**SUBMISSION BY THIRD WORLD NETWORK**

**LEGAL AND REGULATORY BARRIERS TO ACCESS TO HEALTH PRODUCTS**

**INPUT TO HRC RESOLUTION 50/13 - CHALLENGES**

Call for Contributions

OHCHR analytical study on key challenges in ensuring access to medicines, vaccines and other health products

(HRC resolution 50/13)

30 November 2023

1. **Question (a): What are the major obstacles at the national, regional and international levels to ensure equitable access to medicines, vaccines and other health products?**

National level: The health system of a country determines the extent of the nation’s access to medicines, vaccines and other health products (hereinafter collectively referred to as “health products”). A health system that is highly dominated by the private sector presents various challenges to timely access to affordable health products including high out-of-pocket expenditure on medicines. Although [various factors](https://documents-dds-ny.un.org/doc/UNDOC/GEN/G13/135/08/PDF/G1313508.pdf?OpenElement) can impact equitable access to medicines[[1]](#endnote-1), price is a significant barrier as the “price” factor can singularly be determinative of life or death, where a deadly disease is treatable.[[2]](#endnote-2) “*Affordability is the cornerstone of access...Affordability matters for households and health budgets*”[[3]](#endnote-3).

In 2017, [a report by WHO](https://cdn.who.int/media/docs/default-source/essential-medicines/fair-price/chapter-medicines.pdf?sfvrsn=adcffc8f_4&download=true) estimated that:

* 90% of the population in low- and middle-income countries purchases medicines through out-of-pocket payments;
* procurement of medicines covers 20% to 60% of health spending in low- and middle- income countries (LMICs), compared with 18% in OECD countries.

Lack of public provision of health products forces people to procure medicines from the market at an exorbitant price resulting in catastrophic health payment and impoverishment. Decentralised production of generic medicines can ensure affordability through increased supplies and competitive markets, leading to inclusion of essential medicines into **national public procurement programmes** which is crucial to facilitating access. *“If a household is forced to sell an asset, like the family cow, or take its children out of school, this payment can be the final nail in the coffin that buries the family in intergenerational poverty. This is the pathology of poverty when no forms of social protection, such as those provided by universal health coverage, are available and even low-cost generic products are a heavy financial burden”*.[[4]](#endnote-4)

International Level**:** Legal and policy change at the international level is required to promote access to health products. The current mechanism at the international level such as that relating to funding and procurement like UNICEF, Global Drug Facility, the Global Fund to fight AIDS, Tuberculosis and Malaria, GAVI etc do procure and distribute medicines for certain diseases. However, as these mechanisms procure medicines from manufacturers which must be WHO pre-qualified it has the unintended consequence of disincentivising local production in Africa as only a few generic manufactures can afford such certification. The [recent USITC report](https://www.usitc.gov/publications/332/pub5469.pdf) noted that WHO pre-qualification (PQ) “requires significant effort by manufacturers in order to complete the application requirements and address data standards, which may be challenging for some manufacturers”. The report also highlights concerns about the affordability of these processes for smaller manufacturers in LMICs, as they entail a one-time application fee of $25,000 in addition to an annual fee of $20,000 for a comprehensive product assessment.

The legal barriers emanating from WTO Agreements such as [TRIPS](https://www.wto.org/english/tratop_e/trips_e/trips_e.htm) and [TRIMS](https://www.wto.org/english/tratop_e/invest_e/trims_e.htm), as well as bilateral. Regional and plurilateral trade agreements and economic partnerships, are other challenges which reduce the [policy space](https://mpra.ub.uni-muenchen.de/26355/) of States to facilitate the availability of affordable health products.

1. **(b) Please elaborate on the specific barriers, if any, that women and girls, older persons, children, persons living in poverty, or other persons or groups in situations of vulnerability or marginalization face in accessing medicines, vaccines and other health products.**
2. A substantial access barrier specific to women is the lack of access to cancer medicines, where the disease affects women such as breast cancer, cervical cancer, uterus cancer etc. Although medicines and treatment are available, these are not frequently accessible to patients living in developing countries due to the high prices primarily caused by patent monopolies. According to WHO, while 5-year breast cancer survival rate exceeds 90% in high-income countries, percentages are much lower in South Africa (40%) and India (66%).[[5]](#endnote-5) The lack of affordable medicines plays a big role in low level survival of breast cancer patients in developing countries. **Annex 1** provides a table of such medicines and prices.

