low- and middle-income countries have access to affordable medicines and vaccines, e.g.

* the Gavi Alliance, for instance, negotiates prices with vaccine manufacturers based on a country’s ability to pay and the volume of doses purchased, and
* several pharmaceutical companies have also implemented differential pricing for HIV/AIDS medicines, e.g. tiered pricing models, depending on the country’s income level, differential pricing for malaria medicine, and cancer medicine offered at a lower price in low- and middle-income countries.[[39]](#endnote-40)

25. Public-private partnerships can also contribute to delinking the cost of research and development from the final product’s price. This can be done by providing different funding mechanisms, including public funding through grants or subsidies or other innovative financing mechanisms, e.g. advance market commitments. Delinking models allow for a health product to be sold at a lower price and can help to encourage pharmaceutical companies to develop and produce medicines and vaccines for neglected diseases or underserved populations.[[40]](#endnote-41)

26. Regarding the COVID-19 response, public-private partnerships played a critical role in vaccine development, but also showed that publicly funded intellectual property ended up entirely in non-governmental hands. This allowed the exercise of monopoly rights and prices for vaccine doses to be set that were much higher than the actual costs of manufacturing.[[41]](#endnote-42) States must introduce measures for public investments to ensure that the resulting medical technologies that receive public subsidies in their development process will be available and accessible to those who need those medical technologies, domestically and globally.[[42]](#endnote-43)

27. Some countries use pharmaceutical price regulation to ensure access to essential medicines, while still allowing pharmaceutical companies to cover their costs and make a reasonable profit, e.g.:

* **reference pricing**, e.g. setting a maximum price for a group of medicines that have similar therapeutic effects,[[43]](#endnote-44)
* **external reference pricing**, e.g. basing a medicine’s price on its price in other countries,[[44]](#endnote-45)
* **price negotiations with pharmaceutical companies**, e.g. ensuring that medicines are affordable and accessible to patients by negotiating with pharmaceutical companies,[[45]](#endnote-46) and
* **price controls**, e.g. setting a maximum price for a medicine or a group of medicines that are deemed essential for public health.[[46]](#endnote-47)

As regards external reference pricing, to get the lowest price for medicines and make affordable and fair access to essential medicines better, purchasing States should select reference countries whose level of economic development is like theirs.[[47]](#endnote-48) Voluntary agreements between pharmaceutical companies and governments or other organizations that set a medicine’s price are often used for new and innovative medicines that regulations do not yet cover.[[48]](#endnote-49) Other measures of indirect control to regulate the prices of medicines include tax incentives to manufacturers,[[49]](#endnote-50) wholesalers and retailers, and government subsidies for manufacturers.[[50]](#endnote-51)

28. The inclusion of medicines, e.g. those referenced in the WHO Model List of Essential Medicines in social protection schemes is crucial for:

* ensuring that groups in vulnerable situations have access to necessary medications, particularly those in low- and middle-income countries,
* making the life of those who have illness as comfortable as possible, and
* promoting fair access to health-care services.

The use of health insurance schemes to reimburse patients the cost of essential medicines is also common in some States.

29. Non-governmental organizations have a crucial role to play in ensuring fair prices for medicines and vaccines.[[51]](#endnote-52) By engaging in advocacy, conducting research, working with other stakeholders and building capacity, they can work towards improving access to essential medicines and vaccines for all individuals and communities, particularly for neglected diseases that affect people in low- and middle-income countries.

3. Resolving problems concerning intellectual property

30. Approaches to increase access to intellectual property management include:

* responsible patenting policies,
* transparency about existing patents, and
* a willingness to engage in non-exclusive voluntary licensing.[[52]](#endnote-53)

31. The continuing discussion on trade-related aspects of intellectual property rights regarding vaccines and medicines has generated different views on the appropriate balance between protecting intellectual property and ensuring access to affordable medicines and vaccines, particularly in low- and middle-income countries. Article 15 of the International Covenant on Economic, Social and Cultural Rights:

a) provides the right to enjoy the benefits of scientific progress and its applications, and

b) confirms the benefits to be derived from international scientific cooperation.

Under the human right to enjoy the benefits of scientific progress, scientific knowledge, information and advances must be shared and made accessible to everyone, without discrimination. Therefore, States should direct their own resources and coordinate the actions of others to ensure scientific progress and ensure that the applications and benefits of that scientific progress are distributed and available, especially to groups in vulnerable and marginalized situations.[[53]](#endnote-54)

32. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) includes provisions for using compulsory licensing. This allows Governments to grant licences to third parties to produce and sell patented medicines or vaccines without the patent holder’s consent, under certain conditions.[[54]](#endnote-55) Those provisions can help to increase access to essential medicines and vaccines in underserved areas. While States did not approve the initially proposed waiver of certain protections under the TRIPS Agreement, at the 12th Ministerial Conference of the World Trade Organization (WTO), held in Geneva in June 2022, States agreed to allow countries to use compulsory licensing to produce for their own consumption and also to export.[[55]](#endnote-56) Pharmaceutical companies should not seek to limit, reduce or compromise the flexibilities and other features of the intellectual property regime that are designed to protect and promote access to existing medicines.[[56]](#endnote-57) Pharmaceutical companies should stop using intellectual property rights in a way that is inconsistent with every person’s right to have access to essential medicines and safe and effective vaccines.[[57]](#endnote-58)

