



Republic of Moldova

Vaccine Procurement Aspects

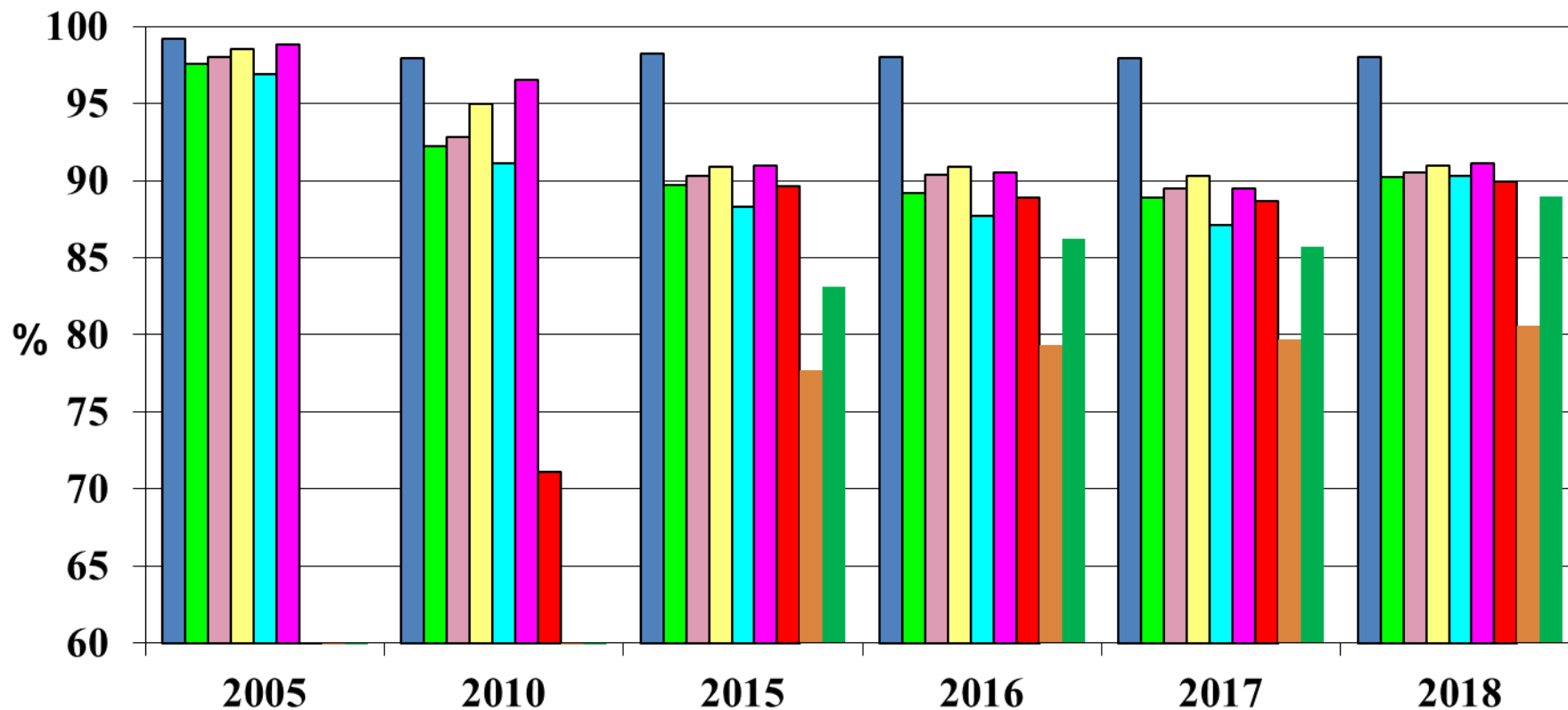
Vaccine Procurement Workshop
Tbilisi, April, 2019

Background

- **aprox. 4.000.000** – population
- **aprox. 40.000** – birth cohort
- NIP – **13 Antigens** (recent implemented, Rota – 2012 and PCV -2013, HPV -2017, IPV - 2018)
- Vaccination coverage - around **90%**
- Procurement of vaccines through **UNICEF**
- Fully self financed from state budget (except IPV – GAVI)
- Annual budget for NIP vaccines – **1,3 mln USD**
- **Cost per 12 months aged child – 26,4 USD**

