

11th meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE)

Copenhagen, Denmark

17-18 March 2011

ABSTRACT

The European Technical Advisory Group of Experts on Immunization (ETAGE) met on 17-18 March 2011 to review and discuss immunization activities and developments in the WHO European Region and provide advice to the WHO Regional Office for Europe on appropriate activities. Main topics for discussion included responses made to the recent importation and outbreak of polio, progress towards the 2015 measles and rubella elimination goal, lessons learned from the implementation of pandemic influenza (H_1N_1) 2009 vaccines, vaccine financing, vaccine adverse event monitoring systems, activities to strengthen National Immunization Technical Advisory Groups (NITAGs), and the regional response to the Decade of Vaccines (DoV) initiative.

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Abbreviations

AFP acute flaccid paralysis

CDC United States Centers for Disease Control and Prevention

DoV Decade of Vaccines initiative

ECDC European Centre for Disease Control and Prevention

EIW European Immunization Week

ETAGE European Technical Advisory Group of Experts on Immunization

EU European Union

EUVAC.NET European Surveillance Community Network for Vaccine Preventable

Diseases

GAVI Global Alliance for Vaccines and Immunization

HPA UK Health Protection Agency

JRF WHO/UNICEF Joint Reporting Form

MRRVC Measles and Rubella Regional Verification Commission

NID national immunization day

NITAG National Immunization Technical Advisory Group

PAHO Pan American Health Organization

RCC European Regional Commission for the Certification of poliomyelitis

eradication

SAGE Strategic Advisory Group of Experts on Immunization

SIA supplementary immunization activity

SIVAC Supporting National Independent Immunization and Vaccine Advisory

Committees initiative

TESSy The European Surveillance System
UNICEF United Nations Children's Fund

VENICE Vaccine European New Integrated Collaboration Effort

VPD Vaccine-preventable diseases

VPI Vaccine-preventable Diseases, Immunization and Influenza

Programme of WHO

WER Weekly Epidemiological Record

WHO World Health Organization

WHO Europe World Health Organization European Regional Office, Copenhagen

WHO HQ World Health Organization Headquarters, Geneva

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Executive summary

The European Technical Advisory Group of Experts on Immunization (ETAGE) held its eleventh meeting on 17-18 March 2011 at the WHO Regional Office for Europe, Copenhagen, Denmark. Main topics for discussion included responses made to the recent importation and outbreak of polio, progress towards the 2015 measles and rubella elimination goal, lessons learned from the implementation of pandemic influenza (H₁N₁) 2009 vaccines, vaccine financing, vaccine adverse event monitoring systems, activities to strengthen national immunization technical advisory groups (NITAGs), and the regional response to the Decade of Vaccines (DoV) initiative.

Although the intention is for ETAGE to meet formally at least once every year, the last meeting was held in September 2009. The delay was caused in large part by the additional workload placed on the WHO Secretariat in responding to the polio outbreak in Tajikistan and providing support for deploying pandemic influenza vaccine. This experience has highlighted the need for rapid, easy information exchange between WHO and ETAGE, in the form of a focal point from VPI.

The Regional Office's efforts to support and strengthen immunization services in the Region remains seriously underfunded, with the majority of funding support coming from sources outside of the Region. To maintain the regional immunization gains that have been made, greater efforts are required to advocate for funding from within the European Region to support activities within the Region. Adequate funding support was provided specifically for polio outbreak response activities, but funding support for strengthening routine immunization services, although far more cost-effective than outbreak response, has not been so readily forthcoming.

Last year saw the first import-related outbreak of polio in the Region since regional certification of elimination in 2002, highlighting the ongoing challenges to maintaining poliofree status. Low levels of vaccine coverage in high risk populations led to the transmission of imported wild poliovirus in Tajikistan and spread into at least 4 other countries in the Region. Extensive multiple rounds supplementary immunization activities (SIAs) appear to have stopped virus transmission, as no new cases have been reported anywhere in the Region since September 2010. Analysis of responses to the polio outbreak should provide programmatic lessons for planning responses to any future outbreaks, exposing, for example, any bottlenecks in the detection, reporting or response processes. The outbreak has highlighted the problem of susceptible adult populations in several countries of the Region. These adult populations are likely to remain at risk of polio, and other vaccine-preventable diseases unless ways can be found to identify the susceptible target age groups and to provide them with vaccines.

Recent large measles outbreaks have occurred throughout the Region, involving different age-groups, and often starting in specific sub-populations. Measles outbreaks continue to be reported in 2011, particularly from western European countries. Under-reporting of measles, lack of data on suspected cases and inconsistent reporting of outbreaks continues to be a problem. Revised regional measles and rubella surveillance guidelines have now been developed and are being provided to all Member States. The Region has also seen large rubella outbreaks, particularly in central Europe. Many Member States have not yet adopted case-based reporting for rubella, and some western European countries are failing to report data. There is a need both for more active investigation and response to rubella outbreaks, and for molecular data on outbreak strains.

In response to the influenza A (H₁N₁) global pandemic more than 350 million doses of vaccine were distributed globally, of which over 50 million were administered in the European Region. The majority of countries in the Region implemented their immunization strategies in a step-wise, phased manner, starting with one or more target groups and then expanding. Available evidence suggests there was generally low vaccine coverage in the priority target groups in many countries. Reasons for low coverage included late delivery of vaccine, doubts over vaccine safety and the need for a vaccine, health care workers unconvinced of the need for a vaccine or doubting the vaccine efficacy, and lack of communications campaigns directed at specific target groups. Improvements in communications, information availability, education of health care workers and vaccine deployment mechanisms are needed. Member States require better advice on pandemic vaccine strategies and guidance on handling mass immunization campaigns and similar emergency responses before the next influenza pandemic strikes.