33. Pharmaceutical companies can voluntarily license their patents and industry knowledge to generic manufacturers in low- and middle-income countries. The generic manufacturers can then produce and distribute affordable generic versions of medicines and vaccines. The terms of these agreements may include provisions for pricing, distribution, quality control and other aspects of production and sale. Voluntary licensing agreements that are limited in geographic scope can help ensure that the product is targeted to areas of greatest need, while also protecting the market for the branded product in other regions. Non-exclusive voluntary licences have been used for HIV and hepatitis, and some companies agreed during the COVID-19 pandemic to issue non-exclusive voluntary licences for their COVID-19 medicines and vaccines. Recently, and for the first time, a company used a voluntary licence for medicine for a non-communicable disease; namely, cancer.[[58]](#endnote-59)

34. Patent pooling, i.e. an agreement between patent owners to licence one or more of their patents to one another or other companies, can be an effective strategy for increasing access to vaccines and medicines, particularly in low- and middle-income countries. In patent pooling, companies or institutions that own patents related to a specific technology or product agree to share their intellectual property rights with each other or with a third party. This creates a larger pool of intellectual property, making it easier for generic manufacturers to produce and distribute essential medicines and vaccines. This approach increases competition and can lower the price of essential medicines and vaccines, making them more accessible to patients, including those who might not be able to afford them otherwise. It can also help to increase innovation and reduce costs.[[59]](#endnote-60)

35. One example is the Medicines Patent Pool,[[60]](#endnote-61) established in 2010 as a public health initiative to promote access to affordable and quality medicines for diseases, e.g. HIV, tuberculosis and hepatitis C.[[61]](#endnote-62) The Pool negotiates voluntary licences with pharmaceutical companies to allow generic versions of patented medicines to be produced and sold in low- and middle-income countries at lower prices.[[62]](#endnote-63) During the COVID-19 pandemic, the Pool reached an agreement with some pharmaceutical companies to issue non-exclusive sublicences to manufacture their antiviral medicines.[[63]](#endnote-64)

36. Through the patent pool mechanism, licensing by patent holders has accelerated, with broader geographical coverage and improved terms and conditions, allowing increased competition. In turn, patent holders are rewarded with fair royalties that are multiplied as low-priced generics bring a surge in demand. Generic manufacturers benefit from the simplified procedure of dealing with a single negotiating body and the ability to enter the market before patents expire.[[64]](#endnote-65)

37. Access to transparent patent information is a key element in ensuring that people can enjoy their right to health. For example, companies that engage with a patent pool must disclose information about their patents, which the pool then makes public.[[65]](#endnote-66) When information about the status and specifics of intellectual property protection is readily available, competitors can confidently introduce affordable health technologies that are similar to off-patent products.[[66]](#endnote-67) Additionally, governments, generic companies, researchers, and civil society can more easily monitor and challenge questionable patent applications and approvals. To help achieve this, several countries and organizations have published patent databases and conducted surveys and analyses.[[67]](#endnote-68)

38. The Access to Medicine Index is another example of public scrutiny that aims to improve industry behaviours and the responsible management of intellectual property. The *Access to Medicine Index 2022* report showed that more companies were taking part in voluntary licences and technology transfers.[[68]](#endnote-69)

39. The COVID-19 pandemic also showed that fulfilling the human rights obligations of international assistance and cooperation is crucial to ensure that essential medicines, vaccines and health products are widely shared as a global public good. The international community must support low-income countries in financing a basic package of essential medicines for everyone if those low-income countries are unable to do so domestically.

4. Increasing regional and local production

40. One lesson learned from the response to the COVID-19 pandemic is that the limited number of vaccine manufacturers[[69]](#endnote-70) was a main reason for unfair vaccine distribution.[[70]](#endnote-71) Initiatives aimed at strengthening regional and local production of health products, medicines and vaccines can help to:

* increase access to essential health-care services,
* reduce dependence on imported products, and
* support economic development in specific regions.

Examples include:

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| **The Pharmaceutical Manufacturing Plan for Africa, under the umbrella of the African Union** | This aims to increase the local production of essential medicines by promoting investment in local pharmaceutical manufacturing and research and development. The plan has the potential to reduce dependence on imported medicines in Africa and increase access to essential medicines in the region. |
| **The Access and Delivery Partnership** | The Access and Delivery Partnership, led by the United Nations Development Programme, aims to strengthen the local manufacturing and distribution of health products in developing countries. This is focused on building national capacity to produce medicines and health technologies, e.g. diagnostic tools and medical devices. |
| **The COVID-19 Vaccine Global Access Facility (COVAX)** | Concerning vaccine equity, there are valuable lessons to be drawn from the COVAX Facility. This aims to ensure fair access to COVID-19 vaccines by supporting the development of regional and local vaccine manufacturing capacity. |