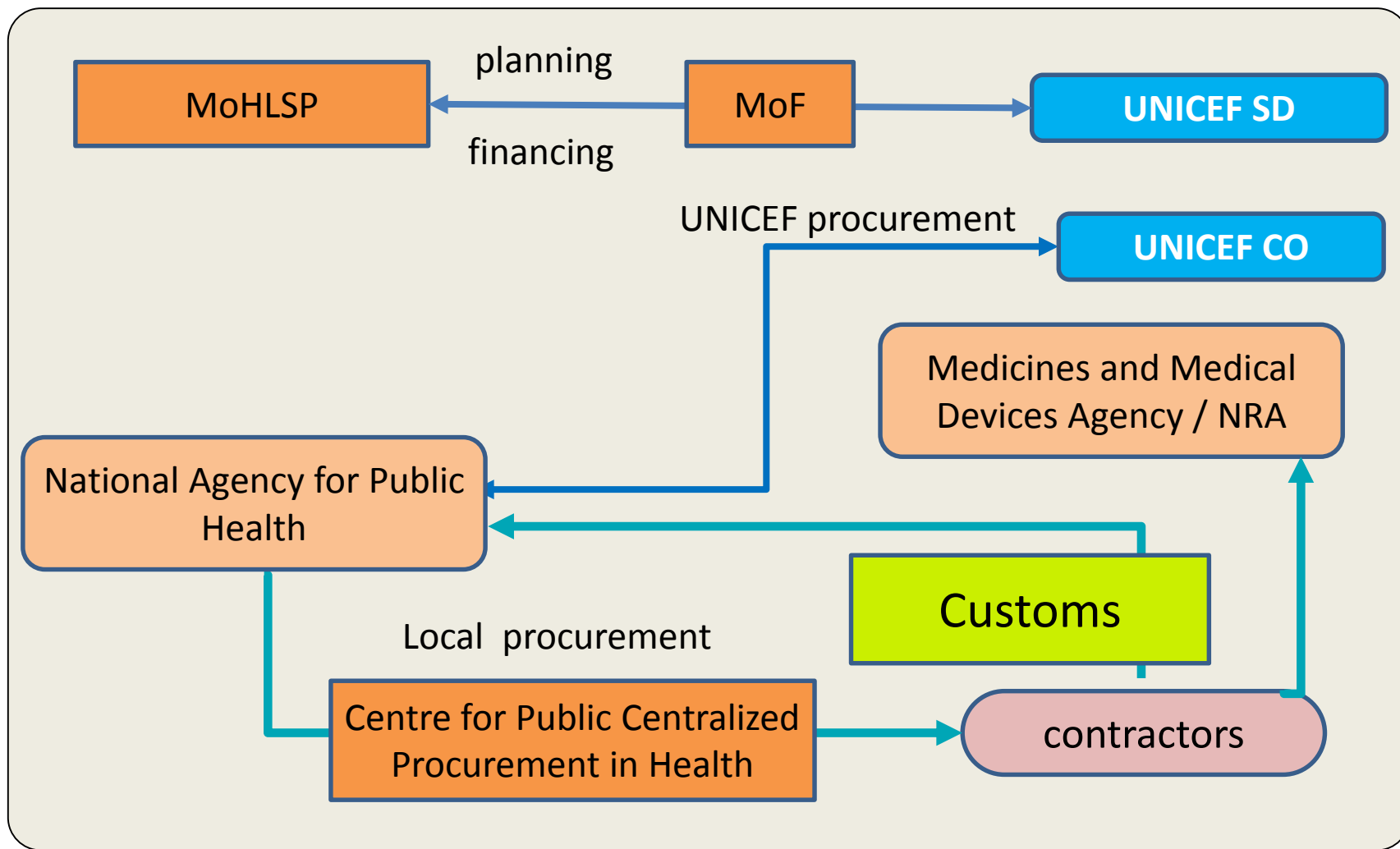


Vaccination coverage at 12 months age, Republic of Moldova, 2005 -2018



■ BCG
 ■ Pertussis
 ■ Diphtheria
 ■ OPV
 ■ MMR
 ■ HepB
 ■ Penta
 ■ Rota
 ■ PCV

Vaccine Procurement Organogram



Forecast and Planning

- Planning for procurement is done only annually
- Annual forecast to UNICEF by NAPH&MoH:
 - no long term (multi-year) forecasting mechanism in place
 - target population data:
 - National Bureau of Statistics
 - Maternities register
 - Family doctors evidence register
- Request for Cost Estimate is planned between the MoH, Country Office and/or Supply Division
- Specifications are identified via the on-line Supply Catalogue
- The request include delivery schedules and quantities
- Upon receipt of the request a CE is prepared at SD
- Target arrival dates are indicated

