**Republic of Armenia**

**INFORMATION**

**On key challenges in ensuring access to medicines, vaccines and other health products**

1. The main obstacles to access to vaccines are the following:
* Misconceptions about the effectiveness and safety of vaccinations, in particular: “the vaccines are not safe, they are of poor quality, they are out of date", "vaccinations are not necessary because there are no diseases", "vaccinations suppress and weaken a person's immune system",
* Vaccination refusers (members of various sectarian groups),
* False contraindications by specialists in a narrow field (gynecologists, neurologists, surgeons, allergists, dentists, etc.).
1. Aiming to ensure access to vaccination among all groups of the population of the Republic of Armenia
2. In remote locations without medical centers, mobile vaccination units are created, temporary vaccination points are established for implementation of vaccinations,
3. Implementation of vaccinations by means of mobile vaccination groups in the places of residence of persons with diseases or pathological conditions with stably expressed or strongly expressed locomotor function disorders,
4. Epidemiologically indicated preventive vaccinations are administered to both the citizens of the Republic of Armenia and to foreign citizens or stateless persons living in the Republic of Armenia, regardless of registration.
5. According to Annex No 1 to Decision of the Government of the Republic of Armenia No. 642-N of 30 May, 2019, medicines are allocated to beneficiaries included in social or special groups of the population with full or partial reimbursement of their cost, according to the approved list <https://moh.am/images/legal-375.pdf>:

 Beneficiaries approved by the mentioned list receive medicines with respect to the main list of medicines [https://moh.am/uploads/56-N\_inkorporacvac.pdf](https://moh.am/uploads/56-N_inkorporacvac.pdf?fbclid=IwAR1WGe7q7x1fqg-8WFfjewXTvlCKJNvPCHo31AGjPfOWSAYMhJkZQtgREPU):

According to Annex N2, in case of diseases officially listed, medicines are allocated to the beneficiaries with their full reimbursement as well <https://moh.am/images/legal-375.pdf>:

Medicines are allocated to the beneficiaries through medical organizations providing primary health care services.

According to to Decision of the Government of the Republic of Armenia No. 1080-N of 15 August, 2019, obtaining medicines by patients is carried out via electronic prescriptions.

The immunization process in the Republic of Armenia is regulated by the following legal acts.

1. Decision of the Government of the Republic of Armenia N 2129, 17.12.2020
2. “Organization and implementation of the process of immunization in organizations providing medical care and service in the Republic of Armenia" approved by the order No. 21-N of the Minister of Health of the Republic of Armenia of August 17, 2020, in accordance with the requirements of the sanitary rules and hygienic norms No. 3.3.1.003-20.
3. **Medicines are registered in the Republic of Armenia under general and simplified procedures. The simplified procedure is applied to medicines defined by the decision of the Government of the Republic of Armenia, registered in a member country of The International Council for Harmonisation (ICH) or pre-qualified by the World Health Organization.**

In the framework of conditional registration of new vital medicines that have not undergone full testing an application for registration of experimental vaccines can be submitted as well

1. **and (h**) – With the support of WHO Regional Office for Europe, a methodology for clarifying knowledge on vaccines and public opinion about vaccination in general has been developed.

A survey was also carried out among specialists in narrow fields in order to identify approaches and behavior regarding vaccinations.

A public awareness policy will be developed based on the results of the abovementioned research.

A workshop on "Localization of WHO immunization programs in Armenia" was organized. A working group for the development of measures for localization program of WHO immunization programs was formed in accordance with the order No. 2380-A of the Ministry of Health of the Republic of Armenia dated 31.07.2017.

From September 2017 to April 2018, in cooperation with WHO, a qualitative study was carried out on "Clarifying the approaches and practices on vaccinations among health workers of the Republic of Armenia", the purpose of which is to find out the approaches and behaviors of health workers in the vaccination process and their reasons.

Vaccines are purchased mainly through the Procurement Service of the United Nations Children's Fund, open tenders are also organized as well to allow vaccine manufacturers to participate in the procurement process.

Every year, during September-October, Ministry of Health of the Republic of Armenia submits a application of purchase, reflecting the next year's ans long-term needs.

**g) One of the main problems is the circulation of unregistered medicines.** The Law of the Republic of Armenia "On Medicines" (hereinafter referred to as the Law) is quite flexible from the point of view of regulation and includes a comprehensive toolkit to ensure the physical availability of medicines, providing for the import of registered medicines both directly from the holder of the registration certificate or a person duly authorized by him, as well as from a person who is not a right holder ( parallel importation), and in some cases the production and importation of unregistered medicines is also allowed (Article 16, Part 23 and Article 21, Part 6).

For the latter, the Law defines specific cases and conditions, because the circulation of unregistered medicines is risky: a number of data about the unregistered medicine is unknown, such as the complete quantitative and qualitative composition, the manufacturers involved in the production process, the composition of the packaging materials used, the quality specification.

These factors serve as basis for considering the importation of an unregistered medicine as an exception under the Law.

In order to reduce possible risks, a draft of amendments to the Law was also developed, ensuring additional restrictions.

Another problem is illegal circulation of medicines.

Illegal medicines circulating in the market include both registered medicines that are imported from countries where they are more affordable and unregistered medicines including particularly large number of expensive and new generation anti-tumor medicines, medicines for the treatment of rare diseases. Many of them require special storage and transportation conditions.

Internationally accepted instruments have been implemented to combat illegal circulation, which require continuous improvement:

* Increase in the number of registered medicines as a result of flexible mechanisms of the circulation of medicines (for example, mutual recognition of registration, registration of vital medicines with state budget funds, reduction of national specific requirements, etc.).
* Implementation of an effective system to control medicine market.
* Implementation of medicine price regulation mechanisms.
* Development of medicine costs reimbursement systems
* Establishment of effective medicine implementation mechanisms.

The distribution of vaccines in the Republic of Armenia is carried out on a centralized basis.

Vaccines from the national warehouse are transported quarterly to regional warehouses by refrigerator-vehicle, and from regional warehouses are distributed monthly by refrigerator-vehicle to organizations providing medical care and service.

In order to improve the thermal regime in the vaccine supply chain in the Republic of Armenia, an evaluation of the thermal regime in the vaccine supply chain was carried out in 2018 with the participation of a WHO expert.

**In order to ensure the effective management and safety of vaccines, the saturation of the refrigirators is regularly assessed at all levels, and WHO pre-qualified vaccine storage refrigerators are distributed to medical centers carrying out vaccination.**

In order to implement electronic management of vaccine warehouses and real-time temperature curve monitoring systems, works are currently being done to provide the existing cold-rooms, refrigerators, vaccine reception and packaging zones with electronic temperature monitoring devices and to connect them to the vaccine management software application in the "Armed" electronic healthcare system.