5. Ensuring governments manage distribution

41. Transparent, competitive and fair public procurement and generic substitution have also proven successful in making essential medicines more affordable.[[71]](#endnote-72) Here, the Guiding Principles on Business and Human Rights also extend to commercial transactions of States; notably, procurement. The Guiding Principles oblige States to exercise adequate supervision of the need for service providers to respect human rights, including by stating this in contracts or through legislation.[[72]](#endnote-73) The World Bank, for example, is assisting countries globally with vaccine procurement and deployment through vaccine financing operations.[[73]](#endnote-74)

42. Another key element of guaranteeing access to medicines and vaccines is to respect donation standards. For example, a key constraint in achieving universal access to COVID-19 vaccines has been the allocation of doses, with developing countries receiving vaccines last.[[74]](#endnote-75) The pandemic also highlighted the need to introduce a system to ensure that receiving countries receive vaccines with a shelf life that will allow countries to roll out their vaccination programmes.[[75]](#endnote-76) Implementing the WHO Guidelines for Medicine Donations involves helping entry and ensuring fair distribution of medicines and vaccines.[[76]](#endnote-77)

43. As part of the obligation to address practices that prevent fair access to medicines and vaccines, States must subject the pharmaceutical value chain, both upstream and downstream, to policy regulation that protects rights, especially the rights of persons in developing areas where the costs to the end-user are restrictive. The value chain includes pricing, research and development, manufacturing, registration, distribution, procurement and marketing.[[77]](#endnote-78)

44. Some States use competition laws to ensure access to medicines, by promoting a competitive marketplace that can prevent monopolies and anticompetitive practices that may restrict or limit the availability of essential medicines. These approaches include measures against practices, e.g. the charging of excessive prices, restrictions preventing other companies from accessing the market, collusive tender practices and restrictive agreements.[[78]](#endnote-79) For example, competition laws can be used to prevent pharmaceutical companies from abusing their patent rights or engaging in so-called pay-for-delay tactics that delay the entry of generic drugs into the market. This then limits competition and drives up prices.[[79]](#endnote-80)

45. Well-formulated and enforced competition laws can counter anticompetitive practices at every stage of the pharmaceutical supply chain.[[80]](#endnote-81) Competition laws can be used to promote innovation and the development of new medicines by ensuring that pharmaceutical companies can compete and invest in research and development without undue restrictions. This can enhance access to essential medicines through a competitive market with fair prices, freedom to choose among various productions, innovation and the availability of high-quality medications.[[81]](#endnote-82)

46. One approach to tackle the problem of complicated and time-consuming medical registration processes is to streamline procedures without compromising on stringent safety and quality standards. States have adopted measures, e.g. reducing redundant paperwork and bureaucratic processes, and streamlining the review and approval process for medicines. Additionally, increasing transparency and stakeholder engagement could help to ensure that the registration process is effective, efficient and responsive to patients’ and health-care providers’ needs.[[82]](#endnote-83) National regulatory agencies can also play a role in determining fair pricing by evaluating the safety, efficacy and quality of medicines and vaccines and by setting standards for pricing and reimbursement.[[83]](#endnote-84)

47. Governments can also facilitate the production of generic medicines. This can be through measures, e.g. expedited review processes, flexible regulatory pathways and reliance on data from other regulatory authorities. By reducing barriers to entry for generic manufacturers, governments can promote competition in the market and lower prices for consumers.[[84]](#endnote-85) Continuously engaging with stakeholders is important to receive feedback on how effective regulatory activities are.[[85]](#endnote-86)

48. An efficient procurement system relies on:

* transparent management,
* a limited selection of medicines based on a restricted list,
* accurate forecasting of demand,
* competitive tendering,
* multi-product agreements,[[86]](#endnote-87)
* bulk purchasing,
* pre-qualification of suppliers,
* close monitoring of selected suppliers, and
* reliable financing.[[87]](#endnote-88)

Bulk purchasing allows governments to negotiate lower prices for essential medicines and vaccines.[[88]](#endnote-89) Quality assurance and good procurement practice means that suppliers are certified for good manufacturing practices. In decentralized systems, some States have centralized price negotiations and require lower levels of government to place orders through the successful bidder at the centrally negotiated price to maintain purchase volumes.[[89]](#endnote-90)

49. Data on purchase prices and quality test certificates are critical for other governments in benchmarking their purchase prices and making good procurement decisions. Examples of public repositories to promote transparency of medicine prices and quality include the Market Information for Access to Vaccines[[90]](#endnote-91) and Global Fund Price and Quality Reporting[[91]](#endnote-92) initiatives.