Further, [a 2021 report by Protect Our Care](https://www.protectourcare.org/wp-content/uploads/2021/06/POC-How-High-Drug-Costs-Hurt-Women-.pdf), on how high drug costs hurt women reiterates that:

* many diseases mainly prevalent in poor populations have no medical treatments or only old and ineffective ones;
* access also suffers from the lack of products adapted to perform well in resource-constrained settings with a tropical climate;
* women are more likely than their male counterparts to use prescription drugs[[6]](#endnote-6) yet women are less able to afford healthcare due to economic and social inequality;
* in the US for example, eight in ten single parents are women, women are disproportionately responsible for prescription costs of children;
* one in ten women (in the US) are uninsured, resulting in insufficient health care access and poorer health outcomes.
1. Children with rare diseases in developing countries are often denied access to the most effective medicines. Though there are breakthrough medicines to treat rare diseases such as Spinal Muscular Atrophy, Cystic Fibrosis and Duchenne Muscular Dystrophy, exorbitant pricing prevents access. **Annex 2** provides a list of such medicines. Research also shows the practice of hiking prices of existing drugs when repurposed for the treatment of rare disease.[[7]](#endnote-7)
2. **(c) Are there any legal or regulatory challenges that impact the accessibility and affordability of medicines, vaccines and other health products?**

There is a need for more research and understanding into the production and access barriers posed by **trade secrets and regulatory approval requirements** around biological drugs, including vaccines. Much of the technical and critical know-how that relates to the development of biologics are protected by trade secrets[[8]](#endnote-8) which are unlimited in duration and can stonewall generic entry by biotherapeutics known as biosimilars (i.e. non- originator biologic products). In the case of small molecules, generic manufacturers only have to show bioequivalence[[9]](#endnote-9), which is relatively less expensive and easy to carry out. In jurisdictions where data exclusivity affecting timeliness of drug registration does not exist (or has expired), the pharmaceutical regulatory agency is allowed to rely on originator data for marketing approval and tests for safety and efficacy of the product are not repeated since these have been already established by the originator.[[10]](#endnote-10) However, generally in biologic manufacture, the approach of regulation is that **the process is the product**, and therefore the non-originator has to follow the manufacturing process of the originator as an identical product may not be possible if an alternate manufacturing process is used.[[11]](#endnote-11) The originator protects its manufacturing process as a trade secret. Hence the requirement for clinical trials for non-originators as well. This involves time and financial resources, and has ethical considerations since control groups for clinical trials need to be replicated.

The high cost of manufacture together with a higher degree of entry barriers result in non-originators taking a longer entry time and fewer competitors in the market. Prices of biosimilars do not drop as much as they do when generic small molecules enter the market. However, [scientists question](https://healthpolicy-watch.news/revise-biosimilar-guidelines-scientists-demand-who-says-not-now/) the scientific rationale behind this approach for biosimilars.

Recently however, new developments have led to a reconsideration of the biosimilar approval process:

* in 2021, the Medicines and Healthcare products Regulatory Agency in the UK changed its guidelines for the approval of biosimilars in the country by dropping the need for comparative clinical trials;
* In 2022, the WHO similarly amended its own guidelines for the approval and regulation of biosimilars, by doing away with the compulsory need for comparative clinical trials.

There is an urgent need to reform biosimilar guidelines at the national level to avoid unnecessary clinical trials. However, for vaccines, there is still no regulatory pathway whatsoever for non-originators, or generic or follow-on manufacturers. It is important that WHO and other relevant agencies look at the possibilities of developing a non-originator pathway for vaccines.