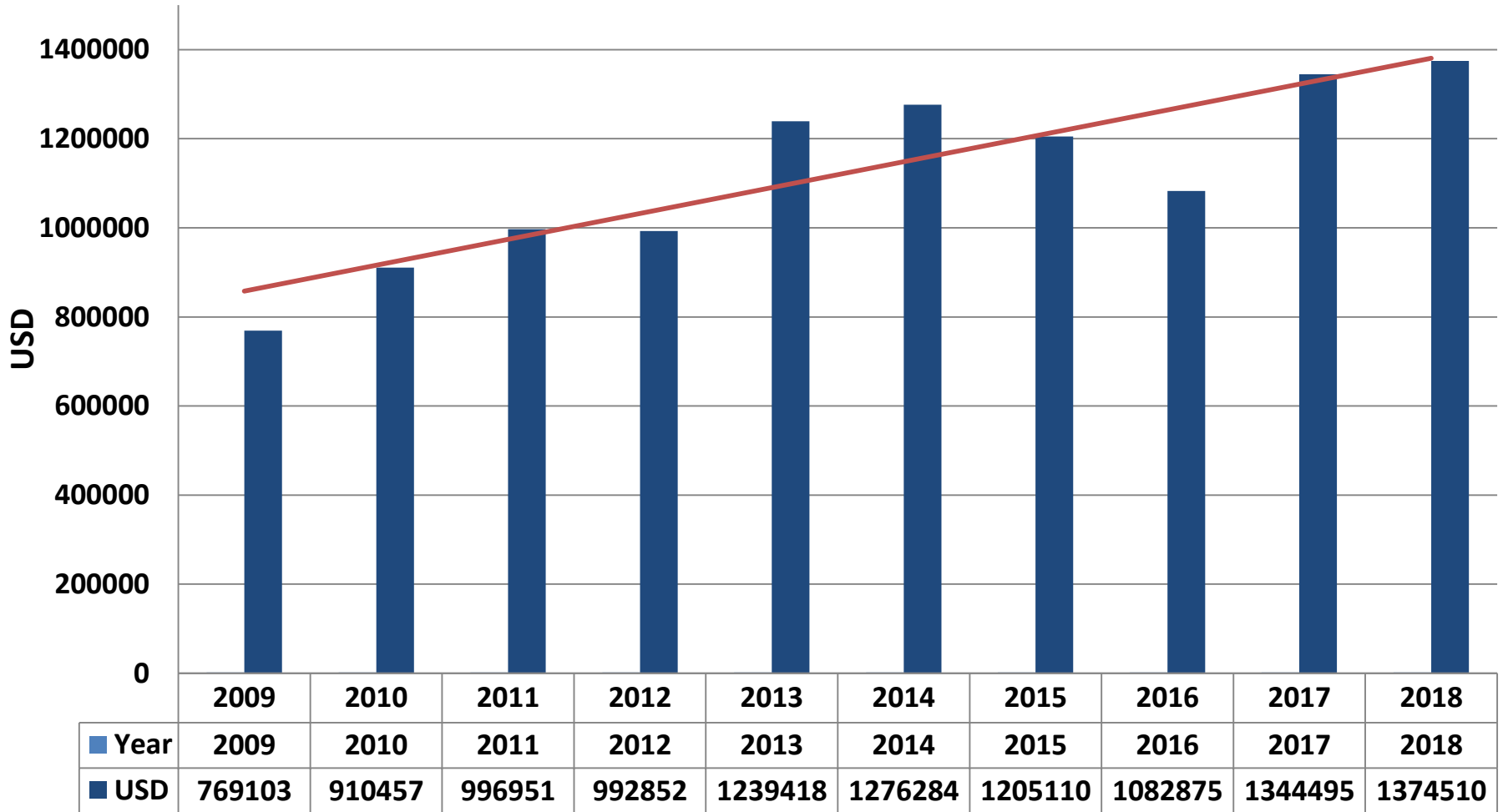
Registration – ensuring quality

- Vaccines have to be registered in the Republic of Moldova
- NRA (MMDA) responsible for registration and quality assessment
- Registration costs:
 - 1.500 USD - first presentation form
 - registration for next presentation of the same vaccine - 850 USD
 - registration is valid for 5 years
- A valid GMP certificate is mandatory for registration
- Vaccine should also be WHO prequalified
- Ensured transparency – online checking
- Shelf life set on min. 18 months