50. The development of appropriate medical devices that respond to the local context and their accessibility has a direct impact on health-care delivery in low- and middle-income countries. WHO has created a compendium of emerging innovative health technologies for low-resource settings to support non-governmental organizations, governments and other stakeholders in making procurement decisions and to ensure greater investment in health technology towards universal access to essential health technologies.[[92]](#endnote-93)

51. Many governments create a national essential medicines list that covers medicines and vaccines that are deemed essential for the population’s health. These lists can be used as a reference for procurement, pricing and reimbursement decisions to ensure that essential medicines and vaccines are always available and affordable. The lists must be adapted to the specific health context, taking into consideration the needs of different segments of the population, e.g. women and children, older persons and persons living in poverty, and must be updated regularly, through a participatory process.[[93]](#endnote-94)

52. Ensuring a robust, efficient and resilient supply chain is also important to ensuring everyone has access to medicines and vaccines. Governments can strengthen supply chain management by investing in coordination, and planning and distribution systems and ensuring that they are properly staffed and equipped. For example, the Global Fund to Fight AIDS, Tuberculosis and Malaria assists countries in procuring supply management and facilitates access to technical assistance and capacity-building services in recipient countries in partnership with technical agencies.[[94]](#endnote-95)

53. As part of States’ responsibility to ensure that essential medicines, vaccines and other health products are available and accessible to everyone without discrimination, States must establish effective distribution and monitoring systems. Additionally, health-care providers must ensure that medications are prescribed and dispensed in a fair and non-discriminatory manner. Some developing countries have successfully adopted certification programmes for distributors.[[95]](#endnote-96)

54. Considering that the distribution chain involves various entities, including private actors, most States have national regulations in place to distribute essential medicines in both the public and private sectors. These regulations typically address how medicines and temperature-sensitive products are stored, transported and handled.[[96]](#endnote-97)

55. Transparency is a core component of good governance. Civil society and patient groups rely on transparent information to hold government authorities, private sector companies and international organizations accountable. Transparency can ensure fairness during negotiations that take place between pharmaceutical companies and procurement organizations. Transparency is also an essential aspect of combating corruption, which can occur at any stage of the medicine chain. Reducing corruption in the pharmaceutical sector can have a direct impact on countries’ investment in health care, while improving access to quality medicines.

56. Regulatory authorities’ work in improving both innovation and access could be significantly supported if accurate information on the costs of research and development, production and distribution of health technologies were available. Most regulatory authorities already mandate the disclosure of information on quality, safety and efficacy of health technologies and some encourage sharing of information on investments made in the research and development of health technologies.[[97]](#endnote-98) However, this information can be difficult to break down and understand.

1. Ensuring that medicines, vaccines and other health products are safe and are of high quality

57. States must protect the population from unsafe and poor-quality medicines. Quality assurance for medicines includes, e.g.:

* registering and marketing good quality, safe and efficacious products under ethically and medically validated clinical trials,
* continuously regulating the quality of production of medicines, and
* preventing substandard and spurious medicines from being sold on the market after registration.[[98]](#endnote-99)

Specific examples include:

* quality control,
* good manufacturing practices,[[99]](#endnote-100)
* quality management systems,
* regulatory oversight, and
* post-market surveillance.

58. Regulatory agencies play a critical role in ensuring the quality of medicines and vaccines. They are responsible for establishing and enforcing quality standards, conducting inspections and audits of manufacturing facilities as well as ensuring that products meet all regulatory requirements. Therefore, they must be adequately resourced.

59. Also, health-care providers must be trained to properly administer medications and monitor patients for negative effects. Ensuring the safety and quality of medicines and vaccines[[100]](#endnote-101) is essential for promoting trust and acceptability.

60. The WHO Prequalification of Medicines Programme[[101]](#endnote-102) can help improve public health outcomes and reduce differences in the level of health by ensuring access to high-quality medicines and vaccines in low- and middle-income countries. The programme was created in 2001 to ensure that the large quantities of low-cost treatments for HIV, tuberculosis and malaria produced by generic manufacturers met the need for stringent assessment. The programme includes a detailed evaluation process, e.g. reviewing the manufacturing facilities, testing the products for quality and safety and assessing the clinical data on the product. This process helps ensure that the products included in the prequalification list meet international standards and are suitable for use in low- and middle-income countries. The programme also negotiates with manufacturers to secure lower prices for prequalified products. This contributes to ensuring that these products are accessible to countries with limited resources. However, the programme has some potential limitations and ongoing efforts are needed to ensure that implementing the programme remains transparent, impartial and effective in achieving the goals.[[102]](#endnote-103)

61. One detection and reporting tool is the WHO Global Surveillance and Monitoring System for substandard and falsified medical products. Information is collected and analysed when working together with national regulatory authorities, international organizations and other stakeholders. The system is designed to improve the accuracy and completeness of data on substandard and falsified medical products, and to facilitate the sharing of information across countries and regions. When needed, WHO issues a global medical product alert to warn countries and populations that a dangerous medical product exists.

1. Promoting the use of medicines, vaccines and other health products for those who need them

62. Promoting good health outcomes means ensuring medicines and vaccines are accepted. This refers to the extent to which patients or individuals are willing to follow their treatment plan. Acceptability is influenced by a range of factors, including:

* cultural codes and customs,
* personal preferences,
* previous experiences with medications or vaccines,
* access to health care, and
* trust in health-care providers or authorities.