1. **(d) Please elaborate on the impact of research and development models for pharmaceuticals and other health technologies, including emerging digital technologies, on the access to medicines, vaccines and other health products?**
2. The current R&D model is based on the ["blockbuster model"](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7592140/#Fn1), which incentivizes pharmaceutical companies to maintain intellectual property monopolies to prolong high prices. As a result, new health products cannot be accessed by the vast majority of people living in developing countries. Further, R&D is evolving. Increasingly, innovation is being driven by small firms which are then acquired by big MNCs. This is part of a larger pattern of mergers and acquisitions in the pharmaceutical industry leading to consolidation of power in [“a small clique of powerful drug manufacturers”](https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/).[[12]](#endnote-12) The current R&D model has resulted in[[13]](#endnote-13):
* **The pharmaceutical sector is becoming more** [**financialised**](https://repository.essex.ac.uk/27744/3/Financialisation%20-%20full%20paper.pdf)**.[[14]](#endnote-14)** Pharmaceutical prices are raised to pay for costly share buybacks and dividends with more **money being spent on marketing and advertising in order to push up sales and less being invested in R&D and the development of new drugs.** Further**,** R&D capability is weakened due to closures of older R&D facilities and the breakup of research teams to cut the costs of production and manufacturing;
* Over **50% of new medicines reaching the market do not present any added therapeutic advance for patients;**
* **Critical health needs are not being met or are sidelined** as production focuses on drugs that offer better sales prospects and which are lucrative. Disease prevention, vaccines, antibiotics and much-needed new cures are often sidelined in favour of high-incidence chronic or life-long treatments (such as diabetes), and there is a severe lack of investment for conditions that mainly affect people in low-income countries;
* Patenting **is increasingly moving upstream in the research process.** Not only are products being patented, but the tools and processes for research that might lead to those discoveries are being patented as well.

Better regulation of the pharmaceutical industry is required. An industry arises from the structure of laws and regulations, informal and informal, that govern it. In the pharmaceutical industry, the ideology of shareholder primacy holds sway.[[15]](#endnote-15) State intervention is required, clearly evidenced in the COVID-19 response where vaccines developers were given billions of public funds with “no strings attached”.[[16]](#endnote-16)

1. **(e) From your perspective, what are the main challenges in terms of international cooperation, partnerships and collaboration to ensure access to medicines, vaccines and other health products?**
2. From a human rights perspective it is important that States play an [important role](https://docstore.ohchr.org/SelfServices/FilesHandler.ashx?enc=4slQ6QSmlBEDzFEovLCuW1a0Szab0oXTdImnsJZZVQdxONLLLJiul8wRmVtR5Kxx73i0Uz0k13FeZiqChAWHKFuBqp%2B4RaxfUzqSAfyZYAR%2Fq7sqC7AHRa48PPRRALHB) in financing R&D and at the same time impose [conditions](https://www.who.int/publications/m/item/governing-health-innovation-for-the-common-good) to facilitate affordable access to medicines especially in developing countries. Failure to check the monopolization of publicly funded R&D compromises access in other developing countries. It in fact amounts to a violation of the extraterritorial obligations of States to uphold human rights. We refer specifically to paragraph 39 of CESCR General Comment No.14 which states: “*To comply with their international obligations in relation to article 12, States parties have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the Charter of the United Nations and applicable international law”.* **In the area of health, States need to prioritise the operationalization of equity.**
3. **(f) What impact, if any, does the existing intellectual property rights regime have on access to medicines, vaccines and other health products. How can global efforts better address intellectual property rights and technology transfer issues to enhance access to medicines, vaccines and other health products?**
4. The current IP regime established through the TRIPS Agreement and trade agreements/economic partnerships compromises the ability of developing countries to fulfil its obligations under Articles 12 and 15.1 (b) of the International Covenant on Economic Social and cultural Rights (ICESCR) as well as other international human rights treaties. The mandate on product patent protection allows pharmaceutical TNCs to monopolise markets in all developing countries without any corresponding obligation to make health products available at an affordable price to patients or governments of developing countries. Though many developing country manufacturers possess the ability to develop affordable generic versions, patent protection prevents production in the absence of a voluntary license, or a compulsory or government use license. According to data on the geographical breakdown of sales of new medcines introduced between 2026-21, top developing country markets popularly known as pharmerging markets account for 3.2% of the total sales (See Annex 3). This clearly shows that patent monopoly obstructs access to patented medicines in developing countries.