Many Member States continue to operate vaccine adverse event monitoring systems that were established in 1980s, developed to detect a small number of well-known adverse events. These systems are focussed on detecting programmatic errors, and almost all aggregate the data rather than provide case-based data. There is an urgent need to promote reform of monitoring systems at country level. Although national regulatory bodies have considerable power, many appear reluctant to push for reform, and several Member States appear to be resisting development of modern monitoring systems. It may now be appropriate to work with the pharmaceuticals regulators in persuading countries to adopt appropriate vaccine monitoring systems. Member States need to be aware that the modern immunization arena has a global impact and global interests, and no longer simply reflects national concerns over vaccinovigilance

The cost of immunization programmes are escalating, particularly with the addition of new vaccines, but the real level of financial support for programmes is either static or declining. The prices countries pay for vaccine varies considerably, especially when self procured, and many middle-income countries pay significantly above the standard UNICEF procurement price. Vaccine pricing is a complex and multidimensional issue, however, and Member States often require assistance in understanding and utilising available pricing information. Group procurement schemes, including UNICEF procurement, the PAHO revolving fund and the Gulf Cooperation Council, can reduce vaccine prices considerably through pooled procurement. In the past, Member States in the European Region have shown little interest in group procurement, but there should now be further exploration of methods for increasing access to vaccine pricing and procurement information, and an assessment of country requirements for, and interest in, group procurement arrangements.

All Member States have been recommended to form their own national immunization advisory groups (NITAGs) to develop national policies and strategies in immunization that are appropriate to national requirements. To date, 34 Member States in the Region have established NITAGs, and six Member States have *ad hoc* advisory bodies. Several activities in capacity development and training, information exchange and experience sharing have been conducted in the past year. There has been close collaboration with the Supporting Independent Immunization and Vaccine Advisory (SIVAC) initiative, which has established a NITAG resource centre and provides online training for strengthening the capacity of countries in the development of evidence-based decision making.

The VPI Strategic Plan 2011-2015 is finalized and will be shared with ETAGE for review. The Plan, intended for use by WHO Europe, describes the programmatic goals, priorities and strategic approaches and includes proposed indicators for monitoring progress in attaining set

goals. The Plan will be used as a guide for defining activities and developing strategic collaborations on VPI activities.

Introduction

The European Technical Advisory Group of Experts on Immunization (ETAGE) meets annually to review the progress of the Vaccine-preventable Diseases and Immunization Programme (VPI) towards the European Regional disease prevention goals. The 10th meeting of the ETAGE was conducted from 29 to 30 September 2009. The 11th meeting of the ETAGE was held at the WHO Regional Office for Europe, Copenhagen, on 17 and 18 March 2011.

Professor Pierre Van Damme chaired the meeting, Professor Christian Perronne was vice-chair, and Dr Ray Sanders was rapporteur.

Objectives of the meeting were to:

- Request guidance from ETAGE towards the regional goal of sustaining polio-free status in the European Region;
- Provide an update on the progress towards the 2015 measles and rubella elimination goal in the Region;
- Review lessons learned from the implementation of pandemic (H₁N₁) 2009 influenza vaccines and discuss the potential impact on immunization programmes and national policies;
- Provide information on immunization and vaccine financing by Member States and on strategies to improve financial sustainability of immunization programmes;
- Discuss vaccine adverse event monitoring systems across the Region and methods for strengthening systems and reporting;
- Review the objectives of the proposed regional cervical cancer prevention workshop in October 2011;
- Provide an update on activities to strengthen National Immunization Technical Advisory Groups (NITAGs) in the Region;
- Review the Strategic Advisory Group of Experts (SAGE) recommendations and the role of NITAGs in implementing SAGE recommendations:
- Provide updates from the Vaccine-preventable Diseases and Immunization Programme;
 and
- Discuss ETAGE meetings in 2011.

Opening remarks

Dr Nedret Emiroglu, Executive Manager, Division of Communicable Diseases, WHO Regional Office for Europe, welcomed ETAGE members, representatives of partner agencies and regional immunization initiatives, representatives of selected Member States, and staff from WHO Headquarters to the meeting. Dr Emirolu assured ETAGE of the WHO Regional Director's continuing support for immunization and the high priority she places on preventive health. The Region has experienced a number of new challenges in the past year, including the outbreak of polio in Tajikistan, but WHO remains committed to the control and reduction of vaccine-preventable diseases. In times of increasing constraints, the importance of

partnerships, both longstanding and new, is highlighted and the WHO Regional Office is actively promoting and strengthening working partnership agreements within the Region.

On behalf of the WHO Regional Director, Dr Emiroglu expressed sincere thanks and appreciation to Professor Paata Imnadze and Dr Dilbar Makhmudova for their service, expertise and dedication as outgoing members of ETAGE.

Professor Pierre Van Damme informed the meeting that terms of reference for ETAGE membership are currently under review and that new terms will be more closely aligned with those of SAGE members. New terms of reference for ETAGE members have been drafted and will be available for circulation and comment by mid-2011.

Report: Progress since the 10th ETAGE

Although the intention is for ETAGE to meet formally at least once every year, no meeting was held in 2010. This was in large part due to the additional workload place on VPI in responding to the polio outbreak in Tajikistan and providing support for deploying pandemic influenza vaccine. Despite the lack of a formal meeting, the Secretariat maintained close working communications with ETAGE and held teleconferences with the ETAGE Chair and Vice-chair.

Of the recommendation made during the 10th meeting of ETAGE, all have been addressed to some extent. A proposed high-prolife meeting with partners to address the immunization funding gap did not take place, but existing partners, and potential new partners, were included in European Immunization Week (EIW) activities. The Secretariat has also continued to engage WHO Collaborating Centres and other technical institutions in providing technical support in facilitating and conducting activities within the Region.

A working group has been established with the European Centre for Disease Control and Prevention (ECDC) to develop a platform for sharing data among the two institutions. Discussions have not yet formally included representatives from Member States or WHO HO.

Significant progress has been made in establishing and strengthening NITAGs. Progress has also been made in revising the VPI Regional Strategic Plan and the final draft will be made available for further comment from ETAGE. Recognising that the 2010 target for measles and rubella elimination would not be met, the target date has been revised and the Secretariat has been working closely with Member States on improving surveillance and delivering vaccines to underserved groups. Criteria for validation of regional measles and rubella elimination have also been developed, with increased focus on the requirement for laboratory-based confirmation of cases.