For example, a medicine or vaccine may be effective in treating or preventing a particular disease but if patients or individuals think it is unsafe or ineffective, they may be hesitant to use it. Similarly, if a medicine or vaccine is difficult to access or administer, or if it causes significant side effects, patients may be less likely to follow the prescribed treatment.[[103]](#endnote-104)

63. Behavioural science plays an important role in ensuring access to medicines and vaccines by identifying and addressing barriers that may prevent people from seeking or following health-care interventions, including vaccines and medicines. These approaches can help identify reasons why some people may be hesitant to take vaccines or medicines, and can be used to ensure public health campaigns and messaging address the correct audience and address their concerns. There are also examples of how behavioural science, including social psychology, can help to improve communication between health-care providers and patients, e.g. through the use of plain language, which can improve patients’ understanding of the benefits and risks of vaccines and medicines.[[104]](#endnote-105) The recent resolution adopted by the WHO Executive Board on behavioural insights for better health is important to acknowledging the centrality of behavioural science in promoting how people enjoy their right to health.[[105]](#endnote-106)

64. To promote acceptability, health-care providers and authorities should consider patients’ or individuals’ perspectives and needs when developing health-care policies and programmes. This includes addressing concerns about safety and efficacy, ensuring accessibility, and promoting education and awareness about the importance of using medicines and vaccines as prescribed.[[106]](#endnote-107)

65. Providing accurate and accessible information on the safety, effectiveness and benefits of medicines and vaccines is essential to build trust and increase acceptability. Health communication should be written specifically for different audiences, using culturally appropriate language and messaging to allow different communities to understand. To improve levels of acceptance, public information campaigns must reach all social groups, especially the most marginalized, to ensure that everyone has access to vaccines.[[107]](#endnote-108)

66. Similarly, engaging with communities and involving them in the decision-making process is essential to increasing trust in and the acceptability of medicines and vaccines. This can include working with community leaders and faith-based organizations,[[108]](#endnote-109) health-care providers and patient advocates to provide information and address concerns.[[109]](#endnote-110) Information campaigns, surveys, interviews and various research methodologies can help contextualize interventions. Understanding people’s concerns allows the design of specifically targeted interventions that are multiple, layered and deployed at the local level, taking into consideration the specific area.[[110]](#endnote-111)