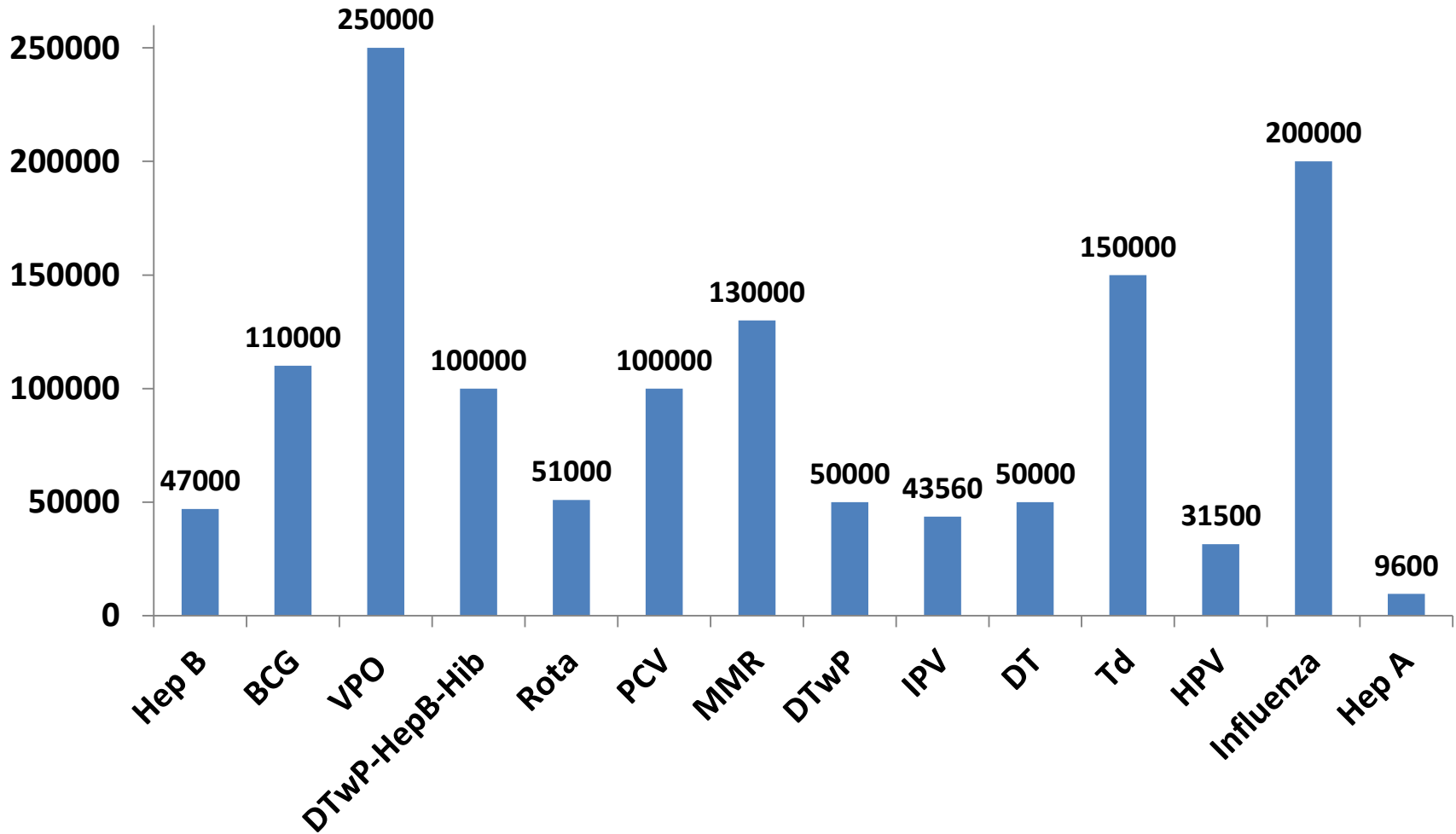
Budgeting and finance

- Procurement of immunization supplies is funded from the centralized state budget managed by the MoH
- The budget estimates for immunization supplies are approved by the Governmental Decree for a period of 5 years NIP
- Annually is approved a separate budget for coming year for NIP
- The MoH can reallocate the flow of resources between different national health programs based on the priority or emerging needs.
- The volatility of the MDL is a challenge (MDL to USD)
- Political commitment for financial sustainability for NIP

