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 Nilgun Aydogan of GAVI Secretariat, and is based on reports and documentation supplied to GAVI by the national authorities and institutions in the country for the year 2013. During the review process inputs from WHO country office, WHO EURO and UNICEF (including supply division) are graciously provided. The country also provided clarifications on financial management and co-financing issues.

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 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

Georgia has not reached the target coverage for almost all the vaccines, and coverage rates are less than 90%. The coverage rate for the OPV was 87% instead of 95%; for the DTP3 was 87%, instead of the 95%; for the Measles coverage was 91%, instead of the 95%; Penta coverage was 87%, instead of the 96% and Rotavirus coverage was 38%, instead of the 59% due to delayed introduction. The only vaccine with more than 90% coverage is BCG, the vaccination rate was as planned and reached 97%.

As a main explanation for such a performance is given the fact that there is a significant difference between the number of surviving infants indicating in the APR (57,005) and the number of surviving infants utilised by the national immunisation program (NIP) (53,157) There are several reasons behind the low uptake of vaccines. There are instances that healthcare workers linking the false contraindications to immunisation, especially in the large cities leading to vaccine hesitancy among parents. Finally, serious communication problems related to the media commentary affected the credibility of the health facility staff and the immunisation program.

The country considers new electronic eHealth system (immunisation service and vaccine stock management modules are included) to improve the data quality used by the immunisation program. In principle, there should be one target/denominator for both national registry and health facility data. A new system is introduced in 2014 for the first time, and goes on parallel with existing reporting system. Absence of computer-skilled staff at service delivery level might be an obstacle for rapid implementation on this tool country-wide.

The health care reform process that is on-going within the health sector for last several years resulted in the frequent changes of the ownership and the funding mechanisms of the health care services. Reform process led to the organizational and functional difficulties in whole health care systems including the immunisation. Since 2012, the private insurance companies cover health programmes, including immunisation. That has caused changes in the quality of service delivery and NIP financing. Most probably the problems with data quality and immunisation services will continue until the whole health care system is adjusted.

In order to strengthen the EPI, several actions were implemented during the reporting period. That among others included establishment of the expert group to coordinate supplementary immunisation activities against Measles outbreak in Georgia, cold chain inventory development and Rota vaccine post-introduction evaluation (conducted in March 2014).

According to the APR, country has a long list of the priority actions in 2014 and 2015. In the light of recent development, it seems too ambitious. Many of listed activities are more the regular activities, then the priority ones. The expert is suggesting revising of the list and developing a
group of the first priorities, in order to use the available resources more efficiently and get maximum result for the improvement of the EPI in country.

Country is not reporting any gender coverage discrepancies or equity issues, especially gender – based barriers.

3. Governance

The Interagency Coordination Committee (ICC) is functioning in Georgia. Representatives from the MoH, NCDC, UN organizations and one CSO are presented at the committee. According the APR, there were eleven meetings of the ICC in 2013. The only minutes available for the consultant was from the meeting of May 2014, which endorsed the APR for 2013. The main topic of the meeting was the quality of the data related to the numbers of surviving infants and the birth rates. The representative from the only CSO was absent during the last meeting of the ICC, and his/her signature is also missing from the list of the APR 2013 approval.

4. Programme Management

The country has a well-developed National Immunisation Programme (NIP), for the five year period (2012-2016), which was endorsed in 2011. The National Centre for Disease Control and Public Health (NCDC) is in charge of the NIP. That includes the developing of the national standards and guidelines, conducting the monitoring of the immunisation program activities, providing expert advice, training of the health care providers and maintaining national level vaccine stock.

The estimated total resource requirement for 2012-2016 is $ 25,4million. "Vaccine supply and logistics" is the most significant cost of the program (45.4%).

According to the NIP, the ICC is coordinating the work of all agencies involved in the implementation of the program.

Immunisation services at the local level are provided at the Primary Health Care (PHC) centres. The reform of the PHC introduced in 2009, brought the PHCs under the direct supervision of the MoLHSA/SSA. Due to the excessive number of PHCs, the process of management of those centres became problematic and negatively affected delivery of all services, including the immunisation.

