



## Internal Appraisal 2014 REPUBLIC OF MOLDOVA

### 1. Brief Description of Process

This Internal Appraisal was conducted for GAVI by independent technical expert Zaza Tsereteli, in close cooperation and with substantive inputs by GAVI country responsible officer (CRO) Nilgun Aydogan, and is based on reports and documentation supplied to GAVI by the national authorities and institutions in the country for the year 2013. WHO EURO, WHO country office, UNICEF Supply Division made significant contributions and updates to the report.

Immunisation decision support team is drafted the dose calculations for 2015 for all NVS programs using the approved targets (numbers of infants & wastage). The number of doses to be allocated (and planned for shipment) for 2015 for the programmes pentavalent are based on the approved targets (2015) as well reported opening stocks (Jan 2014), shipment plan (2014) and target closing stocks (2015). For others programmes, a stock analysis is carried out to determine the right level of stock to be deducted from 2015 allocation. Syringes and safety box calculations are derived from dose calculation. All this is done in consultation with the product managers and (if there are any significant changes) the country, and are signed off by the CRO.

### 2. Achievements and Constraints

Moldova has achieved a high level of coverage rates (over 90%) overall for immunization services being provided in the country. However during the last two years some negative trends have been indicated, as country has not managed to reach the immunization coverage targets. In 2013, the coverage rate for the DTP3 was 90%, instead of 93%. BCG coverage was 96%, instead of 99%. Penta coverage was 89%, instead of 93%, and Rotavirus was 65%, instead of 90%. The main reasons behind the lower coverage rates are increased refusal of vaccination by families (especially in Chisinau) and in Transnistria Region. This latter is not controlled by the central government in Chisinau. It seems that there is an on-going problem with the anti-immunization propaganda by social media and some religious organizations, as same problems were reported in the previous years. Due to the intense internal and external migration, there are also difficulties in determining the accuracy of the denominator – children to be vaccinated.

As for the PCV13, the coverage was 0%, instead of 72%. Due to the late delivery, the vaccination against pneumococcal disease was launched in the country on 01.10.2013. As a result of it, the third dose of pneumococcal vaccine, according to the WHO recommendations, will be given to children only in August of 2014. During the three months of year 2013, one dose of pneumococcal vaccine was administered to 7515 children, two doses to 1707 children.

There are no gender barriers reported in access to immunization. The 2013 APR presents estimations of the sex disaggregated data based on the Multiple Indicator Cluster Survey (MICS), which took place in 2012. The results were officially published in May 2014. Based on the estimations, coverage rates for all the vaccines under the routine immunization are slightly higher in girls than in boys.

Moldova has updated in cold chain equipment, and conditions were improved for the storage and transportation of vaccines. A cold chain assessment mission to the Transnistria region is commissioned by UNICEF, scheduled for June 2014. Capacity building activities were implemented, including a national seminar for doctors, epidemiologists, pediatricians and family physicians on immunization and the introduction of the pneumococcal vaccine, including a pocket guideline on the implementation of PCV for health workers with the support of WHO. WHO Country Office in the Republic of Moldova also carried out a training workshop on effective vaccine management for mid-level VPI managers in the Transnistria region in August 2013. Jointly with GAVI Secretariat, WHO Regional Office for Europe conducted a short follow-up mission to Moldova to assess the national regulatory authority (NRA) progress and assist with GAVI graduation, including a graduation grant to be co-managed by UNICEF and WHO over 2014 and 2015. A comprehensive immunization program review was conducted in the

Transnistria region under the WHO umbrella during 30 March – 10 April 2014, the report of which will be available in July 2014. An IPV introduction assessment mission was conducted in May 2014.

In order to improve the situation with immunization coverage and overcome the latest problems with anti-immunization movement, information campaigns about the benefits and safety of the vaccine were carried out. Within the framework of European Immunization Week, jointly with WHO and UNICEF, the Ministry of Health held a press conference for journalists, followed by demonstrations of vaccine storage conditions at different levels. Currently, courtesy of WHO support, a smart phone application to send vaccination reminders to mobile phone users has been developed and tested, after adjusting it to Moldovan context and language, to be made public during July 2014.

### 3. Governance

The Deputy Minister of Health of Government of Moldova chairs Inter Agency Coordination Committee (ICC). The membership of the ICC consists of senior representatives from the Ministry of Health, Ministry of Finance, National Medical Insurance Center, and National Public Health Center, plus representatives from WHO and UNICEF country offices. Still there is no representative from the civil society organizations (CSOs).

ICC met three times in 2013. The most recent meeting held in May, 2014, has reviewed and approved the APR for 2013. Meeting has also discussed the follow-up on the previous decision of the ICC.