Financing of the programme



Doses procured for 2018



Procurement process

- Two different procurement mechanisms:
 - UNICEF SD for NIP vaccines from 2016
 - Self-procurement for HepA, Infleunza, Antirabic
- Through open public tendering process (competitive bidding) for NIP vaccines were done till 2015
- For self-procurement NRA (MMDA) approves specifications made by NAPH
- Center for Health Centralized Public Procurement in charge for tenders
- MoF and State Treasury are responsible for the actual payments

Achievements

- The current collaboration between the Republic of Moldova and UNICEF is resulting in low pricing, ensured quality, high supply reliability and reliable support level
- Increasing awareness for national stakeholders of financial sustainability and budget availability
- No stock-out in the last 3 years
- No problems with customs clearance, no fees
- Center for Health Centralized Public Procurement
- Reviewed legislation to enable use of current public procurement modalities and policy in use by EU governments for bidding and contracting from 2021
- Provided relevant training to all staff in the process, with specific reference to vaccine procurement training

Challenges

- Self procurement procedure can face weak capabilities after UNICEF mechanism
- Long period without self procurement
- Legal framework offers little room for identifying an innovative procurement process for the vaccine market
- May arise financial issues due to implementation of new vaccines or increasing price of vaccines
- Multiannual forecast, correlated with multiannual contracting and availability of vaccines
- High registration costs limit competition and increase offered prices

Next steps

- To improve legislation
- New trainings for procurement stakeholders for development of staff capacity
- Increase knowledge of global vaccine markets
- SOPs for procurement of vaccines
- Increase of political commitment

Thank you

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Back up slides

Regulatory framework

Government Decision for National Immunization Program for 2016-2020 no. 1113 from 06.10.2016

Law on public procurement no. 131 of 03.07.2015

Government Decision no. 246 from 08.04.2010 for Memorandum of understanding

Government Decision on Centre for Public Centralized Procurement in Health no.1128 from 10.10.2016

Government Decision no. 568 - 10.09.2009 Approving the Regulation on the Procurement of Medicines and Other Medical Products for the Needs of the Health Care System

Government Decision no. 1407 - 10.12.2008 for the approval of the Regulations on the realization of public procurements from a single source

Government Decision no. 794 - 08.10.2013 for the approval of the Regulations on the public procurements using the negotiation procedure

Government Decision no. 804 - 10.10.2013 for the approval of Regulations on the conduct of public procurements through competitive dialogue