5. Programme Delivery

The latest EVM took place in July 2011. Based on the assessment the improvement plan was developed outlining the activities, implementation timeline, estimated budget and responsible bodies, categorized by the nine EVM criteria. EVM follow up assessment was conducted in April 2013. Implementation of the plan was delayed, being affected by frequent reforms and organisational changes; however a good progress is noted starting 2013 with the new management in place.

The immunisation supply chain has been restructured, eliminating one intermediary storage level. The storage capacity of the CVS has been expanded with additional cold room and engaging storage facility of a new site. Vaccine arrival procedures and temperature monitoring have improved. Forecasting, stock management and distribution procedures were strengthened. Country has implemented a comprehensive cold chain inventory and needs assessment and identified needs for further strengthening the cold chain to meet the needs of new vaccine introduction at all levels of the immunisation supply chain and Government has allocated funds for cold chain procurement.

Vaccine stock outs were frequent in Georgia over the last 3 years. The last stock out involved Hepatitis B vaccine, which was out of stock for 6 weeks in 2013. This is an improvement comparing to stock outs of BCG, pentavalent and tetanus toxoid vaccines in 2012.
The next EVM is planned for the September of 2014 and will allow updating of strengths and the needs in the new context.

The introduction of the Rota vaccine was prepared from 2012, but was postponed until 2013, due to the organizational and structural system changes taking place in the health sector. The rota vaccine was introduce in March 2013 and post introduction evaluation conducted in 2014. The summary of the findings of Rota PIE by the evaluators were as follows:

- Denominator and coverage data issues: Vaccine doses administered data were reported on a monthly basis by all visited health facilities to the district public health offices where those data are compiled and submitted to the national level. The overall rotavirus vaccine coverage for children born in 2013 was 48% for dose one and 37% for dose two, using the denominator of 58,579 births. This is lower than the planned coverage of 60%. The denominator being used by health facilities is considerably lower than the number of live births which suggests that some infants are not registered and vaccinated in health facilities.

- Need to implement reminder and recall systems to bring children in for vaccination to improve coverage for full immunisation.

- Weaknesses in the vaccine storage and management: The national vaccine storage site has adequate storage capacity and cold chain monitoring systems in place. Vaccine storage was found to be good at all district public health offices visited. All health facility sites that stored vaccine had thermometers in the refrigerators, but in two (7%) sites the thermometer was not functional. Vaccine was found to be inadequately stored in some sites; the refrigerator was not at the appropriate temperature in four (16%) sites visited. Georgia has a well-established system of forecasting, ordering, and distributing vaccines. The monthly reports are submitted on time by health facilities. The vaccine management guidelines have been updated electronically to include rotavirus vaccine and NCDC has plans to reprint the vaccine management guidelines in 2015, subject to financing. In the last six months, two health facilities (7%) reported having DTP vaccine expire, three (10%) sites had vaccine vials in VVM stage III or IV, and seven sites (24%) ran out of a vaccine.

- Weakness in supervision: In May and June of 2013, NCDC, with WHO support, conducted monitoring activities in target areas of the country to assess the rotavirus vaccine implementation process and coverage. NCDC has no routine supervision plan due to lack of budget. There is a supervision programme in place at the district level. Of the health facilities visited, twenty-seven (93%) had received at least one supervisory visit from the district since rotavirus vaccine was introduced but of those visited only two (7%) received a written report.

- Management of AEFIs and communication skills: Guidelines on AEFI monitoring are part of the vaccine management booklet, which was updated electronically to include rotavirus vaccine. The programme does not have a crisis communication plan in place to manage AEFIs. Since rotavirus vaccine was introduced, there have been seventeen reported cases of AEFIs for all vaccines but none was associated with rotavirus.

The PCV-10 vaccine will be purchased and distributed in 2014 once programmatic readiness is obtained and confirmed by WHO. As of now, the planned introduction of PCV 10 is September 2014.