1. Original title: Compendium of good practices on access to medicines, vaccines and other health products on how everyone can enjoy their right to receive the highest attainable standard of physical and mental health [↑](#endnote-ref-2)
2. See https://www.ohchr.org/en/calls-for-input/2023/call-contributions-good-practices-ensuring-access-medicines-vaccines-and-other. [↑](#endnote-ref-3)
3. See [A/63/263](http://undocs.org/en/A/63/263), annex. [↑](#endnote-ref-4)
4. The World Health Organization (WHO)has described “other health products” as including medical devices, diagnostics, protective equipment and assistive devices. WHO, *Road Map for Access to Medicines, Vaccines and Other Health Products 2019–2023* (2019), p. 2. [↑](#endnote-ref-5)
5. See in particular WHO, *Road Map* *for Access to Medicines*. [↑](#endnote-ref-6)
6. General comment No. 14 (2000), para. 12. [↑](#endnote-ref-7)
7. Jillian Clare Kohler and others, “Corruption in the pharmaceutical sector: diagnosing the challenges” (Transparency International UK, 2016), p. 4. [↑](#endnote-ref-8)
8. Esther de Haan and Albert ten Kate, *Pharma’s Pandemic Profits: Pharma Profits from COVID-19 Vaccines* (Amsterdam, Centre for Research on Multinational Corporations, February 2023), p. 11. [↑](#endnote-ref-9)
9. See [A/HRC/49/35](http://undocs.org/en/A/HRC/49/35) and [A/HRC/52/56](http://undocs.org/en/A/HRC/52/56). [↑](#endnote-ref-10)
10. On the human rights challenges stemming from the lack of universal and equitable access to COVID-19 vaccines, see [A/HRC/49/35](http://undocs.org/en/A/HRC/49/35) and [A/HRC/52/56](http://undocs.org/en/A/HRC/52/56). [↑](#endnote-ref-11)
11. Ibid. See also Veronika J. Wirtz and others, “Essential medicines for universal health coverage”, *The Lancet*, vol. 389 (January 2017). [↑](#endnote-ref-12)
12. WHO, “Access to medicines: making market forces serve the poor” (2017), pp. 14 and 15. [↑](#endnote-ref-13)
13. WHO and United Nations Children’s Fund (UNICEF), “COVID-19 pandemic fuels largest continued backslide in vaccinations in three decades”, 15 July 2022. [↑](#endnote-ref-14)
14. See https://www.who.int/health-topics/gender#tab=tab\_1. [↑](#endnote-ref-15)
15. WHO, “Almost one billion children and adults with disabilities and older persons in need of assistive technology denied access, according to new report”, 16 May 2022. [↑](#endnote-ref-16)
16. See [A/HRC/49/35](http://undocs.org/en/A/HRC/49/35) and [A/HRC/52/56](http://undocs.org/en/A/HRC/52/56). [↑](#endnote-ref-17)
17. WHO, “Access to medicines”, p. 15. [↑](#endnote-ref-18)
18. [A/HRC/17/43](http://undocs.org/en/A/HRC/17/43), para. 32. See also WHO, *Access to NCD Medicines: Emergent Issues during the COVID-19 Pandemic and Key Structural Factors* (2023). [↑](#endnote-ref-19)
19. WHO, “Access to medicines”, p. 15. See also the submission from the Syrian Arab Republic (in Arabic). [↑](#endnote-ref-20)
20. [A/HRC/49/35](http://undocs.org/en/A/HRC/49/35), para. 45. [↑](#endnote-ref-21)
21. Davide Piaggio and others, “A framework for designing medical devices resilient to low-resource settings”, *Globalization and Health*, vol. 17, No. 64 (2021). [↑](#endnote-ref-22)
22. WHO*, Road Map* *for Access to Medicines*, p. 16. [↑](#endnote-ref-23)
23. Florian Till and others, “Governing the public private partnerships of the future: learnings from the experiences in pandemic times”, *Eurohealth*, vol. 27, No. 1 (2021). [↑](#endnote-ref-24)
24. See, for example, Ernst R. Berndt and others, “Advance market commitments for vaccines against neglected diseases: estimating costs and effectiveness”, *Health Economics,* vol. 16, No. 5 (2005). [↑](#endnote-ref-25)
25. See https://www.gavi.org/news/media-room/covax-announces-new-agreement-plans-first-deliveries. [↑](#endnote-ref-26)
26. See https://www.theglobalfund.org/en/. [↑](#endnote-ref-27)
27. See https://www.mmv.org/. [↑](#endnote-ref-28)
28. See https://www.imi.europa.eu/. [↑](#endnote-ref-29)
29. See https://globalhealthprogress.org/collaboration/access-to-oncology-medicines-atom-coalition/. [↑](#endnote-ref-30)
30. Submission from the International Federation of Pharmaceutical Manufacturers & Associations. [↑](#endnote-ref-31)
31. [A/HRC/23/42](http://undocs.org/en/A/HRC/23/42), para. 21. [↑](#endnote-ref-32)
32. WHO, “Access to medicines”, pp. 15 and 16. [↑](#endnote-ref-33)
33. Ibid., p. 24. [↑](#endnote-ref-34)
34. See WHO, “WHO guideline on country pharmaceutical pricing policies” (2020). [↑](#endnote-ref-35)
35. Guiding Principles on Business and Human Rights, principle 11. [↑](#endnote-ref-36)
36. Ibid., principle 15. [↑](#endnote-ref-37)
37. [A/HRC/49/35](http://undocs.org/en/A/HRC/49/35), para. 16. [↑](#endnote-ref-38)
38. See WHO, “WHO guideline on country pharmaceutical pricing policies”, and WHO, *Country Pharmaceutical Pricing Policies: A Handbook of Case Studies* (2021). [↑](#endnote-ref-39)
39. Suerie Moon and others, “A win-win solution? A critical analysis of tiered pricing to improve access to medicines in developing countries”, *Globalization and Health,* vol. 7 (2011). [↑](#endnote-ref-40)
40. *Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines* (September 2016), p. 29. [↑](#endnote-ref-41)
41. [A/HRC/52/56](http://undocs.org/en/A/HRC/52/56), para. 52. [↑](#endnote-ref-42)
42. WHO Council on the Economics of Health for All, “Governing health innovation for the common good”, Council Brief No. 1 (2021). [↑](#endnote-ref-43)
43. Sabine Vogler and others, “Pharmaceutical policies in European countries in response to the global financial crisis”, *Southern Med Review*, vol. 4, No. 2 (2011). See also the submission from the national human rights institution of Argentina (in Spanish) and the submission from Argentina (in Spanish). [↑](#endnote-ref-44)
44. Jaime Espin, Joan Rovira and Antonio Olry de Labry, “External reference pricing”, Review Series on Pharmaceutical Pricing Policies and Interventions, Working Paper No. 1 (WHO and Health Action International, 2011), p. 1. See also the submissions from Luxembourg and Malaysia. [↑](#endnote-ref-45)
45. WHO, report on the 2017 Fair Pricing Forum, p. 7. [↑](#endnote-ref-46)
46. See, for example, Sarah L. Barber, Luca Lorenzoni and Paul Ong, *Price Setting and Price Regulation in Health Care: Lessons for Advancing Universal Health Coverage* (WHO and Organisation for Economic Co-operation and Development, 2019). [↑](#endnote-ref-47)