Administrative restructuring of the WHO Regional Office for Europe has placed VPI within the Division of Communicable Diseases, Health Security and Environment. Recent changes have also resulted in the welcome addition of four additional staff members to VPI, greatly increasing the technical capacity of VPI in supporting Member States. The changes also bring surveillance and laboratory teams back into the programme, facilitating easier information exchange and collaboration, and have reduced the number of administrative layers between the programme and the Regional Director.

Discussion:

ETAGE recognizes and appreciates the effective and professional manner in which the WHO Europe Secretariat and Member States have worked together in responding rapidly to the

outbreak of polio imported into Tajikistan and spread to neighbouring countries. The group also appreciates that the majority of recommendations made at its 10th meeting have been implemented or are in process. Recent experience has demonstrated, however, that improvements are required in the ease with which information is exchanged between the Regional Office and ETAGE. Designation of a nominated ETAGE focal point within VPI would improve timely communications.

Recent experience also suggests that ETAGE meetings should be planned well in advance, as occurs with SAGE meetings. It would be optimal to hold the ETAGE meeting during a fixed week each year, and the first week of October has been proposed as a suitable week, as this corresponds well with the fixed meetings of SAGE. Although there may be advantages to hosting combined ETAGE and national EPI managers' meetings, experience suggests that smaller, sub-region specific meetings for national EPI managers are far more effective. For the foreseeable future ETAGE and EPI managers' meetings will be held separately.

Discussions with WHO HQ on collaboration to develop immunization curricula for pre- and in-service training of healthcare workers will begin in May 2011. The difficulties of establishing generic training curricula appropriate for all countries are recognised, and the requirement for careful allocation of scarce technical resources appreciated. The need to have well-educated and well-informed vaccinators at all levels is now more apparent than ever, and working directly with Member States to improve training standards will continue.

Vaccinology is a rapidly-evolving field, and it may be more appropriate to long-term needs to adopt a modular approach to training, with the development of specific training courses that could be applied locally and a lower cost. ECDC is developing course material in vaccinology and will be interested in distributing this material in future. Good examples of training curricula do exist within the Region, and standardisation of training may be achieved through pairing of institutions from different Member States. It has become clear that improving immunization-related training in the Region is an urgent but complex issue, and a comprehensive overview of needs and goals is required. As this activity is not currently funded within the WHO programme of work, a collaborative approach will be required.

Resource allocation for immunization in the Region remains insufficient, particularly for outbreak response. The majority of funding support for VPI continues to come from outside of the Region, notably from the United States. This has been an on-going problem and attempts to interest funding partners within the Region have not yet been particularly successful. Funding support was provided specifically for polio outbreak response activities, and all affected Member States have conducted appropriate responses, including supplementary immunization activities (SIAs). Further attempts to persuade funding partners, including the Word Bank, are urgently needed to support routine immunization activities in the Region.

Session 1: Global Polio Eradication Initiative

Last year saw the first import-related outbreak of polio in the Region since regional certification of elimination in 2002, highlighting the challenges to maintaining polio-free status. Most countries have maintained ≥95% vaccine coverage, but there are low-coverage pockets in all countries. This has been accompanied by a slow decline in acute flaccid paralysis (AFP) surveillance quality. The first of 457 confirmed wild poliovirus type 1 cases in Tajikistan occurred in January 2010, with the number of cases peaking in May 2010. No new cases have been reported in the country since July 2010. Additional cases were detected in the Russian Federation (14 cases), Turkmenistan (3) and Kazakhstan (1), and a large

increase in the number of AFP cases (147 cases) reported in Uzbekistan. Although no laboratory-confirmed cases were detected in Uzbekistan, the increased number of AFP cases and evidence of importation of wild virus into Russian Federation from Uzbekistan strongly supports the supposition that polio cases also occurred in Uzbekistan. Data from cases detected in the North Caucuses region of the Russian Federation provide evidence for independent circulation of imported polioviruses in under-immunized population groups.

Epidemiological analysis of confirmed cases shows that the age distribution of cases is different in countries, suggesting different immunization profiles between countries. In Tajikistan most confirmed cases (68%) were less than 6 years of age, suggesting a reduction in routine childhood immunization services. In response to the outbreak 20 large-scale immunization activities have been conducted, with more than 45 million doses of polio vaccine distributed during independently monitored activities.

Improvements in AFP surveillance in the affected countries have been seen in the second half of 2010 and in 2011 to date, but the non-polio AFP reporting rate has remained relatively low in the Russian Federation and Uzbekistan. Field visits have been conducted to assess AFP surveillance systems in several Member States, the overall conclusion being that AFP surveillance systems are sensitive enough to detect polio, but problems continue with case-confirmation in some countries. Transportation of stool samples to the regional reference laboratories continues to present problems and cause delays in confirmation of cases.

Synchronised rounds of supplementary immunization activities (SIAs) will be conducted in the affected countries during April and May, and the Russian Federation will conduct an SIA in the Northern Caucuses at the end of March and end of April 2011. At its meeting in January 2011 the European Regional Certification Commission of Poliomyelitis Eradication (RCC) concluded there was no evidence for continued polio virus transmission in the Region, but that all affected countries must provide documented evidence that transmission has ceased.

The molecular epidemiology of poliovirus isolates demonstrates that the origin of the outbreak virus introduced and spread through Tajikistan and neighbouring countries was Uttar Pradesh, Northern India. Genomic sequencing data suggest time of introduction of the virus was late 2009 or early 2010, with strong evidence for a single introduction event. The modest level of evolution seen in the viral isolates suggests that little time was allowed for spread and the outbreak was contained fairly rapidly.

The quality of routine surveillance for polio and AFP varies widely across Region, and has shown a decline in many areas in recent years. Several Member States do not conduct AFP surveillance, and of those that do, several fail to reach the non-polio AFP target of 1 per 100,000 under 15 years of age. Recognising the decline in AFP surveillance, the RCC called for ensuring certification level poliovirus supplementary surveillance. Enterovirus surveillance is currently conducted in 39 Member States in the Region, providing limited, but potentially useful information relevant to polio surveillance. Within the Region as a whole there is clearly a need to refocus attention on the requirement for high quality AFP surveillance. Where maintaining adequate AFP surveillance is not possible there is a need to review the possible impact of ceasing AFP surveillance and strengthening supplementary and alternative surveillance methods. A significant amount of data on supplementary and alternative surveillance exists, and should be reviewed to determine best practices and the core data required for polio surveillance purposes.

