

# Seventh meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE)

29-30 August 2007 Copenhagen, Denmark

Vaccine-preventable Diseases and Immunization programme

#### **ABSTRACT**

The seventh meeting of the European Technical Advisory Group of Expert Group of Experts on Immunization (ETAGE) was held at the WHO Regional Office for Europe in Copenhagen on 29–30 August 2007. Members of the Vaccine-preventable Diseases and Immunization (VPI) programme reported on progress made on previous ETAGE recommendations, such as the introduction of new vaccines, and on milestones planned for 2008–2009. ETAGE especially encouraged VPI to maintain its strong efforts in the areas of maintaining the "polio-free" status of the European Region.

ETAGE congratulated the VPI programme and Member States on progress made towards achieving the regional goal of eliminating measles and rubella by 2010, as well as other regional immunization targets.

Members of ETAGE were also interested in the VPI financial and human resources profile as required to meet regional mandates, and it requests an overview for discussion at the next meeting. Moreover, ETAGE encouraged VPI to raise the visibility of its programme by stepping up communication with Member States and donors about VPI progress and achievements in the Region during the past five years.

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#### **Abbreviations**

AEFI Adverse Events Following Immunization

CDC Centers for Disease Control and Prevention, Atlanta, United States of America

CRI Congenital rubella infection

CSR Communicable Disease Surveillance and Response ECDC The European Centre for Disease Prevention and Control

EIW European Immunization Week

ETAGE European Technical Advisory Group of Experts on Immunization

GAVI Global Alliance for Vaccines and Immunization

GFIPMS Global Framework for Immunization Programme Monitoring and Surveillance

GIVS Global Immunization Vision and Strategies

Hib Haemophilus influenzae type b

HIV/AIDS Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome

IHR International Health Regulations

IPV Inactivated Polio Vaccine
OPV Oral Polio Vaccine

MR Measles and Rubella

RC Regional Committee of the WHO European Region

SIA Supplemental Immunization Activities

VDPV Vaccine-derived poliovirus

VPI Vaccine-preventable Diseases and Immunization programme of the WHO

Regional Office for Europe

VPD Vaccine-preventable Diseases WHO World Health Organization

WPV Wild polio virus

#### Introduction

The seventh meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE) was held at the WHO Regional Office for Europe, Copenhagen, on 29–30 August 2007. ETAGE meets twice a year to review the progress of the Vaccine-preventable Diseases and Immunization Programme (VPI) as it feeds into the regional goals. Dr Pierre Van Damme chaired the meeting, assisted by Dr Patrick Olin. Dr Tatiana Semenenko and Professor Patricia Claeys served as temporary advisers to the meeting. Dr Gudjon Magnusson, Director of the Division of Health Programmes, welcomed ETAGE members, representatives of partner agencies and WHO headquarters and temporary advisers to the meeting. Dr Nedret Emiroglu, Regional Adviser of VPI, opened the meeting and introduced the agenda. The objectives of the meeting were to provide ETAGE members with updates and receive input on the following:

- VPI implementation of previous ETAGE recommendations;
- VPI accomplishments in 2006–2007 and milestones planned for 2008–2009;
- regional overview on Global Alliance for Vaccines and Immunization (GAVI) and the introduction of new vaccines; and
- the status of accelerated disease-control programmes and the preliminary results from 2006.

ETAGE also encouraged VPI to remain vigilant and step up measures regarding:

- measles and rubella elimination and congenital rubella infection (CRI) prevention
- efforts to sustain the "polio-free" status of the European Region.

And finally, ETAGE discussed and endorsed:

- the 2007 report on European Immunization Week (EIW) and plans for 2008 and beyond
- the VPI strategic five-year plan (2008–2013) for remaining a polio-free Region.

#### **Opening statements**

#### **Director, Division of Health Programmes**

Dr Magnusson welcomed the group and highlighted the important role ETAGE plays in terms of setting the technical direction and priorities for the immunization programme in the WHO European Region. He also challenged ETAGE to support VPI by carefully taking into account new data, yet offering outspoken and constructive criticism when needed towards strengthening the regional immunization programme. Dr Magnusson also stressed the importance of equity to ensure the right of every child to receive appropriate, timely and safe immunization that will help avoid vaccine-preventable deaths of about 32 000 children in the Region per year.

#### Chair, ETAGE

Dr Van Damme welcomed the participants. He reminded the ETAGE of their terms of reference; to provide independent review and expert technical input to the WHO European Region's immunization programme, with the objectives of facilitating and accelerating the achievement of the regional targets. He also reminded the participants that ETAGE is an independent advisory body to the Regional Director of the WHO European Region.