The expert wants to point out that there are some discrepancies in the documents presented, related to the ICC meeting and the ICC members signature list. The ICC meeting that adopted the APR for 2013, took place on May 8. However, two members from the ICC signed its approval for the document already on May 5, before the discussions and the ICC decision took place. The date on the Ministers signature is also missing.

### 4. Programme Management

The CMYP 2011-2015 is aligned with national health and development policies and addresses the GIVS strategic areas. It explores costing and financing scenarios and highlights the role of GAVI co-financing support to introduce rotavirus vaccine starting 2012 and pneumococcal vaccine starting 2013 and government's commitment to secure additional funds to fill the funding gap.

In 2013, the post introduction evaluation for rota virus vaccine conducted. The findings of the PIE revealed satisfactory outcomes for the vaccine introduction. The general findings were as follows giving indications of well managed immunisation program. There are weaknesses and some challenges also identified within the program, in particular with implementation of rotavirus vaccine in the Transnistria region, which was put on hold, as well as PCV, on legal and financial grounds.

- None of the health care workers interviewed reported any cold-chain problems and vaccine storage was observed to be appropriate in all but one site. Forecasting, ordering, and distribution of vaccines on a monthly basis worked well.
- Supervisory visits from the national level to the district level are conducted regularly. Most public health centers make quarterly supervisory visits to health facilities in their jurisdiction. Of the health facilities visited, 93% reported receiving a supervisory visit in the past six months.
- Health care worker knowledge was generally good. Sixty-three percent (63%) of the health care workers knew that rotavirus vaccine is intended to prevent rotavirus diarrhoea or severe diarrhoea. The national level reported that medical specialists (neurologists, oncologists, and surgeons) often provide unjustified contraindications against all vaccinations, which leaves vulnerable children unprotected. In the Transnistria region there are additional obstacles to get a vaccine, such as mandatory investigations / exams

before immunization, which significantly delayed the administration of vaccines, in particular rotavirus.

- Auto-disable syringes were being used in all facilities. Most facilities had adverse events following immunization (AEFI) procedures in place but there is no standardized protocol for case investigations nor is there a case report form.
- An immunization communication strategy was developed with UNICEF but is still being finalized. The immunisation program communication plan doesn't take into account the results of the focus group studies and the draft communication strategy. Twenty-six percent (26%) of health care workers experienced resistance from the community regarding rotavirus vaccine. Vaccine hesitant parents are influenced by anti-vaccine publications and some religious groups have also taken a stand against vaccines. WHO plans to implement vaccine information statements, and outbreak communication activities (the latter, jointly with UNICEF).

The immunisation program and coverage issues remain in the eastern region of Transnistria including vaccine supply, governance and financing issues as well as, deficiencies in human resources for healthcare.

## 5. Programme Delivery

The last Effective Vaccine Management (EVM) was carried out in April 2011. According the assessment five of nine criteria scored above 80%, while four (temperature, maintenance, stock management, and Management Information Systems (MIS) and supportive functions) did not. The country has developed the EVM improvement plan and has taken a series of actions to address problems identified. The national vaccine warehouse, as well as refrigerating equipment, was repaired. Capacity of the cold storage was increased, as well as computerised data management was introduced. According the given documents 19 out of 22 recommendations are implemented.

The issue on waste disposal remains unsolved. However there are efforts to address the issue. With support from WHO, under the framework of National Waste Management strategy, a national strategy and regulations on health care waste management have been developed in cooperation with other relevant sectors and stakeholders.

The recent vaccine introductions went according the plans except Transnistria region. The region, which is not under the control of the central government, refused the introduction of the pneumococcal vaccine. Their refusal was mainly based on two reasons:

- a) Pneumococcal vaccine is not included in the immunization schedule approved by the local law;
- b) Lack of funding for co-financing requirements for the PCV13.

## 6. Data Quality

There is a dual system of collection of administrative data on immunization coverage of children in Moldova. The first is based on a monthly collection of data on the number of children to be vaccinated and those vaccinated by single administration of vaccine doses. Second - provides a review of completed vaccination and booster doses by birth cohorts registered with primary health care with the status at the end of the year. No significant coverage differences are recorded between those two data sources.

In the attempt to identify and address denominator based issues, the country developed an electronic tool to review monthly vaccination coverage basing on denominators obtained from 3 sources – maternity hospitals, birth registration offices and children registered with primary health care.