Discussion:

Analysis of responses to the polio outbreak should provide programmatic lessons for planning responses to any future outbreaks, exposing, for example, any bottle-necks in the detection, reporting or response processes. All Member States are required to have developed preparedness plans for possible polio outbreaks, but conducting preparedness evaluation exercises and outbreak response testing would benefit many Member States. Problem areas highlighted in the recent outbreak include delays in providing official notification caused by internal administrative issues and national requirements to withhold information, and inaccurate immunization records in some countries.

Nearly 30% of confirmed polio cases detected in Tajikistan were aged greater than 6 years. Other Member States also reported a significant proportion of the cases among adults. The outbreak highlighted the problem of susceptible adult populations in several countries of eastern Europe, often associated with a temporary breakdown of immunization services following the breakup of the Soviet Union. These susceptible adult populations are likely to remain at risk of polio, and other vaccine-preventable diseases unless ways can be found to identify the susceptible target age groups and to provide them with vaccines.

Polio is no longer a priority for many EU Member States. The recent outbreak has provided a timely reminder that polio remains a threat, but is likely to regain attention only temporarily. While international support for responding to the outbreak was forthcoming, the level of support provided for strengthening routine immunization remains low. The level of funding provided to rapidly contain the polio outbreak could have been far more effectively spent in long-term development of routine immunization systems in the polio affected countries. A change is required in the international mindset to move away from reactive provision of support for outbreak control (not economically attractive) to proactive provision of support for routine immunization (highly economically attractive).

Verification and validation of vaccine coverage assessments remains a significant problem. There is often a significant gap between officially provided figures and independent assessments. The most reliable way to determine true vaccine coverage is to conduct house-to-house coverage surveys. Even when national figures can be validated; underperforming local areas can also be a major problem. These problem areas or groups can sometimes be highlighted through carefully planned serosurveys.

Use of serosurveys remains a problem, however, as guaranteeing non-biased, representative sampling is very difficult in many situations. Even with specific targeting of recognised atrisk groups it is often difficult to include immunization under-served populations in serosurvey activities. One simple way to establish a broadly representative serosurvey is to make use of residual serum from hospitalized children. This has been used successfully in Australia to validate national coverage figures. One difficulty with this method is capturing information of ethnicity or minority status, but this can be addressed through over-representing known at-risk groups in the sample. A considerable amount of information on vaccine coverage assessments and population protection already exists and Member States should be encouraged to share their information and work with WHO and international partners to develop a collaborative research programme in this area.

Session 2: Regional measles and rubella elimination goal

Recognising that the regional target date for measles and rubella elimination of 2010 would not be met the European Regional Committee resolved to accelerate measles and rubella elimination activities and set a new goal for regional elimination by 2015. The Regional Page 8

Office is now working with Member States on accelerating efforts to provide vaccines to vulnerable groups and hard-to-reach populations. The need for accelerated and focused activities has been underscored by the increase in reported measles cases in 2010, with continuing measles endemicity in several western European countries. Recent measles outbreaks have occurred throughout the Region, involving different age-groups, and starting in specific sub-populations. Although different situations have been recorded in different countries, many outbreaks have involved recognized under-immunized populations.

High measles case numbers continue to be reported in 2011, even though problems remain with non-reporting, under-reporting and lack of data on suspected cases. Reporting of outbreaks is also a problem, with a need to improve the reporting form for measles outbreaks to encourage Member States to report. Revised Regional measles and rubella surveillance guidelines have now been developed and are being provided to all Member States in the Region.

The Region has also seen large rubella outbreaks, particularly in central Europe. Many Member States have not yet adopted case-based reporting for rubella, and some western European countries are failing to report data. There is a need both for more active investigation and response to outbreaks, and for molecular data on outbreak strains. The Regional Office is planning to develop guidelines for outbreak response. It is intended that a shared WHO Europe and ECDC reporting platform will be established by September 2011, involving ECDC TESSy (see recommendations 10th ETAGE meeting 2009). Reporting on congenital rubella syndrome (CRS) remains poor throughout the Region.

The Regional Measles and Rubella Laboratory Network now includes 71 laboratories, with a global specialized laboratory at the Health Protection Agency, United Kingdom and three regional reference laboratories. Performance, timeliness and completeness indictors continue to show a steady improvement to target levels. The laboratories are now often the first source of information on an outbreak, but some Member States continue to restrict surveillance data exchange and reporting. There remains a need to improve data quality and strengthen the link between epidemiological and laboratory data. Although improving, reported laboratory information is not yet fully representative of the Region as a whole. Information exchange within the laboratory network is now very good, but information is often not shared at national level. A solution to this problem is to have a single national focal point for reporting all data through a standard system. Laboratories continue to struggle with insufficient funding, with lack of state funding in many countries. Although the Regional Office receives funding support from US CDC for network coordination, additional funding from European partners is urgently needed.

With the new regional resolution for elimination of measles and rubella by 2015, criteria for the verification of eradication are now being finalised and a measles and rubella regional verification commission (MRRVC) is being established. All Member States should have a national measles and rubella elimination plan in accordance with regional strategy, and have established national verification committees. The first meeting of the MRRVC is planned for November 2011.

The requirement to establish and maintain high-level political commitment from Member States, together with adequate allocation of resources in the face of many competing demands, remains a major undertaking. The WHO Regional Director has been active in promoting immunization and in contacting Member States directly. Attempts to further develop a multi-sectoral approach to advocacy, through the EIW and direct contact with professional associations and civil society, are ongoing.

The EIW has proven its use as an awareness-raising tool, celebrating the achievements of immunization in the Region, and providing a feed-back mechanism for the sharing of plans, experiences and best practices between Member States. It has had limited success in addressing issues around vaccine demand and reaching susceptible populations. It is clear that to address these issues traditional communications strategies must change. There is a need to review and map the enabling factors, including opportunity, ability and motivational factors. There is also a need to improve data management and administration of immunization practices at immunization stations, possibly through innovative use of new communications tools.

