



**Permanent Mission
of the Republic of Azerbaijan
to the UN Office and other
International Organizations**

GENEVA

Ref: 0551/12/23/31

The Permanent Mission of the Republic of Azerbaijan to the United Nations Office and other International Organizations in Geneva presents its compliments to the Office of the United Nations High Commissioner for Human Rights, and with reference to the Note Verbale dated 5 September 2023, has the honour to transmit herewith the information received from the relevant authorities of the Republic of Azerbaijan to inform the study on challenges in ensuring access to medicines, vaccines and other health products.

The Permanent Mission of the Republic of Azerbaijan to the United Nations Office and other International Organizations in Geneva avails itself of this opportunity to renew to the Office of the United Nations High Commissioner for Human Rights the assurances of its highest consideration.

Geneva, 1 November 2023



Enclosure: 3 pages

**Office of the United Nations
High Commissioner for Human Rights
GENEVA**

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**Information on the questionnaire about
Human Rights Council resolution 50/13
on ensuring access to medicines, vaccines and other health products**

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

AVAILABILITY

WHO's Essential Drug List, suitable for the specific country (population, health indicator levels, geography, institutional development of public health institutions) is not fully available.

Taking into account the unavailability of some medicines on the market, the government prepared a package of changes to the legislation on medicines, including the introduction of the institute of recognition of foreign registration of medicines. On July 15, 2023, the changes and amendments came into force. These amendments will provide accelerated and easier access to the Azerbaijani market for leading foreign manufacturers.

In addition, the time frame for registration and examination was reduced to allow additional manufacturers to enter the Azerbaijani market. This amendment will reduce the processing period and time for obtaining a registration certificate.

PRICING

Pricing mechanisms usually decrease the base price of the medicines, which makes the drug importation unattractive for large manufacturers to small pharmaceutical markets, as a result affecting affordability. Legal acts establishing the rules for setting prices for medicines in Azerbaijan are constantly analyzed and, if necessary, revised.

Changes in the legislation on medicines, including the establishment of an upper limit in comparison to previous requirement of the fixed price, will open up wide opportunities for the import and sale of medicines. In this regard, the number of drugs on the market will increase and their availability will become possible.

(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.

Low availability of hospital drugs on the market and as result limited list of medicines covered by the state health insurance authorities is one of the barriers. In this regard, the list of medicines covered by the mandatory health insurance authority in Azerbaijan is constantly revised and when necessary increased in scope.

Application of track and trace system in Azerbaijan starting from 01.01.2024 will increase the sustainability of pharmaceuticals market and assist policy-makers in concluding specific policy decisions aimed at strengthening access to medicines, vaccines and other health products.

(c) Are there any legal or regulatory challenges that impact the accessibility and affordability of medicines, vaccines and other health products?

REGISTRATION

Mid-low-volume drugs are unattractive to manufacturers due to lengthy registration process and requirements in certain countries.

Therefore, the government prepared a package of changes to the legislation on medicines, including the introduction of the institute of recognition of foreign registration of medicines. These amendments will provide accelerated and easier access to the Azerbaijani market for leading foreign manufacturers. Amendments include the application of e-receipt system, which will guarantee the accordance of medicines prescribed to the patients with the evidence based clinical protocols. In addition, this system will allow pharmacies and wholesalers to import low volume drugs prescribed for precise number of patients, which will guarantee access to medicines.

GMP RECOGNITION

Absence of recognition of foreign Good Manufacturing Practices (GMP) inspection certificates in the legislation of numerous countries creates barriers for on-time supply and use of necessary medicines.

(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?

Lack of technological know-how and scientific experience exchange

The main challenges in terms of international cooperation, partnerships and collaboration to ensure access to medicines, vaccines and other health products are unwillingness to share specific knowledge and technological progress and desire to sell finished products without giving an opportunity for development and prosperity of low-income countries.

During COVID-19 outbreak, the above-mentioned issues were solved via creation of COVAX platform, which proved the possibility of international approach in ensuring access to vaccines.

(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?

Creation of an international or regional platform to technology transfer of pharmaceuticals may enhance access to medicines, vaccines and other health products. Such platform is able to minimize time to reach the necessary level of development and stability of pharma industry in low-income countries.

(g) What are the main challenges to ensure the quality, safety and efficacy of medicines and vaccines?

Answers to (f), (e) and lack of automated mechanism to control the sales price and to track the movement of drugs;

limited price and safety inspections of pharmacies resulting in increased illegal imports;

lack of sustainable system of cooperation between customs, border service and pharma regulatory authorities in a regional or international level.

Such sustainable system is already used for precursor chemicals, which is developed by UNODC/International Narcotics Control Board (INCB), named PEN Online (Pre-Export Notification) system.

(h) What obstacles do you see to ensuring the affordability of medicines, vaccines and other health products?

Lack of local production, technological development and deficit of raw materials used in pharma industry.

Therefore, certain concessions were included to the amendment package to the law on medicines, prepared by the government and which has come into force in July 2023.