# Technical session 1: Vaccine-preventable Diseases and Immunization Programme for 2007 and plans for 2008 and 2009

Dr Emiroglu presented a comprehensive outline of the VPI programme for 2007. Overall, the Region continues to achieve high coverage for most antigens used, and it recently celebrated its fifth year "polio-free" anniversary. However, more than 500 000 children are still not receiving full primary vaccination; timely vaccination remains a problem for several countries; measles and rubella outbreaks continue to occur; and despite the successful introduction of Hepatitis B across the Region, there are still some western European countries that have not adopted universal vaccination.

To close these gaps, countries can focus on strengthening immunization programme management through national capacity building in the areas of data collection, analysis and response, and strategic planning through formulation and implementation at national and subnational levels. Moreover, countries may develop better immunization delivery systems targeting hard-to-reach groups, including the urban poor, remote populations, mobile groups and minorities. Additionally, timely and accurate reporting of Vaccine-preventable Diseases (VPD) surveillance data remains a key challenge for the Region in measuring progress towards disease control, elimination and eradication goals.

VPI has made great strides towards articulating its strategic and programmatic directions towards 2013 in line with the medium-term strategic planning process carried out under the WHO general programme of work. This process has highlighted the complexity of the regional immunization programme and the importance of developing and strengthening programme and technical partnerships at regional as well as national levels.

ETAGE recognized the importance of partnerships as a means to leverage VPI strengths and to serve as a critical means to address programmatic gaps across the Region. Additionally, ETAGE appreciated the VPI challenge to chart a firm strategic direction in light of the changing nature of global, regional and national immunization priorities, high staff turnover, an intensification of programme activities and the constraints (and opportunities) of merging VPI with the Communicable Disease Surveillance and Response (CSR) unit.

With respect to the programme plan and budget for 2007 and plans for 2008–2009, ETAGE commended VPI efforts to acquire donor funds in 2007. It also expressed understanding for the concerns of a possible funding shortfall in 2008 necessary to meet current VPI technical assistance commitments. In light of this information, ETAGE requested an assessment of the VPI financial and human resources profile required to meet regional mandates.

## Summary of follow-up actions to implement previous ETAGE recommendations

Mr Eric Laurent delivered a brief presentation on VPI actions taken to address general and disease-specific recommendations from the previous ETAGE meeting in October 2006. ETAGE was pleased with the comprehensive and focused VPI action in response to these recommendations.

# Technical session 2: Accelerated disease control, measles and rubella elimination and CRI prevention

Dr John Spika described progress made towards the regional goal for the elimination of measles and rubella (MR) and prevention of CRI by 2010 and the actions planned for 2008–2009. ETAGE recognized the progress and continued achievements of VPI towards this goal.

In this area, ETAGE realized that continued Member State attention to maintain political commitment and sufficient financial and human resources is critical to achieve the MR elimination target in the Region.

ETAGE was pleased to note the regional progress in MR elimination as evidenced by the record-low number of reported cases to date. Also, it welcomed the commitment of five Member States to conduct MR supplementary immunization activities (SIAs) to address susceptible populations and the increasing number of countries reporting case-based surveillance data for measles and rubella. Conveying the importance of surveillance in monitoring progress towards the regional goal are of paramount concern to VPI and ETAGE.

ETAGE also welcomed developments of Member States in reporting to WHO and other partners. It appreciated the increase in national awareness of the importance of responding to measles outbreaks by implementing high quality outbreak investigations, implementing measures to vaccinate remaining susceptible populations and reporting findings to WHO and the European Centre for Disease Prevention and Control (ECDC). ETAGE noted that outbreak investigations conducted in 2006 and 2007 showed an increased quality in investigation efforts and greater collaboration between national immunization programmes, ECDC, the Centers for Disease Control and Prevention (CDC), United States of America and the WHO Regional Office for Europe.

For the next biennium, VPI plans to support country efforts to focus immunization activities on hard-to-reach populations and those with low access to health care services, and to strengthen routine immunization services delivery. ETAGE supported these plans.

ETAGE recognized that the 2010 MR elimination goal is ambitious and urged VPI to intensify efforts with Member States and partners to meet this target. ETAGE urged Member States to broaden efforts to define susceptible populations and to use every opportunity to vaccinate these groups. This could be done by strengthening routine immunization and related surveillance systems, or by increasing political commitment and national awareness through participation in EIW as well as through other means.