To address communications issues, WHO Europe is developing a toolkit that would allow Member States to address immunization services communications and information response issues in a systematic manner. A WHO vaccines communications working group has been formed, and has conducted two meetings to date. A VPI communications strategy is in development and will be available in July 2011. It would be advantageous to have an ETAGE member participate in the WHO vaccines communications working group meetings.

Discussion:

To improve the standard of media coverage of immunization-related issues there is a need to cultivate working relationships with the media as standard practice, not only at times of crisis. Immunization services also need to have a higher on-line visibility. Effective collaboration with the media requires a pool of reputable 'spokespersons' available to brief the media as required. This can be very labour intensive and intrusive and finding appropriate experts may prove to be difficult.

Session 3: Implementation of vaccine for pandemic (H₁N₁) 2009 influenza

Objectives of the Vaccine European New Integrated Collaboration Effort (VENICE) survey on pandemic influenza $A(H_1N_1)$ 2009 vaccination, were to describe pandemic vaccination policies, identify country specific vaccine recommendations, estimate vaccine coverage and describe management of national programmes. This was a cross-sectional survey using an online questionnaire developed by the VENICE collaboration for ECDC, but was shared with WHO Europe where it was administered to all national immunization programme managers. Forty-eight of 53 Member States responded to the survey, 45 reported having a pandemic vaccination plan and 41 implemented a vaccination plan.

In implementing their vaccination programs, the majority of countries did so in a step-wise, phased manner, starting with one or more target groups and then expanding delivery of vaccine. Health care-workers and persons with chronic underlying medical conditions were the groups most often included as the first priority, followed by pregnant women. Available evidence suggests there was generally low vaccine coverage in the target groups in many countries. Reasons for low coverage included late delivery of vaccine, doubts over vaccine safety and the need for a vaccine, health care workers unconvinced of need for the vaccine or doubting vaccine efficacy, and lack of communications campaigns directed at specific target groups.

More than 350 million doses of vaccine were given globally, with over 30 different vaccines licensed. In the Region, over 50 million doses of pandemic influenza $A(H_1N_1)$ 2009 vaccines were administered. Vaccines were provided in several different formulations, which tended to add to public mistrust and political controversy. The regulatory pathways used to license the vaccines were also questioned, and scepticism voiced over the need for rapid licensing

strategies using limited clinical trials. In fact, licensing of seasonal influenza vaccines is usually a rapid process. Regulation of seasonal influenza vaccines is regarded very differently to regulation of other vaccines, due to the constant high rate of evolution of influenza, and a long-standing mechanism for the licensing of new influenza vaccines every year has existed for many years.

In several Member States, decisions on vaccine deployment appeared to have been made in haste, based on limited evidence and with little flexibility for modification. Initial target groups were prioritised without the capacity to reprioritise as the pandemic evolved, and decisions were made without adequate communication on how and why policies were being made or changed. In many countries inadequate attention was paid to providing appropriate information to health care workers, many of whom were sceptical of the need for, or indeed the safety of, the vaccines provided.

Discussion:

Improvements in communications and vaccine deployment mechanisms are needed before the next influenza pandemic strikes. Member States require better advice on pandemic vaccine strategies and guidance on handling mass immunization campaigns and similar emergency responses. Experience has demonstrated a gap between official forecasts of emergency situations and the reality of unfolding events, with obvious difficulties experienced in communicating ideas of uncertainty. In several countries this has led to a loss of credibility and mistrust of health authorities. There needs to be far greater flexibility within the system, allowing authorities to modify targets and priorities, but this requires more effective tracking and monitoring systems.

On the whole health authorities were very slow to communicate to the media, and the general population, reasons for their choice of vaccine target groups and of vaccines. In many instances healthcare workers were overlooked in national communications strategies, with the result that many did not understand the pandemic responses or reasons why those responses were selected. There is a need for more research on the best ways to convey information and knowledge, to healthcare workers (and their professional associations), to the media and to the public, preferable on an on-going basis. There is also an urgent need to ensure that Member States regard communications as an integral part of immunization services, rather than as an theoretical concept.

Session 4: Enhancing vaccine adverse event monitoring systems and response in the Region

Many Member States continue to operate vaccine adverse event monitoring systems that were established in 1980s, developed to detect a small number of well-known adverse events. These systems are focussed on detecting programmatic errors, and almost all aggregate the data. There is now a need to move to electronic databases with case-based reporting, and move from detecting known events to surveillance for unexpected events. It is also time to include non-EPI vaccines, such as influenza, and move away from a system where only vaccinators log reports of adverse events to a broad-based system where all healthcare workers can report. Post-marketing surveillance is an essential component of immunization, as is establishment of some form of national health registry. Member States should be made aware that the modern immunization arena has a global impact and interests, and no longer simply reflects national concerns over vaccine safety.

Discussion:

There is an urgent need to promote reform of monitoring systems at country level. Although national regulatory bodies have considerable power, many appear reluctant to push for reform, and several Member States appear to be resisting development of modern vaccine monitoring systems. It may now be appropriate to work with the pharmaceuticals regulators to persuade countries to adopt appropriate vaccine monitoring systems.

Several western European countries have established health registries with extensive electronic databases. Experience gained suggests these systems can be expensive to maintain and complicated to use effectively as it is possible to generate a high level of incidental information that may obscure real events. In a highly immunized population it may also be difficult to separate causal relationships from coincidental events. The system used in the United Kingdom permits consumers to report events, but the data is often not open to interpretation. There is a need to move towards a concept that monitoring systems should be detecting rare serious adverse events, rather than common mild events. It will also be necessary to change immunization communications policy to present the very low risk of adverse events following immunization in perspective with the much higher risks associated with acquiring infections and the significantly higher risks faced in every-day living that are commonly deemed acceptable.

This is a complex area that requires significant input and demands time and resources from WHO Europe, and another area of responsibility that is underfunded.

