System and Role of Pharmacovigilance in Implementing the Ukraine National TB Control Program

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Antalya, Turkey
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Ukraine

- Population: 46 million people
- Territory: 603,700 sq.km
- Regions: 25 + 2 (the cities of Kiev and Sevastopol)
- Treatment facilities: 2,573
Global Fund Requirements That Should be Met by Any National Pharmacovigilance System

- Availability of the National Pharmacovigilance Center, which is approved, functioning smoothly, and interacts with the WHO Programme for International Drug Monitoring
- Availability of the functioning national system for spontaneous reporting
- Availability of the national database or systems for collecting and managing side effects reports
- The National Pharmacovigilance Center evaluates cause-and-effect relations, performs and manages risk assessment and case evaluation and ensures interaction in critical situations as needed
- Availability of a clear strategy for interaction in routine and critical situations
Regulatory and Legal Framework for Implementing Pharmacovigilance in Ukraine

• The 1996 law “On Medicines,” revised and expanded in 1998

• Ministry of Health Executive Order of December 27, 2006, # 898 (with amendments) “On Approval of regulatory regime for monitoring side effects caused by drugs authorized for the medical use in Ukraine” (aligned with the European Union guidelines)
The Pharmacovigilance System in Ukraine

Ukrainian Ministry of Health

National Expert Evaluation Center, UMH

Department of post-marketing surveillance, regional units (27 units)

Health Facilities
Main Methods for Obtaining Information on Drug Safety in the Post-Marketing Phase

- Passive pharmacovigilance—spontaneous reporting of suspected side effects of drugs
- Active pharmacovigilance—monitoring of drug side effects
- Post-marketing studies of safety
Trends in Reporting Drug Side Effects

Database contains over 78.5 thousand reports
# Prevalence of Side Effects among Cases

<table>
<thead>
<tr>
<th>Disease in accordance with ICD-10</th>
<th>Disease prevalence per 100,000 population</th>
<th>Case side effects per 100,000 population</th>
<th>Prevalence of side effects among cases (1 case SE/cases of a disease)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some communicable and parasitic diseases</td>
<td>3,940.7</td>
<td>1.6</td>
<td>2,466</td>
</tr>
<tr>
<td>Tumors</td>
<td>2,159.4</td>
<td>0.5</td>
<td>4,156</td>
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<tr>
<td>Mental disorders</td>
<td>4,651.2</td>
<td>0.7</td>
<td>6,406</td>
</tr>
<tr>
<td>Diseases of musculoskeletal system</td>
<td>10,098.9</td>
<td>1.2</td>
<td>8,493</td>
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<tr>
<td>Respiratory diseases</td>
<td>38438.6</td>
<td>4.3</td>
<td>8,912</td>
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<td>Diseases of urogenital system</td>
<td>10,016.5</td>
<td>0.8</td>
<td>12,287</td>
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<tr>
<td>Diseases of nervous system</td>
<td>4,898.0</td>
<td>0.4</td>
<td>13,253</td>
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<tr>
<td>Diseases of digestive organs</td>
<td>17,930.2</td>
<td>1.2</td>
<td>14,547</td>
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<tr>
<td>Traumas, poisonings</td>
<td>5,142.8</td>
<td>0.3</td>
<td>16,428</td>
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<tr>
<td>Diseases of circulatory system</td>
<td>57,211.9</td>
<td>3.0</td>
<td>19,308</td>
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<tr>
<td>Diseases of endocrine system, nutritional disorders</td>
<td>8,365.1</td>
<td>0.4</td>
<td>20,800</td>
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<tr>
<td>Diseases of skin and subcutaneous tissues</td>
<td>4,990.2</td>
<td>0.2</td>
<td>23,423</td>
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<tr>
<td>Diseases of the ear and mastoid process</td>
<td>3,502.9</td>
<td>0.1</td>
<td>39,301</td>
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<tr>
<td>Diseases of the eye and adnexa</td>
<td>9,235.6</td>
<td>0.1</td>
<td>62,476</td>
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</tbody>
</table>
Active TB Incidence Among the Population of Ukraine

TB incidence in 2012: 68.1 cases per 100,000 population
National Target Social Program for Prevention of TB Incidence (NTSPPTBI) for 2012-2016

- Approved by the Law of Ukraine # 5451-VI of 16.10.2012
- Control of HIV-infection and AIDS and TB prevalence
- Reduction of incidence, mortality, including TB/HIV mortality
- Decreasing the number of new MDR-TB cases
- Improvement of TB detection
NTSPPTBI and Pharmacovigilance

NTSPPTBI: decreasing prevalence, incidence, and mortality

Pharmacovigilance: evaluation of drug efficacy and safety

To improve patient’s health and life quality
Stakeholders

• Ukrainian Ministry of Health
• National Expert Evaluation Center
• National Service of Ukraine on HIV-infection/AIDS and other socially dangerous diseases
• WHO
Pharmacovigilance and NTSPPTBI

• Standardized protocol of TB care contains recommendations on detection of side effects and patient management
• Trainings for TB specialists (in 2013, the regional pharmacovigilance service performed 26 TB trainings for physicians in all regions of Ukraine and in Sevastopol).
• Introduction of targeted (enhanced) spontaneous reporting
• Physicians report cases of major SE or specific toxicity of all TB drugs or any specific drug
Pharmacovigilance and NTSPPTBI: Spontaneous Reporting of Side Effects Caused by TB drugs

Number of reports

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Reports</th>
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<tbody>
<tr>
<td>2007</td>
<td>167</td>
</tr>
<tr>
<td>2008</td>
<td>184</td>
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<tr>
<td>2009</td>
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<td>2010</td>
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<td>2011</td>
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<td>2012</td>
<td>476</td>
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<tr>
<td>11/21/2013</td>
<td>488</td>
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</table>
Purpose of Monitoring TB Drug Safety

- To detect new side effects including those which occur as a result of drugs interaction
- To identify levels and factors of risk including cases when various treatment regimens or drugs are used
- To evaluate safety of TB drugs in special population groups
- To reduce expenses and improve treatment outcomes by means of early detection and management of risks
- To use data when developing and revising recommendations and treatment protocols
To Continue Improving Pharmacovigilance in NTSPPTB1

• Develop a training course on safety of TB drugs
• Use all resources of the regional pharmacovigilance service when training medical staff in pharmacovigilance.
• Develop and introduce monitoring as a method of collecting information on drugs safety and efficacy in the National TB control program
• With the technical and financial support of the USAID SIAPS project, begin development of information system for the optimizing SE monitoring when using the National e-register of TB patients
• Introduce the electronic register of TB patients ("e-manager")