DRUG MANAGEMENT SYSTEM IN THE REPUBLIC OF UZBEKISTAN

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ФАРМАКОНАДЗОР

ВОЗМОЖНОСТИ РЕГУЛИРОВАНИЯ ФАРМАЦЕВТИЧЕСКОГО РЫНКА ЧЕРЕЗ СИСТЕМУ РЕГИСТРАЦИИ

ПОСТРЕГИСТРАЦИОННЫЙ КОНТРОЛЬ КАЧЕСТВА

ТРЕБОВАНИЯ К РЕГИСТРАЦИОННЫМ ДОКУМЕНТАМ
Pharmaceuticals subject to the State Marketing Authorization

- Treatment and prophylactic medicines, diagnostic tools, health food and parapharmaceuticals;
- Pharmaceutical substances and biologically active additives used in drug manufacturing;
- New combinations of authorized drugs;
- Drugs in new doses, dosage forms and compositions or innovative technology medicines;
- Generics;
- Health products.

Medicines produced in the pharmacies (own-name preparations) do not require authorization.
Diagram of drug registration in the Republic of Uzbekistan

**Applicant** (set of documentation and data)

- Pharmacopeial committee
  - Preliminary expert examination of scientific and technical documentation

- Specialized expert committee

- Pharmacopeial committee Panel

**Directorate of Medicines and Medical Equipment Quality Control**

- Preliminary expert examination by the State Center for expert examination and standardization of medicines

**Expert committee at the Directorate**

- Clinical trials
  - Pharmacological committee meeting

- Pharmacological committee panel
State registration of drugs is to be performed within no more than six months after the application to the registration authority.

6 months

One-stop principle
Steps of expert examination and registration of drugs

- **I. Establishment of a purpose and scope of expert examination**
  Directorate of Medicines and Medical Equipment Quality Control, MH RU

- **II. Pre-registration expert review**
  Directorate of Medicines and Medical Equipment Quality Control, MH RU:
  - State Center for expert examination and standardization of medicines
  - Pharmacological committee
  - Pharmacopeial committee
  - Drug control committee
  - Medical equipment committee

**III. External expert review (as required)**
Authorized expert agencies, freelance experts

**IV. Decision on drug registration**
Directorate of Medicines and Medical Equipment Quality Control, MH RU
Part I
- General documentation

Part II
- Chemical, pharmaceutical and biological documentation

Part III
- Pharmacological and toxicological documentation

Part IV
- Clinical documentation
Trends in registration/re-registration of drugs (1996 – 2013)

- Отечественные ЛС
- СНГ
- Зарубежные

Total

<table>
<thead>
<tr>
<th>Year</th>
<th>1996</th>
<th>2001</th>
<th>2006</th>
<th>2011</th>
<th>2012</th>
<th>9 months of 2013</th>
</tr>
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<td>1670</td>
<td>2080</td>
<td>2994</td>
<td>3371</td>
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<td>638</td>
<td>1127</td>
<td>1320</td>
<td>1337</td>
<td></td>
</tr>
</tbody>
</table>

9 months of 2013
Registration of drugs and medical products in the Republic of Uzbekistan

Locally manufactured drugs: 134
Foreign drugs: 3588
Locally manufactured medical products: 435
Foreign medical products: 173
Local in-vitro diagnostics: 19
Foreign in-vitro diagnostics: 18
Local in-vivo diagnostics: 7
Foreign in-vivo diagnostics: 17

Ministry of Health of the Republic of Uzbekistan
Directorate of Medicines and Medical Equipment Quality Control, MH RU
State registry
2013
17
<table>
<thead>
<tr>
<th>Year</th>
<th>Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998</td>
<td>- Reforms of the TB control program in line with the international standards were initiated.</td>
</tr>
</tbody>
</table>
| 2001-2005 | - In accordance with the WHO recommendations, TB detection and treatment standards (for susceptible TB) were introduced.  
- TB care system was decentralized and integrated with the PHC. For this purpose, a special infrastructure was established – a network of sputum collection points and DOTS units in all polyclinics and rural ambulances.  
- Implementation of the GF grant (TB) 2005-2009 |
- Expansion of access to culture examinations  
- Stage-by-stage introduction of the program for detection and treatment of drug resistant TB.  
- Implementation of the GF grant (TB), Round 8, 2010-2013 |
Ministry of Health of the Republic of Uzbekistan

2009
• Signed the Beijing Declaration which expresses the call to ensure universal access to diagnostics, treatment and prevention of MDR-TB;

2011 год
• Supported the Roadmap for prevention and control of drug-resistant TB: Consolidated action plan and to prevent and combat M/XDR-TB in the WHO European region, 2011–2015

2012 год
• With the technical support of the WHO, the National plan for prevention and control of M/XDR-TB was developed in Uzbekistan for 2012-2015.
The national sampled survey of DR-TB prevalence in the Republic of Uzbekistan was performed in 2010-2011 by the National DOTS Center and the NRL in Tashkent with technical assistance from:

- WHO
- SNRL (Gauting, Germany)
- MSF
Measures for improvement of TB detection, diagnostics and treatment

- Financing of TB drugs for patients treatment is provided by the donors (for DOTS) and by the local budget. The initiation of gradual transition to procurement of the first-line drugs using the State budget funds is planned for 2015.
# List of Drugs Approved for Treatment of Tuberculosis