Session 5: Vaccine financing options and solutions in the Region

The cost of immunization programmes are escalating, particularly with the addition of new vaccines. The WHO/UNICEF Joint Reporting Form (JRF), which collects data on immunization budgets, shows that although many Member States now have a line item for immunization in the national budget, the percentage of national expenditure on routine vaccines financed by the government remain very low in many low income countries. In some Member States the existing financing indicators provide evidence for only a notional increase in national financing of immunization. There is an urgent need for a review of vaccine financing in non-GAVI countries, particularly lower-middle and middle-income countries, if vaccine stock-outs and breakdown of routine immunization services is to be avoided.

Eight countries in the European Region are currently eligible to receive support from the GAVI Alliance for introduction of new and underused vaccines (Armenia, Azerbaijan, Georgia, Kyrgyzstan, the Republic of Moldova, Tajikistan, Ukraine and Uzbekistan). Five of these (Armenia, Azerbaijan, Georgia, Republic of Moldova, and Ukraine) graduated from GAVI support in 2011, and from 2012 the co-financing component with GAVI will consume a considerable and increasing proportion of their routine immunization budget. Some of these Member States will not be capable of absorbing this increase, and there is already evidence of a decline in immunization activities. This development also has a significant impact on overall government health expenditures, and is likely to result in a decrease in immunization activity expenditure, with funding decisions being made on political rather than technical grounds.

Adding new vaccines to childhood immunization programmes raises the average vaccine cost per child from around US\$18 to around US\$30, a major reason for the slow uptake of new vaccines in middle-income countries. Vaccine prices vary considerable, however, especially when self procured, and many middle-income countries pay above the standard UNICEF Page 12

procurement price. Vaccine pricing is a complex and multidimensional issue, and Member States often require assistance in understanding and utilising available pricing information. UNICEF and the Pan American Health Organization (PAHO) are taking steps to make information more widely available and more transparent for end-users.

There are successful examples of group procurement schemes, including UNICEF procurement, the PAHO revolving fund and the Gulf Cooperation Council, which can reduce vaccine prices through pooled procurement. Use of these schemes strengthen the negotiating position of countries, can make vaccine procurement less complex for countries, and allow greater reliability of supply. But use of these schemes may generate long-term dependence on an external body, and Member States in the European Region have shown little interest in the past. There needs to be further exploration of methods for increasing access to vaccine pricing and procurement information, within the Region, and an assessment of country requirements for, and potential interest in, group procurement arrangements.

Discussion:

Information on vaccine price is an essential planning element for countries, but pricing information is not readily made available by producers and distributors. This is compounded by many producers packaging other services together with vaccine provision, so the true price of the vaccine is obscured.

Pooled procurement does occur within the Region, provided by UNICEF, but many Member States fail to take advantage of procurement by UNICEF. It is important to understand why some Member States fail to take advantage of this scheme, which would almost certainly provide them with less costly vaccines. It may also be helpful to compare the advantages and disadvantages of the UNICEF scheme and the PAHO revolving fund. The recommended retail price of most vaccines is accessible, and UNICEF posts annual price projections, but these represent the two extremes in price and it is difficult for Member States to appreciate what is a reasonable price to pay.

There is a general lack of vaccine price negotiation skills in many middle income countries, and without a detailed knowledge of the market and experience in negotiating the best prices; they often pay higher prices for their vaccines. Opportunities for partnering richer countries with lower-income countries to procure vaccine should be explored as well. The area of vaccine pricing and procurement is clearly very important in the Region, and would benefit from an ETAGE working group investigating the issues and reporting back to a future meeting.

Session 6: Update on NITAGs

Operating processes and membership of the Strategic Advisory Group of Experts on immunization (SAGE) have recently been updated with nomination of a new chairperson and new members. There is now more emphasis on the establishment of formal working groups, with a code of conduct and strict policy for declaration of interests for members. Quotas have been set for industry attendance at meetings and guidelines developed for evidence-based review. Formal requirements for SAGE members are being used to update the terms of reference and guidelines for ETAGE members. There continue to be strong links between the SAGE and ETAGE, with information sharing and inter-meeting collaboration.

All Member States have been recommended to form their own national immunization technical advisory groups (NITAGs) to develop national policies and strategies in immunization that are appropriate to national requirements. To date, 34 Member States in the

Region have established NITAGs, and six Member States have *ad hoc* advisory bodies. Supporting countries to develop NITAGs is a significant area of work for WHO Europe and several activities in capacity development and training, information exchange and experience sharing have been conducted. There has been close collaboration with the Supporting Independent Immunization and Vaccine Advisory (SIVAC) initiative, which has established a NITAG resource centre and provides online training in strengthening the capacity of countries in the development of evidence-based decision making. As with other immunization areas of activity, this function remains underfunded.

Discussion:

Western European countries with developed NITAGs and advisory bodies would be interested in participating in NITAG training activities, but funding such participation is an issue that needs to be addressed. WHO Europe could look at the possibilities of finding support for cross-border sharing of expertise, for countries where the number of appropriate experts is limited. SIVAC has developed the web-based NITAG resource exchange centre and can provide support to help train experts in these countries. The Robert Koch Institute in Berlin also supports development of methodologies for developing a framework for evidence-based decision making for immunization services and will be holding its next meeting in April 2011. WHO Europe should be a participant in this meeting. There are also limited funds held by WHO HQ supporting inter-group development.

Session 7: Regional meeting on cervical cancer prevention

The scope and effectiveness of screening programmes for cervical cancer vary widely within the Region, from high-coverage public screening programmes to opportunistic screening in private clinics. Reported rates of cervical cancer also vary widely. The Regional cervical cancer prevention meeting in 2007 recommended strengthening actions to consolidate cervical cancer control in the Region, appointing a leading body responsible for cervical cancer prevention, and an assessment of the introduction of human papilloma virus (HPV) vaccine. HPV vaccine has now been introduced in 20 Member States, predominantly in western Europe, but vaccine coverage rates have been variable, from over 80% in Portugal and the United Kingdom to less than 40% in France and Germany.

Given the activities of the past four years it is time to hold another meeting on cervical cancer control, to review national policies and programmes for introducing HPV vaccines and organized screening, and define regional priorities for future actions. Cervical cancer prevention involves a broad range of WHO Europe programmes at both regional and global level and there is an increasing need to coordinate programmes, both in terms of activities conducted and obtaining support from international partners.