Finally, ETAGE recognized the value of certification of the elimination of measles and rubella as an important tool for monitoring progress towards the regional target. It also said this could be an

incentive for lagging countries. In this regard, ETAGE encouraged continued efforts to establish a regional certification process for measles and rubella. As such, VPI will gather evidence and develop strategies to ensure consideration of the process before providing a process update at the 2008 meeting of the Regional Immunization Interagency Coordinating Committee.

Also, where appropriate, VPI will promote Member State development of national review commissions for MR elimination that may integrate with polio eradication certification. ETAGE also encouraged VPI to promote understanding among Member States of the dynamic nature of the certification process. It requires long-term commitment of financial and programmatic resources, continuous monitoring and evaluation and rapid and high-quality response to imported virus.

#### Vaccine-preventable diseases surveillance

ETAGE recognized that some programmatic gaps impede regional and national efforts to monitor regional progress towards MR elimination and other immunization targets. A key gap is high-quality surveillance for measles, rubella and congenital rubella infection. This particularly relates to the lack of standardized data management structures and common reporting tools available to Member States. Such tools would facilitate seamless reporting of the case-based surveillance data from districts to the national level and finally to the Regional Office.

Also, ETAGE encouraged VPI and ECDC to advance the dialogue with the European Commission as soon as possible to drive the approval and clearance of communicable diseases case definitions. Application of these case definitions – including those for rubella and CRI and congenital rubella syndrome at the country and regional levels – will greatly enhance and accelerate surveillance activities for these entities.

Moreover, ETAGE endorsed the continued efforts of VPI to strengthen national VPD surveillance systems through increasing collaboration with partners. These include ECDC, disease-specific surveillance networks like EUVacNet and consensus bodies such as the Strategic Advisory Group of Experts (SAGE), MECACAR and other expert committees. These collaborative activities may be boosted by ETAGE members' advice and experience. They may attend SAGE, for example, and can liaise and advance dialogue with members of other global and regional expert committees to glean experience and practices relevant to the European Region.

ETAGE agreed to review and comment on the document, "Indicators for monitoring progress towards elimination and targets consistent with having achieved elimination". To assist in this review, ETAGE asked VPI to clarify related definitions as appropriate in the context of the regional surveillance environment.

ETAGE endorsed the VPI efforts to pilot the implementation of the indicators outlined in the above-mentioned document in the European Region as a foundation for certification efforts. ETAGE also welcomed the VPI's use of this tool as an incentive for countries to increase political and resource commitment to strengthen their national VPD surveillance systems.

# Update on global polio eradication and the regional efforts to remain polio-free

Dr Eugene Gavrilin presented the global polio eradication efforts in 2006–2007 and the regional actions to sustain polio-free status. ETAGE commended European Region Member States and the Regional Office on the five-year polio-free anniversary celebrated in June 2007.

ETAGE recognized the seriousness of the ever-present threat of wild poliovirus importations from the remaining polio-endemic countries. However, ETAGE was encouraged that the regional programme takes actions to prevent this by developing relevant guidelines, acquiring additional financial resources for the polio laboratory network and by developing innovative approaches to ensure maintenance of high-quality surveillance support.

ETAGE endorsed this regional effort and strongly recommended that urgent response to wild poliovirus importation should become an established regional norm.

However, ETAGE agreed that the absence of circulating wild poliovirus, decreased funding support and the attention required to introduce new diagnostic protocols all constitute threats to continued high performance of national laboratories to confirm circulating wild polio virus in the Region.

ETAGE also noted the importance for Member States to maintain high immunization coverage as the foundation for sustaining regional polio eradication. It was also noted that Member States lack good information that can help them decide whether to choose oral polio vaccine (OPV) or inactivated polio vaccine (IPV) as the optimal vaccine of choice for their national programs. ETAGE suggested VPI to endorse a regional position consistent with a global recommendation that is an anticipated outcome of the WHO SAGE meeting to be held in November 2007 and to share with Member States as appropriate.

In general, ETAGE fully endorsed and supported the polio-free plan in its current form with the understanding that periodic updates would be required to reflect future decisions of expert committees.

## Regional overview on GAVI and new vaccine introduction

## Immunization system strengthening and new vaccines

Dr Andrei Lobanov presented an overview of the GAVI and new vaccine introduction activities in the Region and linked these issues to the VPI programme work. VPI is coordinating a broad and comprehensive approach to strengthening national immunization systems. It supports new vaccine introduction by carrying out extensive technical assistance in the GAVI-eligible countries of the Region. The technical assistance is focused on supporting: multi-year planning, application development for GAVI awards for immunization systems strengthening, health systems strengthening and new vaccine introduction. VPI is also assisting national efforts to develop vaccine regulations, and assists in areas such as surveillance of adverse events following immunization (AEFI), vaccine procurement, vaccine management, injection safety and health care waste management.

