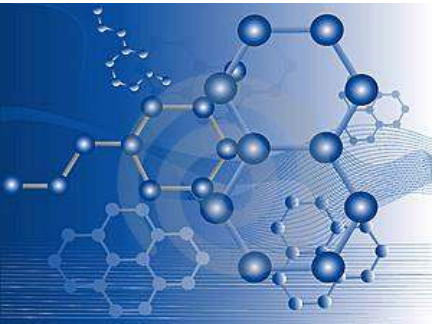
MARKET SURVEILLANCE AND CONTROL
Import authorization procedure

Anna Tsaghikyan



REGULATION OF MEDICINAL PRODUCTS

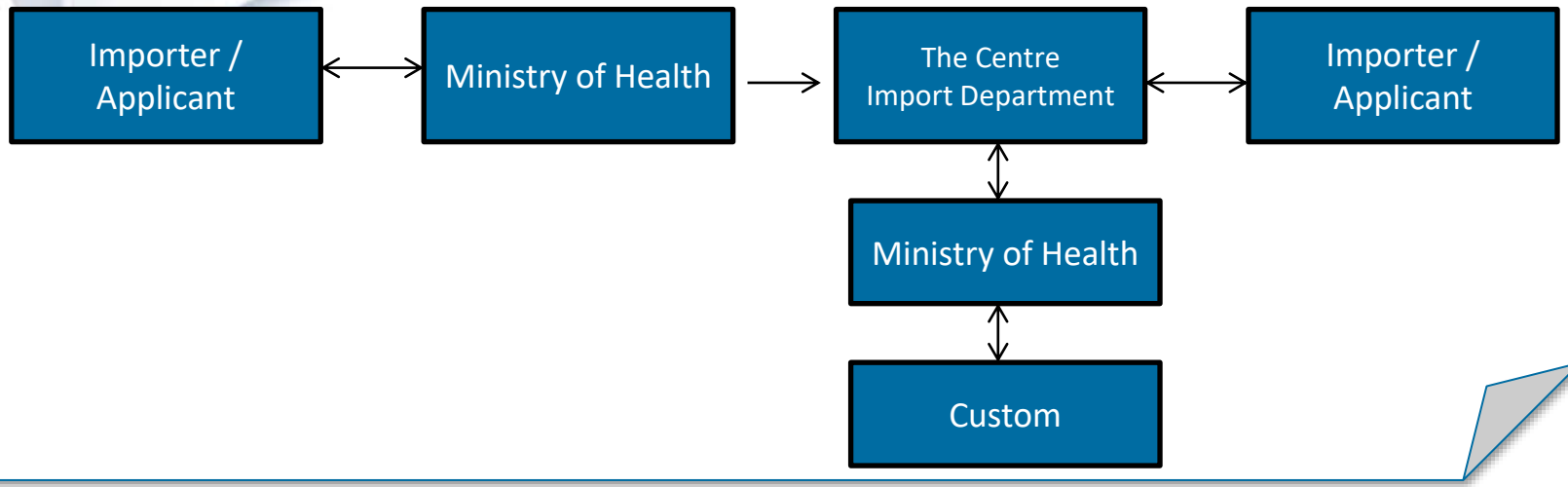
LEGAL BASIS OF REGULATION

- Law on Medicines (2016)
- Decision of the Government №202-N (2019)

Submission of the application

The applications and all required documentation are submitted by National Single Window for Foreign Trade system ("Single Window" Portal) since November 1, 2013.

Users



Required documentation for commercial import

1. Wholesale license of medicinal products (of the applicant)
2. Manufacturing license in case of importing drugs, researched pharmaceutical products, pharmaceuticals and herbal raw materials
3. Commercial invoice, signed and (or) sealed by the supplier
4. Documents for the transportation of medicinal products, in accordance with the type of vehicle:

   a. air waybill (sealed with the stamp of the customs warehouse and the relevant notes of the customs officer),

   b. transit declaration (if available) or transport (transportation), commercial or other documents,

   c. international waybill (CMR),

   d. postal bill of lading.