To address the challenges of product patent protection the TRIPS Agreement prescribes the use of flexibilities, as reaffirmed in the [Doha Declaration on the TRIPS Agreement and Public Health](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm). However, there are challenges to the full utilisation of the flexibilities:

* First, a majority of developing countries lack pharmaceutical manufacturing capacity themselves and therefore need to depend upon other countries having manufacturing capabilities, through the use of flexibilities like compulsory license or government use license. However, often, pharmaceutical MNCs obtain patents in producing countries, blocking supply;
* Second, developed countries often use [political pressure](http://www.unsgaccessmeds.org/final-report) to prevent the use of TRIPS flexibilities. This has created a chilling effect and is a clear violation of obligations under various human rights instruments;
* Third, trade/economic partnership agreements containing [TRIPS plus](https://www.wto.org/english/res_e/reser_e/ersd201414_e.htm) provisions have considerably reduced the scope of the TRIPS flexibilities, especially in relation to the scope of patentability criteria and test data reliance for generic product approval. Further bilateral investment treaties also create a [chilling effect](https://www.southcentre.int/question/investment-agreements-a-new-threat-to-the-trips-flexibilities/) on the use of TRIPS flexibilities through the threat of Investor-to-State Dispute Settlement cases;
* Fourth, many governments view public health flexibilities as an option or within the discretion of the government. As a result, there is a lack of political will to utilise these flexibilities to ensure access to affordable health products. As pointed out by the [Rapporteur on the Right to Culture](https://www.ohchr.org/en/calls-for-input/call-input-report-patent-policy-and-right-science-and-culture): “*Although exclusions, exceptions and flexibilities are fully part of international intellectual property law, such as the TRIPS Agreement, they remain optional from the perspective of trade law. From the perspective of human rights, however, they are often to be considered as obligations”;*
* Fifth, most developing country governments do not have the institutional mechanism to monitor the impact of patented health products on affordable access in a transparent way. As a result, neither government or citizens are in a position to initiate the process to operationalise the use of flexibilities such as compulsory license and government use.
1. The TRIPS Agreement has allowed a model of health innovation that amplifies pre-existing inequalities in health - discriminating against race, women and the poor. Policy makers in the developed world where pharmaceutical TNCs are headquartered have the obligation to address such inequalities which are in violation ICESCR, and other human rights instruments.
2. **(g) What are the main challenges to ensure the quality, safety and efficacy of medicines and vaccines?**
3. The current norms and standard setting in the area of quality, safety and efficacy of health products do not consider access and affordability of the products. As a result, the aim is to set very “high” standards which increase compliance cost and have implications on affordability. There is an urgent need for the norms and standard setting body to look at alternative pathways to ensure quality, safety and efficacy along with affordability. In other words, current norms and standard requirements favour big companies and prevent competition. The *de facto* mechanism for the setting of quality standards in medicines and vaccines is the [ICH](https://www.ich.org/) (the International Council for Harmonization of Technical Requirements for Pharmaceuticals in Human Use) an initiative of pharmaceutical MNCs where the six founding members (pharmaceutical industry associations and drug regulatory authorities of the US, EU and Japan) are permanent members of the ICH decision making body. This gives rise to a deep conflict of interest, with the setting of norms and standards that are often not supported or not in line with the development of science and technology.[[17]](#endnote-17)
4. **(h) What obstacles do you see to ensuring the affordability of medicines, vaccines and other health products?** (see above)
5. **(i) What concrete recommendations would you make to enhance access to medicines, vaccines and other health products?**
6. From the Right to Health and Right to Science perspectives, the State has an obligation to play an active role in ensuring access to health products. This requires active monitoring and needs-based interventions in all determinants of access to health products from R&D to the dispensation of health products. Thus, we propose the following concrete actions:
* **Equity in R&D:** It is important to be **mission-focused in R&D**, to monitor and support R&D with the objective of promoting availability and affordability of health products. At present, developed countries provide R&D funding to develop new medicines and vaccines without imposing conditions to ensure affordability and availability to developing countries. Where public funding in R&D imposes terms such as the US’ “march-in” provisions, these are seldom invoked. During COVID-19, publicly funded vaccines and other products were monopolised for profit. The inaction of developed countries to ensure availability of much needed health products in developing countries violates extra-territorial obligations of the latter under the various human rights instruments. **Developed countries further bear a responsibility to fund health in an equitable and pro-active manner**: ensuring that LMIC governments build capacity in health innovation and manufacturing, towards a crisis response that is inclusive and effective through fostering local and regional innovation networks, without subjecting health expenditure to an increased debt burden and debt repayments.
* **Local production:** States, according to their own science and technology capacities, should encourage R&D. For instance, countries which do not have the ability to develop new health products but the ability to reverse engineer or process R&D should invest to develop affordable health products with an aim to introduce the products in the market at the earliest. The COVID-19 pandemic has shown us the need to maintain local production capacities at the national level, or regionally at least (for reason of economies of scale). In the case of pandemics or other infectious diseases with the potential to become a public health emergency of international concern under the International Health Regulations (IHR) 2005 there should be a network of manufacturers at the regional level to ensure supply of essential medicines. The on-going negotiations at WHO to amend the IHR and develop a new pandemic instrument are opportunities to create the necessary mechanisms.