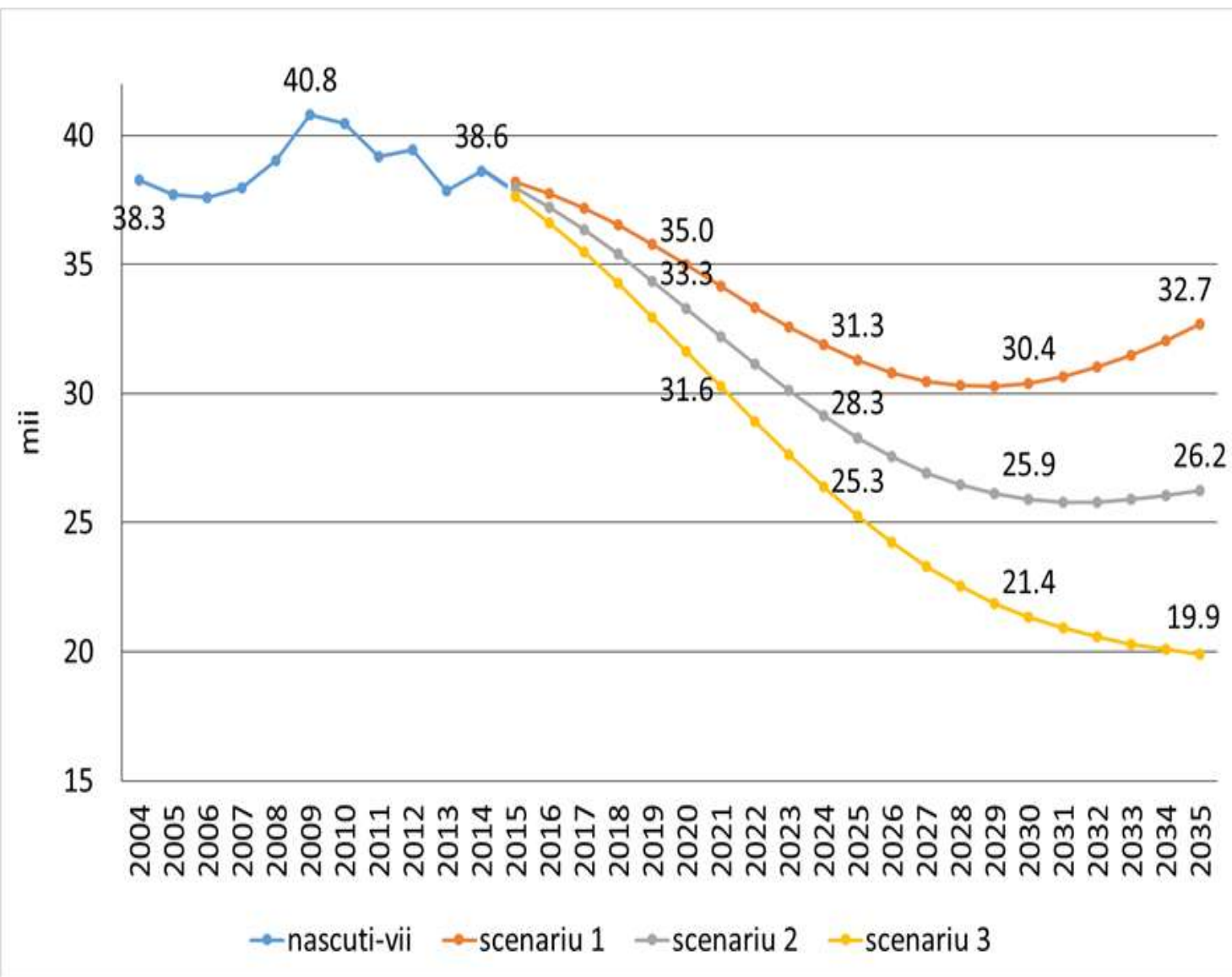
Government Decision no. 1380 - 10.12.2007 on the approval of the Regulations on the activity

Latest shortages

- Repeated tenders (DTP, Td, bVPO – 2015 BCG 2014)
- Lack of bidder (Td, bVPO, DTP, ROR – 2015)
- Increasing/high prices (Td, bVPO – 2015)
Delayed procurement/supply (Td 2014) (BCG - 2015)

| Vaccine | Presentation | Manufacturer / Price per vial (USD) | Procurement Mechanism |
|-------------|--------------|-------------------------------------|-----------------------|
| HepB | 1 dose | Serum Institute / 0.2 | UNICEF |
| Pentavalent | 1 dose | Serum Institute / 1.10 | UNICEF |
| MMR | 1 dose | Serum Institute / 2.85 | UNICEF |
| MMR | 5 doses | Serum Institute / 7.25 | UNICEF |
| BCG | 20 doses | NCIPD Ltd, / 2.10 | UNICEF |
| bOPV | 10 doses | GSK / 1.80 | UNICEF |
| IPV | 1 dose | Bilthoven / 3.50 | UNICEF |
| DTP | 10 doses | Serum Institute / 2.00 | UNICEF |
| DT | 10 doses | NCIPD Ltd, / 1.67 | UNICEF |
| Td | 10 doses | NCIPD Ltd, / 1.29 | UNICEF |
| PCV13 | 1 dose | Pfizer / 3.30 | UNICEF |
| Rota | 1 dose | GSK / 2.31 | UNICEF |
| HPV | 1 dose | Merck / 4.50 | UNICEF |