Required documentation for commercial import

5. Certificate of analysis of each batch number of medicinal product, issued by the manufacturing company and (or) the holder, with the mandatory indication of the batch number, production and expiration dates of the imported batch, and in the case of the vaccine, also the batch release certificate, issued by the competent authority and summary protocol issued by the manufacturer. In the case of purchasing medicinal products from intermediary organizations, the certificate of analysis issued by the manufacturing company must be signed and/or sealed of the intermediary organization
6. Document certifying the manufacturing chain of the companies participating in the production of a given series of the imported medicinal product (Batch Release Certificate), in the absence of the necessary data to verify compliance with the registered drug
7. data of the thermal indicator of the transportation process of medicinal product that require special thermal storage conditions
8. packing list with mandatory indication of batch numbers and quantity.

EXAMINATION of MEDICINAL PRODUCTS

Total duration – 5 days (extension - additional 10 days)

Sampling

Documentation compliance

Identification with the registered version /pharm.am/

Expert conclusion

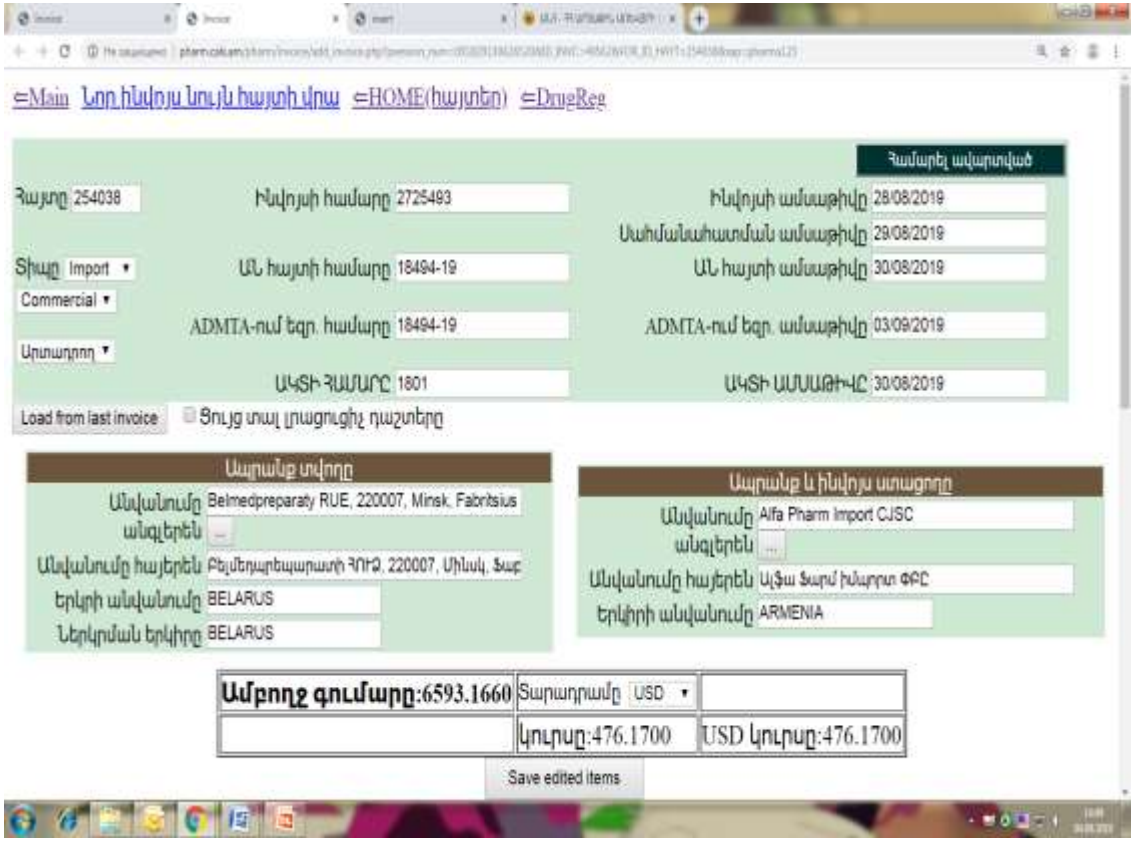
DATABASE of Applications (HaytDoc)

Invoice:

- ✓ Number and date of Application
- ✓ Name of importer
- ✓ Name and country of supplier/exporter
- ✓ Number and date of invoice
- ✓ Number of sampling act
- ✓ Number and date of expert conclusion
- ✓ Currency