Discussion:

While there is a clear need for coordination of programmes on cervical cancer prevention, there is little funding identified to hold a meeting. However, the European Regional Director has made it a priority and funding will be sought to hold this meeting in 2011.

Session 8: Updates in Vaccine Preventable Diseases and Immunization

The VPI Strategic Plan 2011-2015 is now finalized and will be shared with ETAGE for review. The Plan is intended for use by WHO Europe and describes the programmatic goals, priorities and strategic approaches. It also includes proposed indicators for monitoring Page 14

progress in attaining set goals. The Plan will be used as a guide for defining activities during the 2012-2013 biennium and for developing strategic collaborations on VPI activities.

The newly announced Decade of Vaccines initiative (DoV) will provide an opportunity for further efforts in the effective delivery of vaccines. The aims of the DoV include:

- establishing and sustaining broad public and political support for vaccines and financing of immunization services;
- strengthening the equitable delivery of immunization services to achieve universal coverage of safe and effective vaccines by 2020 in order to prevent, control, eliminate or eradicate vaccine-preventable diseases;
- cultivating a robust scientific enterprise to produce innovation in the discovery and development of new and improved vaccines and associated technologies, and;
- creating the right market incentives to ensure an adequate and reliable supply of affordable vaccines.

A Global Vaccine Action Plan is currently being developed and will be presented at the World Health Assembly 2012 meeting. The WHO European Regional Office will work with WHO Headquarters to ensure that the Decade of Vaccines has significance for all countries in the European Region.

Discussion:

At its meetings over the past several years ETAGE has made many recommendations, particularly on strengthening immunization services and on collaborative partnerships for funding and guiding immunization programmes. To avoid repeating recommendations and to aid ETAGE members, particularly new members, it would be helpful to compose a list of all past ETAGE recommendations and provide them to current ETAGE members.

Conclusions and recommendations

Conclusions:

- ETAGE recognizes and appreciates the effective and professional manner in which the WHO Europe Secretariat and Member States worked together to respond rapidly to the polio outbreak. Despite the additional workload resulting from responding to the polio outbreak and support in deploying pandemic influenza vaccine, the majority of recommendations made at its 10th meeting have been implemented or are in process. It notes, however, that improvements are required in the ease with which information is exchanged between WHO and the ETAGE. Designation of a nominated ETAGE focal point within VPI would improve timely communications.
- ETAGE appreciates the restructuring of the Regional Office that has permitted full staffing of VPI, but notes that immunization in the WHO European Region remain grossly underfunded. The majority of funding support for immunization still comes from sources outside of the Region, while funding agencies from within the Region continue to support activities in other regions. To maintain the regional immunization gains that have been made, greater efforts are required to persuade funding agencies from within the Region and Member States to support activities within this Region.

- Vaccine coverage estimates continue to present problems to the programme, and
 potentially obscure the presence of large susceptible populations. A systematic
 approach to verification/validation of reported coverage levels is urgently needed.
 While serosurveys have a role to play in determining population susceptibility to
 infectious diseases, great care and attention to detail are required in their planning and
 interpretation. Greater technical guidance on the planning, implementation and
 interpretation of serosurveys is required before Member States invest time and
 resources on large-scale seroepidemiological studies.
- Recent experience gained in responding to the polio outbreak may provide
 programmatic lessons in determining potential bottle-necks in outbreak detection and
 response to vaccine preventable diseases in general. The Regional Certification
 Commission requires that all Member States develop and maintain outbreak
 preparedness plans, but recent experience may have highlighted omissions or
 inadequacies in those plans. Regular evaluation and validation of these plans is
 needed.
- ETAGE appreciates the update and summary of SAGE activities and recent discussions, and strongly endorses the requirement to maintain the strong working relationship between SAGE and ETAGE.
- Experience gained from European Immunization Week activities and responding to
 the influenza pandemic has underlined the importance of effective communication
 strategies in advocacy, and implementation of, immunization services.
 Communications must be regarded, and funded, as a core component of modern
 immunization services and Member States that fail to recognise this, and fail to build
 national capacity in communications, place their immunization gains at risk.
- According to the new GAVI eligibility criteria, five countries in the Region graduated in 2011 and will no longer be eligible for full GAVI support. They will be expected to fund an increasing proportion of their vaccine procurement costs for new and underused vaccines at a time when many Member States are experiencing economic contraction in public service budgets. ETAGE notes with concern that withdrawal of GAVI support threatens to compromise the introduction of new vaccines as a composite part of an integrated approach to prevention and control of childhood infections in these countries.
- ETAGE appreciates the revision and imminent publication of the VPI Strategic Plan 2011-2015.
- ETAGE is encouraged by the development of NITAGs within the Region, and acknowledges the high level of commitment shown by WHO Europe and its partners in developing these groups. Further work is required and ETAGE urges WHO to continue with its support for this endeavour. The Group also appreciates the NITAG

resource centre provided through the SIVAC initiative and encourages all Member States to participate fully in this initiative.

Recommendations:

- 1. The continued importance of polio to Member States should be re-emphasised, and the possibility of losing regional polio-free status made clear to all. Mechanisms should be sought for WHO Europe to enlist support from ECDC in promoting continued regional vigilance and protection against polio.
- 2. ETAGE recommends WHO Europe to urge Member States that no longer have effective AFP surveillance to strengthen their supplementary and alternative surveillance systems to ensure they operate at certification standard levels. There is a need to review detailed available data from supplementary and alternative surveillance systems to understand what is available and determine the core data required for polio surveillance purposes.
- 3. ETAGE recommends that WHO Europe encourages Member States to share and improve the use of existing data on vaccine coverage and levels of population protection, and collaborate with WHO in developing additional studies.
- 4. ETAGE recommends the development of an ETAGE working group to review available information on age-stratification of polio-, measles- and rubella-positive cases in recent outbreak countries to determine if there is a problem with susceptible adults and provide guidelines to all Member States for reducing the size of susceptible adult populations.
- 5. ETAGE urges that Member States be encouraged to review their measles and rubella case and laboratory reporting systems and ensure that there is consistency of reporting, moving towards a single, combined epidemiological and laboratory data reporting mechanism at national level.
- 6. ETAGE recommends that an ETAGE working group be established with appropriate terms of reference to investigate current vaccine pricing systems, communication of vaccine pricing issues to Member States, and mechanisms to develop the skills required for Member States to more successfully negotiate vaccine procurement prices. The ETAGE Working Group should also investigate the underlying factors that allow or prevent Member States benefitting from group vaccine procurement systems (e.g. UNICEF, revolving funds).
- 7. ETAGE recommends that to provide better insight into public perceptions of, and confidence in, vaccines, an individual with a background and expertise in the social sciences be an ETAGE member.