* **Public provision:** The most effective way to ensure access to affordable health products is through public provision of such products. The lack of public health provision, requiring patients to procure medicines through out-of-pocket expenses, can lead to catastrophic health payments and impoverishment. Therefore, it is important to constantly expand the public provision of medicines to cover new medicines with proven efficacy. However high costs resulting from patent protection and unnecessary regulatory requirements prevent the inclusion of new medicines into essential medicines lists. In such cases, there should be greater use of TRIPS flexibilities by States to ensure supply of and access to essential medicines.
* **Public procurement:** Bulk public procurement or pooled procurement offers a cost-effective way of procuring health products so as not to unreasonably burden the health budget. All public procurement should be carried out in a transparent manner with details as to prices and to ensure quality, safety and efficacy.
* **Regulation of quality, safety and efficacy**: Regulatory authorities and WHO need to take into account the rights to health and science while setting norms and standards to ensure the quality, safety and efficacy of health products, as superfluous compliance requirements can increase the prices of such products thereby reducing timely access. In this regard, countries need to update their biosimilar guidelines in line with WHO’s latest biosimilar guidelines as well as the UK MHRA Biosimilar Guidelines. WHO must call for an expert consultation (including through an online process) to explore the possibilities of a non-originator pathway for vaccines.
* **IP:** The [DOHA declaration](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) reaffirms the **right** to use public health flexibilities. From a human rights perspective the use of flexibilities is not an option but an obligation to realise the Right to Health. However, at present, developed countries exert pressure on developing countries when public health flexibilities such as compulsory license are invoked, in violation of their human rights obligations. Human rights obligations also require optimal implementation of public health flexibilities in States’ national IP law. In this regard, countries should incorporate the exception to trade secret protection as provided for in [Article 39.3 of the TRIPS Agreement](https://www.wto.org/english/docs_e/legal_e/27-trips_04d_e.htm). Further, the Working Group on Business and Human Rights should monitor the abuse of IP rights by the pharmaceutical industry and its impacts on the rights to health and science.
* **Price control**: There should be transparency and regulation of prices and profit margins for all essential and lifesaving health products in countries where the population is buying health products from the private market.
* **Monitoring of access**: From a human rights perspective, it is important that governments monitor prices of health products and its impact on access. This will facilitate the use of law and policy tools including compulsory and government use licenses where needed. In this regard, Ministries of Health should establish monitoring mechanisms looking into the prices of products and impact on access, with a special focus on the impact of patents and other IP on prices of health products and access.
1. See Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines, 2013, available @ <https://www.ohchr.org/sites/default/files/Documents/HRBodies/HRCouncil/RegularSession/Session23/A-HRC-23-42_en.pdf> [↑](#endnote-ref-1)
2. <https://www.wipo.int/export/sites/www/scp/en/meetings/session_17/health/twn.pdf> [↑](#endnote-ref-2)
3. <https://cdn.who.int/media/docs/default-source/essential-medicines/fair-price/chapter-medicines.pdf?sfvrsn=adcffc8f_4&download=true> [↑](#endnote-ref-3)
4. <https://cdn.who.int/media/docs/default-source/essential-medicines/fair-price/chapter-medicines.pdf?sfvrsn=adcffc8f_4&download=true> [↑](#endnote-ref-4)
5. <https://www.who.int/initiatives/global-breast-cancer-initiative> [↑](#endnote-ref-5)
6. See also <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7312791/> [↑](#endnote-ref-6)
7. <https://www.bmj.com/content/370/bmj.m2983/rr-0> [↑](#endnote-ref-7)
8. This can include data originating from research, cell-lines, sequence IDs, vectors, constructs, media conditions, methods of isolation, storage conditions, manufacturing processes and clinical trial data, among others. [↑](#endnote-ref-8)
9. I.e.  clinically interchangeable with, or therapeutically equivalent or bioequivalent to, the innovator product: <https://extranet.who.int/prequal/medicines/bioequivalence> [↑](#endnote-ref-9)
10. It is important to note however, proposals under free trade agreements (FTAs) like the Trans Pacific Partnership Agreement (TPP), or the EU-India FTA, or the UK-India FTA - where pharmaceutical companies have been lobbying for extended data exclusivity periods - are indicative of the wave of arguments for longer protection times to data exclusivities. Data exclusivities not only prevent access to much needed health technology, they impede innovation as well as innovation relies on prior knowledge. [↑](#endnote-ref-10)
11. Crager SE, Improving Global Access to New Vaccines: Intellectual Property, Technology Transfer, and Regulatory Pathways, Am J Public Health 2018;108(Suppl 6):S414-S420. doi:10.2105/AJPH.2014.302236r [↑](#endnote-ref-11)
12. <https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/> [↑](#endnote-ref-12)
13. <https://www.ucl.ac.uk/bartlett/public-purpose/sites/bartlett_public_purpose/files/who_councileh4a_finalreport-complete_2105202329.pdf> [↑](#endnote-ref-13)
14. Busfield (Joan), Documenting the Financialisation of the Pharmaceutical Industry, available at <http://repository.essex.ac.uk/27744/3/Financialisation%20-%20full%20paper.pdf>. Busfield highlights that the focus on shareholder primacy results in (among other things) companies becoming short term oriented in seeking to maximise immediate shareholder returns. “Lazonick and colleagues (2017) analysed data on the eighteen US pharmaceutical companies over the period 2006-15 included in the Standard and Poor’s top-500 Index in January 2016 and found that over this period they distributed 99 percent of their profits to shareholders, 49 per cent as dividends and 50 per cent as share buybacks.” See also <https://victorroy.com/new-page-1>. [↑](#endnote-ref-14)
15. <https://rooseveltinstitute.org/wp-content/uploads/2020/07/RI_Profit-Over-Patients_brief_201902.pdf> [↑](#endnote-ref-15)
16. <https://www.bmj.com/content/376/bmj.o565> [↑](#endnote-ref-16)
17. <https://www.researchgate.net/publication/303246756_Reining_in_the_Regulators_Transnational_Regulatory_Networks_and_Accountability>

