**Office of the High Commissioner for Human Rights**

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

The Czech Republic's contributions

*29 November 2023*

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| 1. (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**:  In the Czech Republic, equal access to medicines, vaccines and other health products is at a very good level.  **Pricing and reimbursement regulation**: Pricing and reimbursement of medicines and health products can affect access. High co-payments and reimbursement restrictions may hinder access for some patients.  Re-export: Due to lower national prices, some medicines are exported abroad, limiting access.  **Global level:** Global supply chain issues (supply shortages of pharmaceuticals, medicines, packaging materials, logistical challenges), market forces: Pharmaceutical industry often prioritizes profitability over equitable access. Distribution of medicines according to the purchasing power of the country.  **At all levels:** one of the main barriers to access is the lack of transparency in pricing of innovative products by industry, where extremely high prices of some new products, coupled with lack of clinical data, create great pressure and increasing frustration on public health systems (payers, governments, providers, patients). |
| 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. |  |
| 1. (c) Are there any legal or regulatory challenges that impact the accessibility and affordability of medicines, vaccines and other health products? | **Regulatory challenges:** excessive regulatory requirements can impact on the supply of medicines and the availability of medicines (e.g. limits for nitrosamine impurities).  The Czech Republic, like other EU countries, uses a reference pricing system which can affect the pricing of medicines and hence their affordability and availability on the market.  Health Technology Assessment (HTA) and cost-effectiveness assessment of medicines and health technologies can influence which products will be available in the healthcare system. The outcome of an HTA can determine whether a product is covered and, if so, at what price.  Parallel trade, where medicines are imported from countries with lower prices, can affect the affordability of medicines. Legal restrictions on parallel trade may have an impact on improving availability.  Negotiations between pharmaceutical companies and health insurers play a role in determining the prices of medicines and health products. Delays or lack of transparency in these negotiations can have an impact on patient accessibility.  Competition in pharmaceutical and medical product markets can affect affordability.  At the level of centralised registration of innovative products, the EMA accepts in many cases clinical data that are not applicable in terms of pharmacoeconomic analyses, which inevitably affects downstream processes, namely HTA and price and reimbursement regulation, leading to accessibility and affordability for patients in the real world. |
| 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? | 1. In order to ensure the availability of certain drugs (for example, drugs to combat antimicrobial resistance), it is desirable to incentivise research and development of new anti-infective and diagnostic tools. 2. **Cost of innovation:** The development of new drugs and vaccines is costly and time-consuming. The high costs associated with clinical trials, research and development are often offset by the sale of patented products, which can result in higher prices and limited access for patients, especially in lower income countries. Furthermore, the development of digital health technologies such as medical apps and telemedicine platforms also have associated R&D costs. These costs can affect the pricing and availability of digital health technologies. However, there is a lack of transparency (consensus on costing principles - 'fair return'); 3. **Market-based incentives:** Profit incentives in the pharmaceutical industry can lead to the development of medicines and other health technologies that are more likely to be profitable in high-income markets. For example, infectious and rare diseases may receive less attention due to limited market potential, which may limit access. 4. **Global health equity:** Global health disparities may result from pharmaceutical companies' pricing and distribution strategies. Low- and middle-income countries may have difficulty accessing life-saving medicines due to high prices and limited supply. In addition, access to health-related applications, telemedicine services and portable devices may also be limited in regions with poor coverage and may thus exacerbate health inequalities. |
| 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? | 1. From the perspective of the Czech Republic, several main challenges related to international cooperation, partnership, and collaboration in ensuring access to medicines, vaccines and other health products can be identified: 2. **Coordination across the EU:** promotion of multilingual packaging, cooperation within the EU (agreement of some Member States on medicines supply), communication between marketing authorisation holders and regulatory authorities. Harmonisation of regulatory processes, negotiation of prices between different EU countries can be a complex, time-consuming issue. Within the EU, in some cases there is competition between EU member states, either directly (when negotiating price in the global market based on the desire to obtain medicines at risk of shortage) or indirectly, e.g. by agreeing to terms and conditions of multinational pharmaceutical companies, e.g. hiding a negotiated rebate or HTA-related discount granted to one state from other states. As a consequence, medicines prices may be increased (i.e. made more difficult to access) in EU member states with lower bargaining power (usually smaller markets, with lower purchasing power), increasing inequality within the EU. 3. **Linkages to global supply chains:** the Czech Republic is linked to global supply chains, therefore supply shortages of essential medicines (ATBs) due to global shortages affect the availability of medicines, vaccines simultaneously and at national level. 4. **International procurement and distribution:** the EU initiative, regional projects - the challenge of harmonising conditions. Ensuring transparency in medicines pricing. |
| 1. (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? | So far, the Industrial Property Office of the Czech Republic (the IPO-CZ) has not identified any obstacles or bottlenecks in the IPR regime that could affect access to medicines, vaccines, and other health products. Patent or utility model applications on medicines, vaccines and other health products are filed, however, if granted these products are subject to marketing authorization issued by the State Institute for Drug Control (SÚKL). Having said that, the availability of these products for patients on the market is not directly related to the patent/utility model procedure under the IPR regime. In our view, more relevant information should be provided by manufacturers, distributors and the Ministry of Health (i.e. SÚKL – concerning the legal and regulatory requirements).  The Czech Republic has in place rules for concluding licenses as a tool for the commercialization of patents or utility models as well as the mechanisms for granting compulsory licenses in case of the threat to an important public interest (for example, population health care, the environment or interests related to the defence of the state).  