A key point of discussion in this session was reluctance of many countries to advance efforts to introduce new vaccines into their national immunization program portfolio. One of the main contributing factors is the lack of high-quality and relevant data based on which national programs can make decisions in support of appropriate immunization policies.

To this end, ETAGE supported VPI's measured and comprehensive approach to new vaccine introduction, saying it helped prevent confusion and fragmentation in countries considering introducing new antigens into their national immunization schedule. It further recognized the value of VPI guidance and efforts to facilitate access to appropriate information for decision making. Consideration of this information and approach encourages countries to take deliberate measures to base new vaccine introduction policies on scientific evidence and merit that are appropriate and consistent with existing national health care delivery systems. In keeping with GAVI and other partner concerns, such policies should be supported by financial and infrastructural resources that guarantee long-term sustainability of the availability and supply of vaccines.

While ETAGE welcomed the positive benefits of the GAVI HSS approach to support national immunization programmes, it also recognized the need to encourage the use of HSS funds to address key programmatic needs such as surveillance systems strengthening.

#### Immunization quality and safety

National commitment coupled with VPI technical assistance has led to substantial progress in the area of immunization quality and safety over the past year. Overall, countries have continued to optimize quality and safety of immunization as reflected in the increased use of auto-disable syringes and the institution of a Region-wide surveillance system for AEFI. Another evidence of this is the adoption of a comprehensive approach to health care waste management in seven priority countries.

## The regional strategy on Human Papilloma Virus

Professor Patricia Claeys presented the regional strategy on Human Papilloma Virus (HPV). ETAGE recognized the importance of involving global bodies to examine issues related to introducing the HPV vaccine to provide public health safeguards related to vaccine efficacy and to foster sustainable vaccine delivery.

About 600 000 new cases of cervical cancer are discovered in the Region every year, but the process supporting the introduction of the HPV vaccine to address this issue is not straightforward. The HPV draft strategy note from VPI outlines regional strategies for the introduction of HPV vaccines and provides the Member States with the framework and guidelines for evidence—based decision making. It is intended for technical experts, national immunization managers, experts in the decision-making process and other people and institutions interested.

In support of this strategic approach, ETAGE recognizes VPI efforts to provide Member States with technical assistance and guidance that encourages a comprehensive decision-making approach to HPV introduction. Such guidance will encourage Member States to be mindful of developing policy that strikes an appropriate balance between dependence on the benefits of disease reduction attributable to immunization, and ensuring the continued broad public access to

known prevention tools and interventions such as early detection screening for cervical cancer and other related conditions. Additionally, when considering HPV introduction, countries should consider the duration of immunity, other vaccine efficacy concerns and that the long-term impact on disease reduction are still largely unknown at this point.

Related to this, ETAGE encouraged Member States to re-examine the need for proper – and targeted – surveillance indicators, and to ensure that monitoring systems are in place before vaccine introduction to monitor and evaluate vaccine impact on disease reduction.

VPI is working on a regional strategy in this area, and ETAGE committed to a 14-day review period to assist VPI in finalizing the strategy before issuance to Member States.

ETAGE members also requested to be updated on any new scientific information related to HPV efficacy and introduction methods when available to VPI.

# European Immunization Week: Review of 2007 and plans for 2008–2009

Ms Katrine Habersaat presented the results of the EIW held in April 2007; the lessons learnt and plans for the third EIW, scheduled for 21–27 April 2008. ETAGE appreciated the continued success of EIW as shown by the growth in Member State participation from 9 to 25; the impressive array of country activities and the nature and extent of national resources committed to the initiative.

Recognizing the effectiveness and usefulness of the EIW, ETAGE endorsed the activity as an annual Region-wide event.

European Immunization Week has grown considerably in just two years, with 25 Member States now actively engaged, and as such has become a greater success than was predicted. In order to maintain the success gained and ensure a sustainable and quality-based initiative, ETAGE agreed that VPI should now focus on consolidating its EIW activities rather than expanding its geographical scope. VPI should keep informing and inviting new Member States to join the initiative, but an increase in the number of participating Member States in 2008 should not be a specific criterion for success.

Moreover, ETAGE also supported continued efforts by national programmes to use EIW as a platform to address challenges such as targeting hard-to-reach populations, increasing routine vaccination uptake, strengthening surveillance and other programmatic enhancements.

Finally, ETAGE expressed concern about the potential adverse impact of the involvement of vaccine manufacturers in supporting national EIW activities. As such, the ETAGE encouraged VPI to explore possibilities of building a network of Member State entities, such as public health associations, which can advise national immunization programs on how to involve vaccine manufacturers to safeguard the integrity and efficacy of their EIW activities.