<table>
<thead>
<tr>
<th>Drug’s Name</th>
<th>Presentation</th>
<th>Number of manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid</td>
<td>Tablets, 100 mg; 200 mg; 300 mg</td>
<td>5</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>Capsule, 150 mg; 300 mg</td>
<td>4</td>
</tr>
<tr>
<td>Streptomycin</td>
<td>0.5 g; 1 g</td>
<td>5</td>
</tr>
<tr>
<td>Capreomycin</td>
<td>0.5 g; 0.75 g; 1 g; 2 g</td>
<td>2</td>
</tr>
<tr>
<td>Prothionamide</td>
<td>Tablets, 250 mg</td>
<td>1</td>
</tr>
<tr>
<td>Cycloserine</td>
<td>Capsule, 250 mg</td>
<td>1</td>
</tr>
<tr>
<td>Levofloxacian</td>
<td>Tablets, 250 mg; 500 mg; 750 mg</td>
<td>3</td>
</tr>
<tr>
<td>PAS</td>
<td>13.49 g/500 mg</td>
<td>2</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>Tablets, 400 mg</td>
<td>3</td>
</tr>
<tr>
<td>Pirazinamide</td>
<td>Tablets, 150 mg; 500 mg; 750 mg; 150 mg</td>
<td>1</td>
</tr>
</tbody>
</table>
### TB DRUGS INCLUDED IN THE LIST OF ESSENTIAL DRUGS

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid</td>
<td>Tablets: 100 mg; 300 mg&lt;br&gt;Solution for injections: 10%; 25%, 5 ml/ampule.</td>
</tr>
<tr>
<td></td>
<td>Syrup: 20 mg/ml, 100 ml; 200 ml; 500 ml/vial</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>Tablets: 200 mg; 400 mg; 600 mg; 800 mg; 1000 mg</td>
</tr>
<tr>
<td></td>
<td>Solution for injections: 10 ml and 20 ml/ampule</td>
</tr>
<tr>
<td>Prothionamide</td>
<td>Tablets: 500 mg; 400 mg (orally disintegrating, 150 mg, with a 150 mg mark)</td>
</tr>
<tr>
<td>Streptomycin sulphate</td>
<td>Powder for injections: 0.5 g; 1 g</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>Capsules: 150 mg; 300 mg&lt;br&gt;Solution for injections: 1.5 mg; 3 ml/ampule</td>
</tr>
<tr>
<td></td>
<td>Tablets: 50 mg; 150 mg; 300 mg; 450 mg; 600 mg</td>
</tr>
<tr>
<td>Prothionamide</td>
<td>Tablets: 250 mg</td>
</tr>
<tr>
<td>Rifampicin + Isoniazid</td>
<td>Tablets: 60 mg+ 30 mg; 150 mg+ 75 mg; 300 mg+ 150 mg; 60 mg+ 60 mg; 150 mg+ 150 mg</td>
</tr>
<tr>
<td>Medicine</td>
<td>Formulations</td>
</tr>
<tr>
<td>----------</td>
<td>--------------</td>
</tr>
<tr>
<td>Rifampicin + Isoniazid + Ethambutol</td>
<td>Tablets: 150 mg + 75 mg + 275 mg</td>
</tr>
<tr>
<td>Rifampicin + Isoniazid + Pirazinamide</td>
<td>Tablets: 60 mg + 30 mg + 150 mg; 150 mg + 75 mg + 400 mg; 150 mg + 150 mg + 500 mg</td>
</tr>
<tr>
<td>Rifampicin + Isoniazid + Pirazinamide + Ethambutol</td>
<td>Tablets: 150 mg + 75 mg + 400 mg + 275 mg</td>
</tr>
<tr>
<td>Изониазид + Ethambutol</td>
<td>Tablets: 150 mg, 400 mg</td>
</tr>
<tr>
<td>Para-Aminosalicylate Sodium</td>
<td>Solution for infusions: 3%, 400 ml/vial</td>
</tr>
<tr>
<td></td>
<td>Tablets: 0.5 g</td>
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</tbody>
</table>
Treatment regimens
(standards of treatment)

Standard treatment regimen

6 Cm(Km) E Z Lvx ProCs PAS /18 E Z Lvx Pro Cs PAS

• Source of SLD financing:
  *GF funds*

• Sources of financing for infrastructure, human resources, capacity building, logistics:
  *State budget funds*
Supply of TB drugs

- Financing of TB drugs for patients treatment is provided by the donors (for DOTS) and by the local budget. The initiation of gradual transition to procurement of the first-line drugs using the State budget funds is planned for 2015.
Calculation of needs (projection and planning)

Procurement (planning, tendering, bid award, implementation of monitoring)

Warehouses and supply management

Distribution

Supply system management

Management information system

Financing
WHO prequalification issues

Acknowledgement of the accreditation certificate of the laboratories at the State center of expert examination and standardization of drugs by ISO/IEC 17025.

Drugs used by the Global Fund to fight AIDS, tuberculosis and malaria undergo quality control at the State center of expert examination and standardization of drugs.
A/ WHO prequalified laboratories of quality control.
The State center of expert examination and standardization prepares the documentation to apply for the WHO prequalification.

B/ LABORATORIES FOR QUALITY CONTROL OF DRUG CERTIFIED BY ISO/IEC 17025

| Test Centre in the Structure of The State Centre of Examination and Standardisation of Medical Products, Uzbekistan | ISO/IEC 17025:2005 (Date of issue: 22 Aug 2011) | PHYSICAL ADDRESS: 16, Ozod Str Umarov pass 100002 Tashkent, Uzbekistan | EMAIL ADDRESS: Jalilov Kh.K | YES | YES |
The state center of expert examination and standardization

Chemicopharmaceutical laboratory
The state center of expert examination and standardization

Microbiological control

Identification of antibacterial toxins
Identification of histamine-like agents
THANK YOU FOR YOUR ATTENTION