TB Drug Management in Azerbaijan

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Implementation of the DOTS program in Azerbaijan

- Stage 1—1995 insufficient financing by the donors
- Stage 2—2003 inclusion of 19 districts
  - 2004 additional inclusion of 28 districts
  - 2005 all districts in program
  - 2009 last year of humanitarian aid
Implementation of the DOTS-Plus Program in Azerbaijan

• August 2008—pilot project for 20 courses of second-line drug treatment financed by the Global Fund
• 2009—70 courses of treatment
• 2010—240 courses of treatment
• 2011—362 courses of treatment
• 2012—300 courses of treatment
• 2013—560 courses of treatment
Strengths

- Uninterrupted supply of TB drugs financed by the government and external donors (same drugs with the same quality)
- Administration of the combination drugs
- Capacity for MDR-TB treatment
- Opportunity of comparison with the international rates.
Actions Taken

- January 3, 2008—Ministry of Health (MoH) issues executive order to cancel sale of first-line drugs (FLD)
- 2010—the national budget completely covers the need in FLD.
- 2012—partial purchase of second-line drugs (SDL)
- Annually, the government allocates about 3,000,000 manat (comparable to euro) to the TB control program for FLDs, SLDs, and drugs to manage side effects
Process of Procurement

• Request preparation (National Tuberculosis Program [NTP])
• Request approval (MoH)
• Procurement process (Center of Innovations and Supply)
• Quality control
• Distribution of TB drugs (NTP, MoH)
Request Preparation

- Annual request for FLDs is being prepared by the NTP on the basis of the number of patients in the previous year with consideration of the remaining drugs and a one-year buffer.
- The request for the SLDs is based on the projected number of patients with consideration of treatment regimens.
Procurement Mechanism

• Open tender
• Direct purchases
• Negotiations
Special Conditions That Regulate the Procurement of TB Drugs

- Drug registration in the country
- WHO prequalification
- Compliance with GMP (Good Manufacturing Practice)
- Shelf-life of a drug at the time of delivery
Drug Registration

MA application to CAEED

Presentation of the required documents

Preliminary expert evaluation (15 days)

Customer notification on the specialized expert evaluation

Conclusion of a contract on the performance of a specialized expert evaluation

Expert evaluation by CAEED

CAEED presents the drug for registration

Obtaining the registration certificate

Submission of additional documents and materials

Refusal of registration

Additional expert evaluation

CAEED requires additional documents and materials

As needed
Import of drugs

- License (Import permit from the MoH)
- Agreement
- Invoice
- Quality certificate
- Certificate of origin
Quality Control

Every batch of supplied drugs undergoes expert quality examination at the CAEED, after which the drug can be utilized.
Distribution of TB drugs

• For the FLDs distribution the NTP prepares quarterly allocation approved by the MoH
• Distribution to the facilities through the Center of Innovations and Supply
• Distribution of SLDs through NTP
Challenges

• Lack of registration of some drugs
• No registration of capreomycin
• No registration of the combination drugs
• Mono-treatment