**ANNEX 1 AND 2**

ANNEX 1: PRICES OF BREAST CANCER MEDICINES

ANNEX 2: PRICES OF RARE DISEASES MEDICINES

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| --- | --- | --- | --- |
| **S.No** | **Drug Name**  | **Price (USD)\*** | **Conditions treated with the drug** |
| **WOMEN CANCER**  |
| 1 | Ribociclib | $6,064-$15,162 (price per month) | Metastatic breast cancer |
| 2 | Abemaciclib | $3,835 (14 tablets of 150 mg. A patient is required to twice daily for 30 days. So effective ppm ~ $15340 ) | Metastatic breast cancer |
| 3 | Palbociclib | $13,000 (21 capsules) | Metastatic breast cancer |
| 4 | Pembrolizumab | $11115 (given every 3 weeks) | Cervical Cancer |
| 5 | Pertuzumab | $6,682 (14 ml) | Breast Cancer |
| 6 | Ado-Trastuzumab Emtansine | $3,949.90 (for 100mg injection) | Breast Cancer |
| 7 | Atezolizumab | $14,540 per month | Breast Cancer among others |
| 8 | Niraparib | $18,215 (30 tablets) | Ovarian, breast |
| **RARE DISEASES FOR CHILDREN** |
| 9 | Risdiplam | £7,900 per 60-mg (80-ml) vial | Spinal Muscular Atrophy |
| 10 | Trikafta (Elexacaftor/tezacaftor/ivacaftor) | $311,503 per year | Cystic Fibrosis |
| 11 | Zolgensma (Gene Therapy) | $2.1 million for the single treatment | Spinal Muscular Atrophy |
| 12 | Spinraza  | $145219 for a supply of 5 ml | Spinal Muscular Atrophy |

	* Prices from Drugs.com**ANNEX 3**

 [↑](#endnote-ref-17)