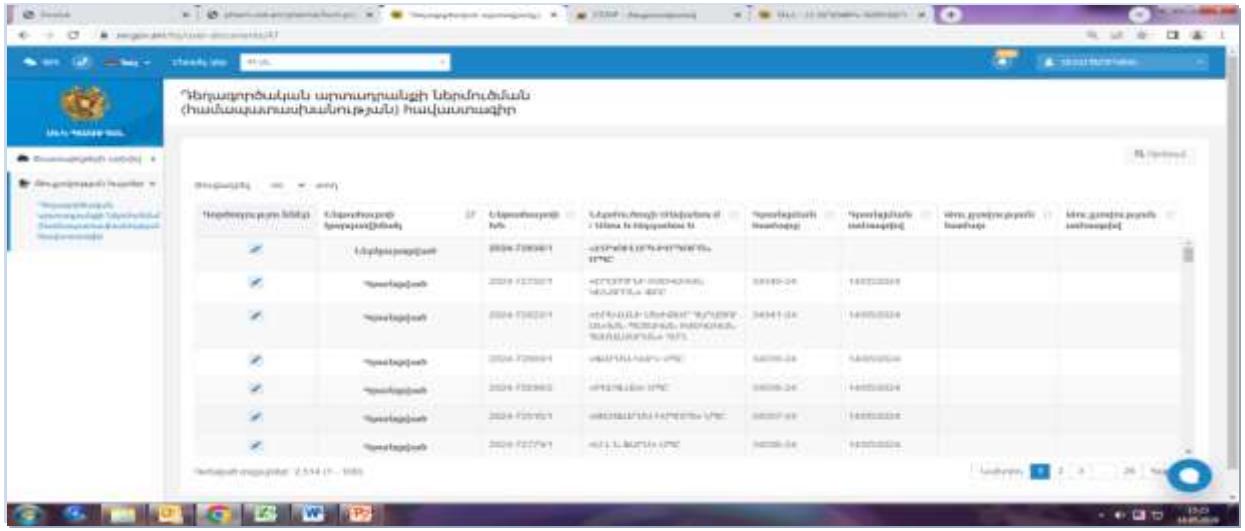
Medicine:

- ✓ Trade name
- ✓ Generic name
- ✓ Dosage form
- ✓ Dosage strength
- ✓ Manufacturing Country
- ✓ Manufacturer
- ✓ HS code
- ✓ Batch number
- ✓ Expiration date
- ✓ Imported quantity
- ✓ Invoice price per unit
- ✓ Discounts / concessions (if available)
- ✓ Total amount
- ✓ Registration status
- ✓ Correspondence to the registered one



DATABASE of Single Window

- Document number
- Application type
- Application number
- Registration date
- Certificate number
- Certificate issuance date
- Certificate expiration date
- Details of importer and exporter
- Details of importing medicines (transmitted from HaytDoc by XML file)
- Submitted documentation
- Notes section



Review of number of import applications

Total staff of the Department – 9; Experts - 8

- **2022 – 3107 applications (30035 medicines)**
- **2023 – 3507 applications (33230 medicines)**
- **01.01.2024 - 31.03.2024 – 812 applications (8271 medicines)**

THANK YOU FOR YOUR ATTENTION!!!

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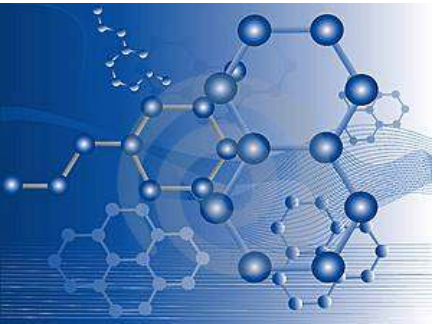
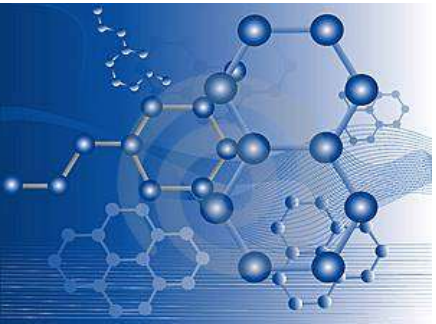
Questions