#### Technical session 3: VPI Strategic Plan for 2008–2013

Mr Eric Laurent presented the VPI strategic plan for the six-year-period 2008–2013. ETAGE congratulated VPI on its progress in developing a new strategic plan, saying it was a pragmatic document that would help create a stable programme platform and structure, which again would help define priorities. The plan will also assist VPI in monitoring programme progress towards its stated goals and help guide the use of resources through 2013.

While no strategic plan is perfect, ETAGE recognized that the document could benefit from further review from the VPI team, ETAGE members and from a selected group of partners. ETAGE particularly recommended paying attention to the following areas:

- review programmatic intent and prioritization of elements contained within each strategic objective;
- define baseline surveillance and performance targets to ensure that the purpose is clearly stated. This would also ensure that the targets offer Member States a reasonable and feasible challenge;
- revise the respiratory diseases sections, including paying special attention to bacterial meningitis and pneumococcal infections;
- better articulate the broad health systems strengthening approach;
- revise new and underused vaccines (put in separate sections), health-care waste management and safe injection areas; and
- develop new sections for rotavirus surveillance, diarrhoeal diseases and critical nondisease-specific components such as financial sustainability, advocacy and communications.

In addition to these suggestions, ETAGE also proposed that VPI revise the strategic plan to reflect a general approach for each strategic area that would encompass the following "pillars":

- communication: to consider the interests of partners, health care professionals, anti-vaccine groups and the media;
- partnership: to reinforce collaboration, avoid duplication and promote complimentary programs and synergy and;
- sustainable management: to support planning, networking, training, and evaluation.

ETAGE, on its side, committed to comment on the VPI strategic plan to the ETAGE chair by 30 September 2007.

As for the time frame for completing the strategic plan, ETAGE endorsed the proposed 31 December 2007 deadline.

#### **Key conclusions and recommendations**

ETAGE congratulates the VPI programme and Member States on progress made towards achieving the regional goal of eliminating measles and rubella by 2010, as well as other regional immunization targets.

ETAGE appreciates VPI actions and progress made towards the recommendations put forward at the 6th ETAGE meeting in October 2006.

ETAGE congratulates VPI on the effort to secure financial support for technical assistance and country staff and deems this appropriate to achieve regional goals and objectives.

ETAGE is interested in the VPI financial and human resources profile as required to meet regional mandates, and it requests an overview for discussion at the next meeting.

ETAGE encourages VPI to raise the visibility of its programme by stepping up communication with Member States and donors about VPI progress and achievements in the Region during the past five years.

#### WHO commitments by the next ETAGE meeting

Based on the discussion at the ETAGE meeting, the WHO Regional Office for Europe agreed on a number of commitments, for which progress will be reported at the 8th meeting of ETAGE.

- describe efforts to improve regional and national surveillance systems for priority VPDs, including innovations in operational strategies for both field investigation and laboratory network components;
- report on progress of merging Communicable Disease Surveillance and Response (CSR)
  with VPI, with special attention to challenges and benefits of this integration process to
  meeting regional goals and objectives;
- report on progress in implementing the Global Framework for Immunization Monitoring Systems (GFIMS);
- report on efforts to work with other communicable disease programs to create synergies that improve overall health systems performance; and
- report on global and regional efforts to advance commissions for the certification of elimination of measles and rubella.

## Proposed topics for the next ETAGE meeting

The meeting decided that by 1 October 2007, the WHO Regional Office for Europe would circulate suggested agenda topics to ETAGE, which will help make the final selection through a teleconference scheduled for February 2008. The dates for the 8th ETAGE meeting – which will be held in June or July 2008 – will be decided by 31 December 2007.

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The following topics were discussed at this meeting, and will be taken into consideration when finalizing the agenda:

- HSS and the impact of health sector reforms;
- the impact of comprehensive multi-year plans for immunization (cMYPs) on national immunization program performance;
- review of WHO commitments, in particular those relating to ECDC;
- updates on the European Immunization Week and polio eradication in the Region;
- an in-depth review of the VPI surveillance strategy for 2008–2013;
- final review and endorsement of the VPI strategic plan;
- review global recommendations on immunization schedules and booster doses;
- review the WHO Regional Office for Europe immunization work plan and budget for the next biennium;
- review of global recommendations for national immunization program consideration for IPV versus OPV in national schedules;
- update on the planning process supporting the merger of VPI and CSR (or endorsement of merger plan); and
- feedback from the November 2007 SAGE meeting.