# Government takes over TB medicines supply in Moldova: way forward

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Fighting Drug-Resistant TB in the 21st Century: Novel Approaches to Improving Access to anti-TB Medicines and Pharmaceutical Services

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# Background of TB Programme implementation

- New Revised National TB Programme 2001-2005

- DOTS programme: launched in 2001 as project in 3 rayons with expansion over the country by 2004

- DOTS Plus programme: May 2005 as project with 100 patients' enrolment and expansion from September 2007

# TB medicines supply: FLD

- > 2001 –public procurement from MoH and local budgets
- 2001-2004 – GDF grant of FLD
- 2005-2012- direct procurement of FLD using GFTAM sources
- 2008-2012- gradual take over by Government
- 2013 – full coverage by the state budget

# TB medicines supply: SLD

- 2005 – 2015: GDF/GLC mechanism from IDA- approved 4850 patients

- 2005-2006: Government procurement for 30 and 50 patients. Cm supply for 50 patients was interrupted and patients transferred in GLC cohorts

- 2013: first procurement from Government budget – estimation for 130 patients

# Pharmaceutical regulation

- Prohibit import and use of pharmaceuticals and health products without marketing authorization in R. of Moldova with exceptions
- Exceptions for import of non- authorized medicines: cataclysms, catastrophes, epidemics, epizooties, systemic poisoning, other cases that threaten the health of people, absence of analogues or substitutes on the pharmaceutical market.
- Import' authorization only of medicines with registered manufacturers' price in the Catalog of Price
- Essential Medicines List in line with OMS, ed. 2011
- Prescription under INN ( 2012)
- Prohibit issue of FLD and SLD medicines from the community pharmacies

# Marketing authorization

- Revised regulation in July 2012
- CTD format
- Simplification of procedure for marketing authorization of medicines registered by the SRA from the countries member of the EEA, FDA, EMA, Canada, Switzerland, Japan, Australia,
- Approved GMP regulation in March 2013 with implementation from October 2013

# Public procurement regulation

- General regulation: Law on public procurement; secondary legislation: regulations for different methods of procurement; reports; working group for tender's organization etc.

- Special regulation on procurement of medicines and health products for the health system approved by the Government Decision # 568 from 10/09/2009

- All medicines and medical devices from public budget are purchased through centralized procedure.

# Funding of FLD medicines supply

- Ministry of Health' budget
- National Health Insurance House
- Local budget (municipal, authorities on the left bank of the river)
- Departmental budget ( Ministry of Justice for penitentiary system)

# Public procurement of medicines

- Based on EML
- Centralized procurement
- Medicines procured under INN
- Transparency management ( written working groups decision, advertisement)
- Methods: Tender. In few cases: request of quotations

# Public procurement of TB medicines

- Regulation provisions: 95% FDC and 5% single formulations for FLD.
- Standard treatment regimen for sensitive TB in line with WHO.

1st category: intensive phase 2(HRZE) and continuation phase: 4 (HR)
2nd category: intensive phase: 1 (HRZE) 2S/2(HRZE) and continuation phase: 5(HR)E

- Standard treatment regimes for MDR-TB treatment: 8CmEtoCsLfxZ/ 16EtoCsLfxZ.
- Reserve medicine for revision of the scheme according to resistance profile for MDR-TB with: PAS, Mfx, Amx/Clv

# Public procurement of TB medicines (2)

- Estimation of medicines: morbidity method
- Estimation tool for FLD : GDF spreadsheet
- Estimation tool for SLD: adjusted GDF spreadsheet by the country
- Buffer stock for FLD

# Quality Assurance Policy

- Medicines' Authorization
- Surveillance of medicines quality and quality control of medicines imported or produced locally
- Pharmacovigilance activity and rational use of medicines
- Licensing of pharmaceutical activity
- Accreditation of entrepreneur and public institutions
- Supervision and control over the pharmaceutical activity
- Information on medicines

# Quality requirements for public procurement of medicines

- Medicines should be registered in Moldova, present on the market and registered in the National Catalog of manufacturer' prices
- Manufacture should comply with GMP. In case of lack of offers with GMP complied manufacturer, non- GMP will be accepted
- Local company( manufacturer/ distributors) have to be licensed on pharmaceutical activity.
- Medicines should be accompanied with certificate of quality issued by the state laboratory for quality control of medicines;
- Minimum shelf life shall be not less then 60%, in case of medicine with 2 years or more shelf life; In case of product with total shelf life up to 2 years, the minimum shelf life at the delivery should be 80%.
- It is accepted participation of local manufacturer that are not complied to GMP being evaluated as equivalent bidder complied to GMP.
- Exceptions for TB, psychotropic medicines, insulin products and vaccines.