Under the national patent law, licenses are entered in the patent/utility model registers at the request of parties. Licenses are regulated in Sections 11 and 14 of Act No. 527/1090 Coll., on inventions and rationalisation proposals, as amended and in Section 17 of Decree No. 550/1990 Coll., on the procedure in matters of inventions and industrial designs, as amended. The compulsory licenses are stipulated by Section 20 of the Czech Patent Act.  (see <https://upv.gov.cz/en/information-sources/legislation/national>)  In addition, the Protocol amending the TRIPS agreement, done on 6 December 2005 and entered into force on 23 January 2017 introducing regime of effective use of compulsory licensing under the TRIPS Agreement was fully implemented into the Czech legislation by EU Regulation No. 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. EU Regulations are directly effective on the territory of the Czech Republic, as a Member State of the EU.  The IPO-CZ has not yet granted any compulsory license.  On the EU level, an initiative on compulsory licensing that aims at improving the coherence and effectiveness of compulsory licences as a tool to tackle EU-wide crises (while recalling that compulsory licensing should remain a last-resort tool applicable only in the event of failure of voluntary agreements) is being addressed. To this effect, the proposal for regulation was published in April 2023 and it is currently under negotiations amongst the EU Member States at the Council of the EU.  In this connection, we would like to highlight the prompt cooperation of the World Intellectual Property Organization (WIPO) with other UN Organizations, especially with the World Health Organization (WHO) and the World Trade Organization (WTO) as a response to the pandemic. We highly appreciate being regularly updated on WIPO, WTO and WHO trilateral cooperation activities related to COVID-19 pandemic and patents.  **International trade perspective**  Following the COVID-19 pandemic, which struck the whole world, but particularly the most vulnerable (i.e. least developed and developing) countries, the international community is currently identifying the most appropriate lessons to be learned. This is evidenced by the ongoing intense discussions in the WHO and the WTO, or the publication of the US International Trade Commission’s report on the supply and demand of COVID-19 diagnostics and therapeutics[[1]](#footnote-1). Undeniably, a number of countries faced the limitations in access to health products. Lack of these products was caused by variety of factors, including export restrictions, insufficient domestic production capacities, problems in placing products on domestic markets, regulatory measures, etc. One of the key tasks now is to consider how to ensure more equitable geographical access to medicines, vaccines and other health products (not only in pandemic situations).  However, the intellectual property rights (IPR) system has proved not to be a barrier. On the contrary, it is the enabler of ensuring the access to the medical and health-related products as it is absolutely necessary for any R&D activities preceding launch of any pharmaceutical product, and of scientific activities in general. There is no doubt that the geographical concentration of the production of health products, which is currently visible in the global market, should be limited in the future. All these efforts require the granting of licenses, i.e. the use of an element of the existing system of protection of intellectual property rights.  It is also widely recognized that part of the solution is to strengthen existing and create new domestic research centers and production plants in countries that do not have adequate presence of these facilities. The transfer of technology and know-how plays an important role in this area, and developed countries must continue in it. Past experience shows that to be successful, this type of cooperation has mostly been implemented in the context of long-term relationships based on mutual trust and previous good experiences with the partners. Transparency, necessary training, adoption of security measures are other prerequisites for successful transfer of know-how and technology. During the COVID-19 pandemics, voluntary licensing proved to be a good tool, enabling effective and faster transfer of know-how and technology and contributing to a rapid increase in the production of relevant medicines.  For all these aspects, reliable rules-based IPR protection is essential to provide legal certainty to all relevant stakeholders (companies, researchers, and public and private sector representatives). Effective IPR protection not only creates the ecosystem in which cooperation between producers and their competitors could be fostered, but also motivates further investment in R&D. Therefore, we do not believe that weakening the existing international system of IPR, as some countries are currently calling for, would benefit anyone. On the contrary, it could undermine efforts to provide more equitable access to health products in the future. |
| 1. (g) What are the main challenges to ensure the quality, safety and efficacy of medicines and vaccines? | 1. A key area is the manufacture of medicinal substances, where their production in third countries can affect the availability of the final medicinal product in the EU; compliance with strict regulatory requirements. |
| 1. (h) What obstacles do you see to ensuring the affordability of medicines, vaccines and other health products? | **Costly research and development**: the development of new medicines and vaccines is very expensive, and these costs are often passed on to health systems through high prices.  **Market dynamics:** The pharmaceutical industry is often driven by profit motives. Companies set prices based on what the market will bear, which can lead to high prices for essential health products.  **Lack of competition**: In some cases, lack of competition in the market can lead to monopolies, giving manufacturers the ability to maintain high prices. **Pharmaceutical pricing:** Pharmaceutical companies sometimes discriminate on price, charging different prices in different markets based on ability to pay. This can lead to differences in affordability between countries, but at the same time it is not always the case that fewer wealthy countries have lower prices for medicines.  **Global medicines supply shortages. Re-export:** lack of affordable medicines, need to substitute with a more expensive option. |
| 1. (i) What concrete recommendations would you make to enhance access to medicines, vaccines and other health products? | See (e)  The Czech Republic is a member of the EU and follows a collective approach to meet adequate availability of medicines, vaccines and other health products.  Examples of recommendations and measures to ensure availability that have been or are being progressively implemented are:   * Centralised negotiation or coordinated purchasing (essential medicines or highly innovative and at the same time expensive medicines such as ultra-orphans and ATMPs), joint HTA; * Transparency of medicines prices (see Transparency Directive) or, prospectively, transparency of real (net) medicines prices across EU Member States; * Price controls - revisions to maintain affordability (referencing system); * Cross-border cooperation: EU countries often cooperate on research, development and purchasing of medical products, which can improve access and reduce costs; * Digital integration of healthcare: many EU countries are integrating digital health technologies into their healthcare systems, improving access to health services and data. |
| 1. (j) Please add any other information or data you would like to share that have not been covered above? | 1. - |

1. <https://www.usitc.gov/publications/332/pub5469.pdf> [↑](#footnote-ref-1)