Multiple Indicator Cluster Survey (MICS) took place in Moldova in 2012. Official results were presented in April 2014. The estimates for full immunization coverage are based on children aged 15-26 months. By the age of 12 months, 98% received BCG vaccination and the first dose of Hepatitis B vaccine, while the first doses of DPT and Polio vaccines were given to 94 and 95%, respectively. Where the primary vaccination course requires three doses, the proportion of

vaccination coverage declines for subsequent doses of Hepatitis B vaccine to 96% for the second dose, and 94% for the third dose, for Polio vaccination to 95 and 89%, respectively and for DPT to 92% and 91%. However, the dropout rate does not exceed 10% for any vaccination. Coverage for MMR vaccine by 15 months is at 89%.

The percentage of children who received all WHO and UNICEF recommended vaccinations, as also stipulated by the Moldovan National Immunisation Schedule for the primary immunization cycle in the first year of life, is 79%. The percentage of children who received no vaccination is 1%. Significantly lower and insufficient vaccination coverage can be noted for children aged 15-26 months who were vaccinated at any time before the survey in urban areas (82%) compared to rural areas (93%), the lowest being in the Chisinau municipality (71%).

The computerised database was introduced in 2013, with the aim to improve the data collection procedure and the data quality.

## **7. Global Polio Eradication Initiative, if relevant**

There is no separate polio program in the Moldova as the vaccine is well integrated into the routine program. It is expected that Moldova will apply for IPV introduction as part of the global eradication plans to introduce the single dose IPV in 2015.

## **8. Health System Strengthening**

Moldova did not utilise GAVI any cash grant from GAVI to-date except the vaccine introduction grants, although it negotiated a GAVI graduation support grant with the Ministry of Health and GAVI Secretariat to be co-managed by WHO and UNICEF in 2014 and 2015. Moldova embarked on a health sector reform at the end of the 1990s. At that time public financing of the health sector accounted for only 2.9% of GDP. The reforms focused on extending and strengthening the primary health care (PHC) network, health insurance was introduced to make health care more affordable for the population and hospitals became autonomous institutions. In August 2007, the Government issued the National Health Policy Immunizations defined as one of the basic tools to be sustained and promoted in order to achieve diseases prevention and control. By 2008, public health expenditures recovered to 5.6% of GDP and enabled progress towards achieving the Millennium Development Goals. Following the National Health Policy, the Health System Development Strategy for the period 2007-2016 has been developed with the goal to improve people's health, upgrading the financial protection and degree of satisfaction of the public through adequate enhancement of the health system performance. The current national immunization program runs from 2011 until 2015.

Introduction of health insurance in 2004 has improved access and financial protection to the vulnerable population and salaries, but there are gaps in coverage. Health insurance now covers almost 80 per cent of the population and state budget contributions account for nearly 55% of total National Health Insurance Company revenues. Current financing scheme includes Government budget, National Health Insurance Company funds, which now covers all expenses on the maintenance and overheads of health care facilities at the sub-national level (rayon and municipal levels) including payroll, outreach vaccinations etc.

## **9. Use of non-HSS Cash Grants from GAVI**

In 2013, country only spent the remaining funds from the grant for introduction of the rotavirus vaccine in 2012. According the presented document only 6.6% of available funds (9,236 US\$ out of 137,970 US\$) were spent in 2013. The only budget line, which was followed in accordance with the original plan was the salary.

The 100,000 US\$, allocated for the implementation of the pneumococcal vaccine was received with delay, only in September of 2013. Given the length of the internal procedures for drawing up and approving expenditure and procurement on the basis of tenders, it was decided to postpone the usage of this funds until 2014.

In 2014, country is planning to use the available funds on publishing materials for the public and health professionals, as well as documents on accounting vaccines and vaccination. It will be also used to purchase the cold chain equipment, for the training of the staff, surveillance activities and salaries.

## 10. Financial Management

Financial Statements for the Vaccine Introduction Grants utilisation are presented to GAVI. There is no need for the audit of 2013 expenditure due to low level of funds utilisation (US\$ 9,236). The expenditure appears to be eligible.

## 11. NVS Targets

### Penta vaccine

Penta vaccine was introduced in June 2011. The APR reported that 139,000 doses of vaccine were received in 2013. The target for 2015 penta1 is 44,830 which is 17% increase above the achievement for 2013 which was penta1 38,192. It is suggested that while this is above the 10% rule, the target is accepted since this is (relative to GAVI 73) as strong program, and the increase in coverage of 17% is over 2 years and the interim year (2014) is where the increase is occurring (of 11% year on year). The request for 2015 is around 139,923 doses but this will depend on the stocks estimates as well. In addition, the APR reports that the price of DPT-HepB-Hib vaccine, a 1-dose form, is much more expensive than the price of DPT (one dose), resulting in extra cost of the program.

Expected coverage rates and dropout rates are all within satisfactory range. Timely procurement and shipment needs to be ensured in 2014. The proposed wastage level is acceptable.