6. Data Quality

The NCDC medical statistics department collects data from the health care service providers. A problem exists with the quality of the data for the surviving infants. The immunisation information system reports around 4,000 fewer children compared to the report from the medical statistics. The main problem is or the delay in registering or the missing data of the newborns by the primary care facilities. The data quality problem on the PHC level will exists until the changes in the PHC system management will be not introduced.

In an attempt to address denominator related issues, the Ministry of Health supported by partners develops a modular electronic health management information system which incorporates an immunisation registry component and a vaccine stock management component.
Rotavirus and IBD sentinel surveillance data are reviewed at the ICC meetings and sent to the WHO on the monthly basis. Sentinel surveillance data was used while deciding to introduce the Rota and PCV vaccines in Georgia.

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

There is no separate polio program in Georgia; polio implementation is well integrated into the routine immunisation (RI) program. Country together with other countries from this region is certified as Polio free since 2002.

8. **Health System Strengthening**

The on-going process of the health care reforms affected the quality of the immunisation services. In 2012, the ICC composition was changed and for some period it was not possible for the ICC to manage the HSS program implementation. The NCDC management was also changed, and the EPI department was abolished and, as a result, the implementation of the projects, including the HSS was negatively affected.

Considering all of the above-mentioned issues the implementation of the HSS project was delayed until the 2014-2015. At the beginning of the 2014, 124,500US$ are available under the HSS project, in order to implement the remaining four activities.

At the ICC conducted on 14 May, 2013, it was decided to conduct supportive supervision activities at all levels and trainings of health staff, in order to support immunisation goals and it is foreseen that the remaining HSS funds will be used for this purposes.

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

Georgia is not reporting on Immunisation Services Support (ISS) fund utilisation

In 2013, under the New vaccine introduction grant (Rota vaccine), country has used 87,643 US$ from the available 195,111 US$. The remaining funds were carried forward for the activities in 2014. By the decision of the ICC, 3,500 US$ was used for the monitoring and supervision of the measles outbreak response activities in 2013.

In 2013, country has received the NVS introduction grant ($100,000) for the implementation of the PCV vaccine. The ICC is making the decision on the allocation of the grant. It is planned to conduct the training of the medical staff and carry out the information campaign to introduce the PCV vaccine.

10. **Financial Management**

The funds from GAVI are received to the NCDC account. The state accounting agency is monitoring all expenditures from the NCDC account. The ICC approves APR with the information about financial expenditures and funding request for next. There are no major financial concerns.

11. **NVS Targets**

**Penta vaccine**

Penta vaccine was introduced in late 2009. The APR reported that total doses of 167,500 were received for program year of 2013 (57,300 of doses shipped in early 2014 as replacement of short expiration dated vaccines). According to the APR, it was decided that country co-financed procurement of only 53,000 doses of vaccine as the stock at that moment was sufficient. GAVI requested fulfilling of country co-financing obligation completely, so it was decided to procure more 5,000 doses of Penta vaccine. Funds for that procurement were received only in December of 2013, so vaccines were delivered only in the beginning of 2014.
The target for 2015 penta1 is 55,100 and this is 4% more than the 2013 achievement. Country is asking 138,200 doses of vaccine for 2015. Based on the stocks reported, the Secretariat will adjust the doses requested for 2015.

The country uses GSK Lyophilised 2 dose pentavalent vaccine which is no longer available by the supplier. The country was informed about the status of availability and alternative products. The country is considering introduction of IPV containing hexavalent vaccine. The secretariat informed the country partners on the GAVI’s official position on hexavalent introduction based on the self-procurement policy outline. Currently GAVI cannot provide support to hexavalent introduction as Georgia’s NRA is not considered as fully functional by WHO, and the vaccines available in the market are not WHO pre-qualified. In addition, the country is alerted on the additional cost concerns for booster doses due to aP. However country has not made a decision on product preference for pentavalent or moving forward with hexavalent introduction.