Dynamics of actual and predicted births, 2004-2035

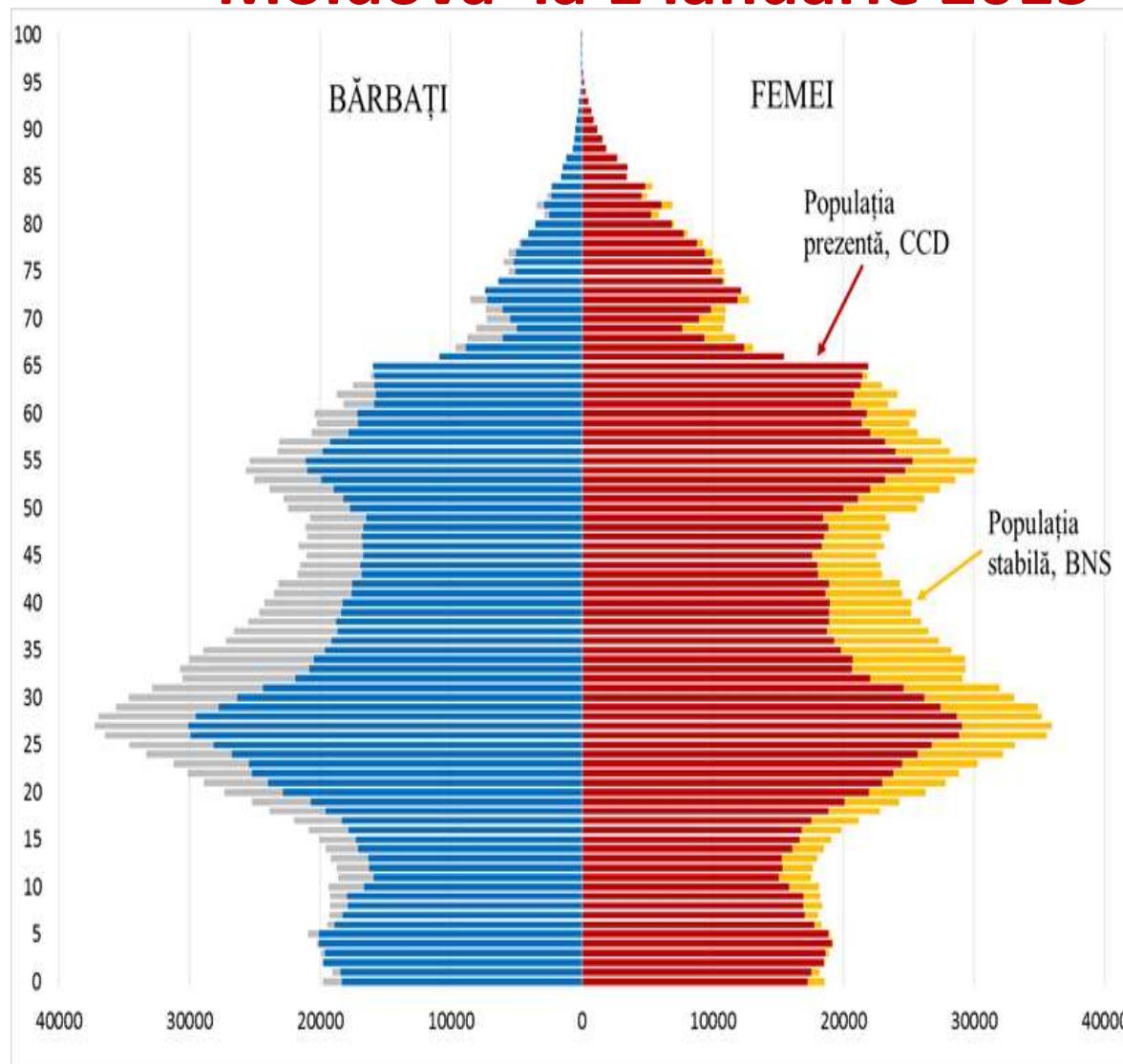


• Dacă TFR se va menține constantă, atunci numărul de nașteri va descrește până la 19,9 mii

• Dacă TFR va crește până la 2,1 copii, atunci numărul nașterilor va crește până la 32,7 mii

Piramida pe vârste și sexe a populației Republicii Moldova la 1 ianuarie 2015

Populația stabilă (BNS) 3555 mii. Include și migrații care lipsesc în țară mai mult de 12 luni.



Populația prezentă (CCD) 2911,6 mii. Calculată conform standardelor europene și nu include emigranți care au lipsit din țară mai mult de 12 luni.