### Rotavirus vaccine

Rotavirus vaccine was introduced in 2012. The APR reported that 90,000 doses of the vaccine were received in 2013. Country is asking 88,620 doses of the Rotavirus vaccine in 2015. (*Please see section 4 of this report for summary of results of the Rota virus vaccine PIE*)

### PCV13 vaccine

The PCV13 vaccine was introduced in October of 2013. APR reported that 66,600 doses of the vaccine were received in 2013. The Transnistria region (which is not under the control of the central Government) has not introduced this vaccine. As it was mentioned above, it was expected to reach the 70% of coverage in 2013. However, due to the late arrival of the vaccine this target was not reached. Country is planning to achieve 95% coverage in 2014. Though, taking into account the difficulties in the Transnistria region and the anti-immunization movement, this target could be unfeasible. Country is requesting 130,000 doses of the PCV 13 vaccine for the year 2015.

The country did not request any change in vaccine presentation.

## 12. EPI Financing and Sustainability

Moldova is a graduating country. The government pays for all the traditional vaccines and is meeting the commitments agreed with GAVI. Moldova fully paid its share of co-financing for 2013. For 2014 and 2015 funds planned in the mid-term expenditure framework 2014-2016, the plan is approved, funds will be allocated.

GAVI and WHO organized a graduation mission to Moldova in 2012 that identified challenges to graduation readiness and developed an action plan to address those challenges. This plan was not costed, as GAVI had no source of support to fund graduation plans at the time. As per the November 2013 GAVI Board decision, the mission returned in February 2014 to assess what had been achieved, explore vaccine procurement and regulatory issues in more depth, and identify

and cost catalytic investments for graduation readiness, with a timeline for activities to be carried out from 2014 to its last year of GAVI support in 2016. The following are some examples of key activities that the graduation plan will support.

- At the time of the initial March 2012 graduation mission, Moldova did not have an established National Immunisation Technical Advisory Group (NITAG). The NITAG was established in October 2013 and has written terms of reference defining its responsibilities. The NITAG includes all recommended disciplines and expertise (paediatrics, public health, epidemiology, infectious diseases, immunology), except health economics. The graduation support would strengthen this nascent organisation, providing training, supporting peer-to-peer learning with a visit to a well-functioning NITAG, and perhaps twinning with this or another well-run NITAG.
- The graduation assessment conducted in March 2012 did not focus on vaccine regulations. A more in-depth assessment of the NRA's role in marketing authorisation and pharmacovigilance was conducted during the February 2014 visit. The graduation support includes support for training staff on market authorization and licensing and visiting a well-run NRA to learn more about Quality Management Systems (QMS).
- In procurement, the graduation investments will support the government in preparing for efficient and sustainable procurement of new vaccines after GAVI support ends. A working group will be formed to look at options, and the graduation investment provides support for laying the groundwork to implement any legal and technical changes needed in procurement processes.
- The graduation investment cover technical assistance and capacity building other program areas for long term sustainability such as strengthening national capacities in addressing vaccine hesitancy and safety issues management and crisis communication, improvement of surveillance, and data quality.

In financing, Moldova has been able to meet its rising co-financing requirements thus far, but these are about to increase steeply as both volumes and the domestic share of Rotavirus and Pneumococcal vaccine paid by the government grow over the next few years. Expensive purchases of other vaccines are also anticipated. Technical assistance to forecast vaccine funding requirements and distribute the financing responsibility between the health ministry and the national health insurance agency will help the government to cope with the rising financial burden associated with graduation.

### 13. Renewal Recommendations

Topic	Recommendation
NVS	<p><u>Penta vaccine</u> Approve 2015 NVS support based on country request target.</p> <p><u>Rotavirus vaccine</u> Approve 2015 NVS support based on country request target.</p> <p><u>PCV13</u> Approve 2015 NVS support based on country request target.</p>

### 14. Other Recommended Actions

Topic	Action Point	Responsible	Timeline
<i>EPI programme Delivery</i>	<p>Country urgently needs to re-evaluate the current strategy to tackle the issue of the vaccine hesitancy and safety.</p> <p>To continue through the UN organizations dialogue with the officials in the Transnistria Region, to follow-up on problems in this region. (May 2014 – a separate EPI review conducted to identify the problems and bottlenecks of the region.</p>		
<i>Governance</i>	The Government is encouraged to consider including CSO representatives to ICC or provide clarifications why CSOs		

	are not part of the ICC.		
<i>Graduation</i>	The country has submitted its plan and budget for graduation for 2,5 years totaling 488,500USD. The documentation is being processed to be submitted to GAVI CEO for approval.		