47. [A/HRC/20/15/Add.2](http://undocs.org/en/A/HRC/20/15/Add.2), para. 31. [↑](#endnote-ref-48)
48. See, for example, National Institute for Health and Care Excellence, “Patient Access Schemes Liaison Unit”. [↑](#endnote-ref-49)
49. Submission from Burundi. [↑](#endnote-ref-50)
50. [A/HRC/23/42](http://undocs.org/en/A/HRC/23/42), para. 22. [↑](#endnote-ref-51)
51. Non-governmental organizations active in this area include Médecins sans frontières, the Drugs for Neglected Diseases initiative, Health Action International and the Access to Medicine Foundation. [↑](#endnote-ref-52)
52. WHO, “Access to medicines”, p. 22. [↑](#endnote-ref-53)
53. [A/HRC/52/56](http://undocs.org/en/A/HRC/52/56), para. 50. [↑](#endnote-ref-54)
54. *Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines*, p. 18; see also the Declaration on the TRIPS Agreement and Public Health. [↑](#endnote-ref-55)
55. See WTO, Ministerial Decision on the TRIPS Agreement, document WT/MIN(22)/30. See also Gita Sen, statement at the OHCHR expert workshop on good practices in ensuring access to medicines, vaccines and other health products, Geneva, 14 February 2023. [↑](#endnote-ref-56)
56. [A/63/263](http://undocs.org/en/A/63/263), annex, para. 32; see also para. 26. [↑](#endnote-ref-57)
57. [E/C.12/2021/1](http://undocs.org/en/E/C.12/2021/1), para. 6; and [A/HRC/49/35](http://undocs.org/en/A/HRC/49/35), para. 18. [↑](#endnote-ref-58)
58. Access to Medicine Foundation, “First voluntary licence for a cancer treatment is a promising sign for future expansion of access to innovative medicines”, 15 November 2022. [↑](#endnote-ref-59)
59. See https://www.wipo.int/patent-law/en/developments/standards.html; and Esteban Burrone, “Patent pooling for global health”, in *The Cambridge Handbook of Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development,* Margaret Chon, Pedro Roffe and Ahmed Abdel-Latif, eds. (2018). [↑](#endnote-ref-60)
60. https://medicinespatentpool.org/who-we-are/about-us [↑](#endnote-ref-61)
61. Medicines Patent Pool, “A decade of making medicines accessible: 18 billion doses of treatment in 10 years – annual report 2020”. [↑](#endnote-ref-62)
62. WHO, “Access to medicines”, p. 22. [↑](#endnote-ref-63)
63. See Medicines Patent Pool, “COVID-19”, and [A/HRC/49/35](http://undocs.org/en/A/HRC/49/35), para. 54. [↑](#endnote-ref-64)
64. WHO, “Access to medicines”, p. 23. [↑](#endnote-ref-65)
65. Ibid., p. 23. [↑](#endnote-ref-66)
66. See WHO, World Intellectual Property Organization (WIPO) and WTO, *Promoting Access to Medical Technologies and Innovation*, 2nd edition (2020); and United Nations Development Programme (UNDP), *Patent Information and Transparency: A Methodology for Patent Searches on Essential Medicines in Developing Countries* (2012), pp. 5 and 9–11. [↑](#endnote-ref-67)
67. *Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines*, p. 36. [↑](#endnote-ref-68)
68. See Access to Medicine Foundation, *Access to Medicine Index 2022*. [↑](#endnote-ref-69)
69. Submissions from Australia and from Burundi (in French). [↑](#endnote-ref-70)
70. [A/HRC/52/56](http://undocs.org/en/A/HRC/52/56), para. 19; and Victor J. Dzau, Celynne A. Balatbat and Anaeze C. Offodile II, “Closing the global vaccine equity gap: equitably distributed manufacturing”, *The Lancet*, vol. 399 (May 2022), p. 1924. [↑](#endnote-ref-71)
71. Loraine Hawkins, “Competition policy”, Review Series on Pharmaceutical Pricing Policies and Interventions, Working Paper No. 4 (WHO and Health Action International, 2011). See also the submission from the Syrian Arab Republic (in Arabic). [↑](#endnote-ref-72)
72. Guiding principle 5. See also Claire Methven O’Brien and others, *Public Procurement and Human Rights: A Survey of Twenty Jurisdictions* (International Learning Lab on Public Procurement and Human Rights, July 2016), p. 19. [↑](#endnote-ref-73)
73. See https://blogs.worldbank.org/voices/tackling-vaccine-inequity-africa. [↑](#endnote-ref-74)
74. [A/HRC/52/56](http://undocs.org/en/A/HRC/52/56), para. 51. [↑](#endnote-ref-75)
75. [A/HRC/49/35](http://undocs.org/en/A/HRC/49/35), para. 53. [↑](#endnote-ref-76)
76. Veronika J. Wirtz, statement at the OHCHR expert workshop on good practices in ensuring access to medicines, vaccines and other health products, Geneva, 14 February 2023. [↑](#endnote-ref-77)
77. Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, statement at the OHCHR expert workshop on good practices in ensuring access to medicines, vaccines and other health products, Geneva, 14 February 2023. [↑](#endnote-ref-78)
78. See, for example, United States of America, Federal Trade Commission, “Agreements filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: overview of agreements filed in fiscal year 2012 – a report by the Bureau of Competition” (2013). [↑](#endnote-ref-79)
79. United States of America, Federal Trade Commission, “Pay-for-delay: how drug company pay-offs cost consumers billions” (2010). [↑](#endnote-ref-80)
80. Hawkins, “Competition policy”, p. 41. [↑](#endnote-ref-81)
81. European Commission, “Competition enforcement in the pharmaceutical sector (2009–2017): European competition authorities working together for affordable and innovative medicines” (2019), pp. 19 ff. [↑](#endnote-ref-82)
82. See, for example, the WHO Global Benchmarking Tool for Evaluation of National Regulatory Systems for Medical Products. See also https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation; https://amrh.nepad.org/who-we-are; https://www.paho.org/en/documents/regulatory-system-strengthening-americas-lessons-learned-national-regulatory-authorities; and https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review. [↑](#endnote-ref-83)
83. See, for example, WHO, *Pricing of Cancer Medicines and its Impacts* (2018). [↑](#endnote-ref-84)
84. See [TD/RBP/CONF.8/3](http://undocs.org/en/TD/RBP/CONF.8/3). [↑](#endnote-ref-85)
85. Submission from Australia. [↑](#endnote-ref-86)
86. Submission from New Zealand. [↑](#endnote-ref-87)
87. WHO, “Operational principles for good pharmaceutical procurement” (Geneva, 1999). [↑](#endnote-ref-88)
88. WHO, “Operational principles for good pharmaceutical procurement” (Geneva, 1999).