Rotavirus vaccine

The introduction of the Rota vaccine was prepared from 2012, but was delayed until 2013, due to the organizational and structural system changes that were taking place in the health sector. It is difficult to report on the amount of vaccines requested and received, as there are several discrepancies in the numbers presented at the table 7.11.2 and the table 7.11.4. According to this table, country required 73,000 doses of Rota vaccine in 2013. It is then reported that the vaccine stock on January 1st 2014 was 98 594, even in 2013 country has received only 75,000 doses of vaccine. Afterwards for 2014 country has requested only 25,500 doses of vaccine. As for 2015, country is asking only 31,500 doses of vaccine (table 7.11.2), while according the table 7.11.4, the number of doses needed in 2015 is 103,020.

The doses will be adjusted by the secretariat based on delayed introduction and stocks.

PCV10 vaccine

The PCV10 vaccine will be introduced in 2014 subject to programmatic readiness. For 2015, Georgia is requesting 157,200 doses of the PCV 10 vaccine. The doses will be adjusted by the secretariat based on delayed introduction.

12. EPI Financing and Sustainability

The central government, local government and donors finance the immunisation program in Georgia. Purchase of vaccines and injection supplies is provided through a state tender procurement by the Georgia Health and Social Program Implementation Center (HSPIC). In 2013, some vaccines procured via UNICEF for measles outbreak. The government pays for all the traditional vaccines and is timely meeting the co-financing commitments agreed with GAVI.

GAVI Alliance conducted a graduation assessment in 2012. The graduation assessment noted the health system and reform processes as key concerns that may impact the program and financial sustainability. A number of recommendations were made and potential activities and next steps particularly in relation to financing, vaccine procurement, quality assurance and increasing public confidence in the national programme. The key recommendations of the assessment were:

- National Regulatory Agency (NRA) functionality insufficient for vaccines creating very real possibility of quality issues.
- Clear identification and dissemination of procedures roles and responsibilities throughout the immunisation system are required.
- Monitoring and reporting within the health reform requires formalisation.
- Fiscal space should be available for increasing requirements of immunisation programme.

In 2013, government budget for immunisation was projected to slightly increase, but there is a need to strengthen the process for UNICEF procurement of vaccines. One of the problems is that the procurement cycle for UNICEF does not coincide with the current government funding cycle.
which causes planning and administrative problems. An added complication is that in current year a universal insurance package being introduced, which will result in more changes for provision of immunisation services. These changes will need to be reflected in the next iteration of the graduation plan. Georgia is in need of technical assistance to deal with this. As per the GAVI Board decision the country will be re-visited and graduation assessment will look into program and financial issues further in order to revise the plan and develop a budget to support the plan. The visit is planned for October 2014.

13. Renewal Recommendations

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<th>Topic</th>
<th>Recommendation</th>
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<tr>
<td>NVS</td>
<td>Penta vaccine Approve 2015 NVS support</td>
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|        | The country uses GSK Lyophilised 2 dose pentavalent vaccine which is no longer available by the supplier. The country has been informed about the supply situation.  
(Please see the section 11 about pentavalent vaccine) |
|        | Rotavirus vaccine Approve 2015 NVS support. |
|        | PCV10 Approve 2015 NVS support. |
|        | Doses for all requested vaccines will be adjusted based on stocks reported and delayed introductions. |

14. Other Recommended Actions

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<th>Topic</th>
<th>Action Point</th>
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<th>Timeline</th>
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<td>Programme Delivery</td>
<td>Building capacity for communication and develop a comprehensive advance communication strategy for immunisation are needed as well as implementation of Rota PIE recommendations to improve the program management and delivery and gain efficiencies for implementation.</td>
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<td>EPI financing and sustainability</td>
<td>The country was visited in 2012 for a graduation assessment. A graduation plan was devised at the time with Alliance partners and agreed with the country. As per the GAVI Board decision the country will be re-visited and graduation assessment will look into program and financial issues further in order to develop plans and budget to support the transition. The visit is tentatively planned for October 2014.</td>
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