# Quality requirements for public procurement of TB medicines: provisions of the regulation

- TB medicines should be produced by the manufacture which complies with GMP according to WHO, or EMA, or FDA standards
- TB medicines and vaccines should be part of WHO pre - qualified List

# Registration status of TB medicines for public tender of 2012 for 2013 year

| | Products | Registered in Moldova | WHO pre - qualified |
|---|---|---|---|
| 1 | HRZE, tab | 0 | 0 |
| 2 | RH 75/150mg,tab | 0 | 0 |
| 3 | Z, tab. 400 mg | 2 | 1 |
| 4 | S, vials 1 g | 0 | |
| 5 | Eto, tab. 250 mg | 1 | 1 |
| 6 | H,tab. 100mg | 2 | 1 |
| 7 | E, tab. 400mg | 1 | 0 |
| 8 | H tab. 300mg | 2 | 1 |
| 9 | Amicacin, vial 1 g | 2 | 0 |
| 10 | Z, tab.500mg | 1 | 1 |

# Quality requirements for public procurement of TB medicines: tender 2013-2014

- Acceptance of non-registered in Moldova, but registered in the country of origin
- TB medicines should be pre-qualified by the WHO or
- TB medicines should be registered by the stringent regulatory authorities
- TB medicines should be produced by the manufacture which complies with GMP according to WHO, or EMA, or FDA standards

- Report on Bioequivalence studies

- Report on inspection of the manufacturer by the SRA valid for the last 3 years

- Package: blisters

- Winner to present the technical specification and to register TB medicines in the country

# Key actors

- MoH: funding; approves the procurement list and approves distribution plan
- NTP: determines needs of TB medicines: list of products, quantities and quality requirements; participate in evaluation of the tender
- Penitentiary Department: defines needs for penitentiary system
- Medicines and Medical Devices Agency: consolidation of the orders, preparing tender documents following MoH' approved requirements, organizes and evaluates tenders, sign contracts on behalf of the MoH.
- National Procurement Agency of the Ministry of Finance: policy development, coordination, approves tenders documents, publishes advertisements, approves tender's evaluation and contract on supply

# Results of public tender for 2013 year

| | Products | Number of bids | Approved supply from |
|---|---|---|---|
| 1 | HRZE, tab | 4 | Macleods PharmaceuticalsLTD, India |
| 2 | RH 75/150mg,tab | 4 | |
| 3 | Z, tab. 400 mg | 3 | |
| 4 | S, vials 1 g | 4 | |
| 5 | Eto, tab. 250 mg | 4 | |
| 6 | H,tab. 100mg | 5 | Lupin, India |
| 7 | E, tab. 400mg | 4 | Swizera Labs Pvt Ltd |
| 8 | H tab. 300mg | 4 | |
| 9 | Amicacin, vial 1 g | 4 | |
| 10 | Z, tab.500mg | 4 | |

# Procurement on the left bank

- Local tender
- Insufficient budget
- Unknown quality
- Recommendation of the NTP review from 2013: to apply for GDF grant
- Approval of GDF grant for 2014

# Challenges

- Lack of registered TB medicines in the State Registered of Medicines ( few only)
- Legislative provisions does not foresee direct procurement from the international agencies for medicines procurement
- Single procurement is possible after repeating twice the tender
- Post -marketing monitoring of the suppliers and products
- Revision on regulation on public procurement of medicines and health products: adjustment of quality criteria for procurement of TB medicines; procurement methods from international agencies
- Public procurement of paediatric formulations.