    submissions from Argentina, Ecuador and El Salvador (in Spanish). See also the submission from Spain (in Spanish). [↑](#endnote-ref-89)
89. [A/HRC/23/42](http://undocs.org/en/A/HRC/23/42), para. 51. [↑](#endnote-ref-90)
90. See https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/mi4a. [↑](#endnote-ref-91)
91. See https://www.theglobalfund.org/en/sourcing-management/price-quality-reporting. [↑](#endnote-ref-92)
92. Available at https://www.who.int/publications/i/item/9789240049505. [↑](#endnote-ref-93)
93. See, for example, WHO, *Model List of Essential Medicines*, 22nd ed. (2021). [↑](#endnote-ref-94)
94. [A/HRC/17/43](http://undocs.org/en/A/HRC/17/43), para. 33. [↑](#endnote-ref-95)
95. Center for Global Development, “Drug resistance: improving standards in the medicine distribution chain”. Available at https://www.cgdev.org/sites/default/files/archive/doc/DWRG/distribution\_chain.pdf. [↑](#endnote-ref-96)
96. [A/HRC/23/42](http://undocs.org/en/A/HRC/23/42), para. 54. [↑](#endnote-ref-97)
97. See, for example, WHO and Health Action International, *Measuring Medicine Prices, Availability, Affordability and Price Components*, 2nd edition(2008). [↑](#endnote-ref-98)
98. [A/HRC/23/42](http://undocs.org/en/A/HRC/23/42), para. 61. [↑](#endnote-ref-99)
99. See submission from the national human rights institution of Argentina (in Spanish). [↑](#endnote-ref-100)
100. See WHO, *Safety Monitoring of Medicinal Products* (2012). [↑](#endnote-ref-101)
101. WHO, “Prequalification of medicines by WHO”. <https://www.who.int/news-room/fact-sheets/detail/prequalification-of-medicines-by-who> [↑](#endnote-ref-102)
102. Elina Urli Hodges and others, “Navigating complexity to improve global access: supporting a more efficient and effective World Health Organization prequalification program” (Duke Global Health Innovation Center and Global Health Technologies Coalition, 2022). [↑](#endnote-ref-103)
103. Kirsi Kvarnström and others, “Factors contributing to medication adherence in patients with a chronic condition: a scoping review of qualitative research”, *Pharmaceutics*,vol. 13, No. 7 (July 2021); and K. Rivet Amico and others, “Advantages to using social-behavioral models of medication adherence in research and practice”, *Journal of General Internal Medicine*,vol. 33, No. 2 (February 2018). [↑](#endnote-ref-104)
104. For other examples, see [A/HRC/52/56](http://undocs.org/en/A/HRC/52/56), para. 23; Fadi Makki, statement at the OHCHR expert workshop on good practices in ensuring access to medicines, vaccines and other health products, Geneva, 14 February 2023; Malaysia, statement at the expert workshop on good practices in ensuring access to medicines, vaccines and other health products, Geneva, 14 February 2023; and submission from New Zealand. [↑](#endnote-ref-105)
105. The resolution will be considered at the seventy-sixth World Health Assembly, which will take place in Geneva in May 2023. See also the submission from Malaysia. [↑](#endnote-ref-106)
106. See also the submission from Luxembourg. [↑](#endnote-ref-107)
107. See [A/HRC/52/56](http://undocs.org/en/A/HRC/52/56), para. 43. [↑](#endnote-ref-108)
108. Submission from Malaysia. [↑](#endnote-ref-109)
109. Submission from the Dominican Republic. [↑](#endnote-ref-110)
110. [A/HRC/52/56](http://undocs.org/en/A/HRC/52/56), paras. 25 and 26. [↑](#endnote-ref-111)