- 8. ETAGE recommends that WHO Europe encourage and support Member States in reviewing the functional capacity of their vaccine post-marketing surveillance systems and adapt them to meet current vaccine quality and safety issues. WHO should consider providing advice and technical support to Member States for reviewing and possibly realigning the national roles, responsibilities and resources for vaccine post-marketing surveillance.
- 9. ETAGE urges that WHO continue supporting the development of NITAGs, including support for the partnering of Member States with well-developed advisory bodies with Member States having recently established NITAGs.
- 10. ETAGE requests the WHO Regional Office to work with WHO Headquarters to ensure that the Decade of Vaccines has significance for all Member States in the Region.
- 11. ETAGE requests VPI to collate all ETAGE recommendations made during this and previous meetings of ETAGE to provide a comprehensive list to serve as a reference for new ETAGE members.

Proposed list of activities, responsibilities and timeframe:

Activity	Responsibility	Timeframe
Nomination of a VPI Programme focal point for communication with ETAGE	WHO Europe (VPI)	End of May 2011
Finalization of VPI Strategic Plan 2011-2015 and	WHO Europe and ETAGE	Circulate and collect comments by mid-May 2011
presentation to ETAGE members for review		Finalized and endorsed by ETAGE by end of June 2011
Plan the next ETAGE meeting the first week of Oct 2012	WHO Europe and ETAGE	Inform ETAGE members by end of June 2011
Hold teleconference		September 2011
Finalize draft terms of reference and codes of conduct for ETAGE members and circulate for comment	WHO Europe and ETAGE	Draft circulated and all comments received by June 2011
Finalize and accept new terms of reference		Finalized by end of June 2011
Develop a collaborative approach on vaccinology training curricula	WHO Europe and WHO HQ	Discussions to begin May 2011
Increase proportion of funding support for immunization from sources within the Region Liaise with western European countries andWorld Bank – discuss with MOH and ministries of development cooperation	WHO Europe (RDO)	Remainder of 2011

WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR EUROPE

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WELTGESUNDHEITSORGANISATION ВСЕМИРНАЯ ОРГАНИЗАЦИЯ З

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ **ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО**

ORGANISATION MONDIALE DE LA SANTÉ

BUREAU RÉGIONAL DE L'EUROPE

Dr Nino Khetsuriani

US CDC

11th Meeting of the European Technical Advisory Group of Experts for Immunization (ETAGE)

17-18 March 2011 18 March 2011

Copenhagen, Denmark Conference Hall 2

PROGRAMME

Thursday, 17 March

Reception desk 08:30-09:00 Registration Prof Pierre Van Damme 09:00-09:30 **Opening remarks** ETAGE Chairperson, Dr Nedret Emiroglu **Executive Manager** Division of Communicable Diseases WHO Europe Dr Rebecca Martin 09:30-10:30 **Progress since 10th ETAGE** WHO Europe 10:30-11:00 Coffee break 11:00-12:30 **Session 1: Global Polio Eradication Initiative:** Dr Sergei Deshevoi *Issues for ETAGE:* Dr Eugene Gavrilin Update on polio outbreak in the Region WHO Europe ➤ Certification level surveillance in Western European countries Review of age cohorts for supplementation immunization activities

Technical	Section 1	l: (continued)	
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	Technical Session 1. (continueu)	
13:30-14:00	- Discussion	
14:00-15:30	Session 2: Regional measles and rubella elimination goal	Dr Rebecca Martin
	Issues for ETAGE:	
	Update on progress to goal	Dr Dragan Jankovic/
	 WHO Regional Office role in outbreaks Strategies to address vaccine demand and reaching susceptible populations 	Dr Mick Mulders
	Collaboration and coordination with ECDC	Mr Robb Butler
		WHO Europe
15:30-16:00	Coffee break	
16:00-16:30	Discussion from Sessions 1 & 2	
		ETTA CE 10
16:30-17:30	Private session - ETAGE	ETAGE and Secretariat
		All

Friday, 18 March

09:45-10:30

19:00-21:00 Dinner at Club Royal

08:30-9:45 Session 3: Implementation of vaccine for pandemic (H1N1) 2009 influenza:

Issues for ETAGE:

ues.	JOI ETAGE.	Dr Dina Pfeifer
	Lessons learned	Di Dina i lenei
\triangleright	Monitoring impact on national immunization programmes	Mr Robb Butler
	National policies and guidance in emergency responses	Dr Annemarie Wasley
	Collaboration and coordination with ECDC	

WHO Europe

Session 4: Enhancing vaccine adverse event monitoring systems and response in the Region

Issue for ETAGE: SAGE* Member

> Removing obstacles to AEFI surveillance

➤ Minimal requirements for AEFI surveillance systems

Dr Dina Pfeifer WHO Europe

Prof Juhani Eskola

^{*} Strategic Advisory Group of Experts on Immunization

10:30-11:00	Coffee break	
11:00-12:00	Session 5: Status of immunization financing in the Region Issues for ETAGE: Support to GAVI graduating countries Guidance to WHO on support for procurement	
		Dr Niyazi Cakmak
	- Immunization financing in the Region	Da Olas Danas
	- Current status of GAVI graduating countries	Dr Oleg Benes
12:00-13:30	- Vaccine procurement mechanisms	WHO Europe
12.00-15.50	Lunch	
13:30 -14:00	Update on SAGE and its recommendations in 2010	Dr Philippe Duclos WHO Headquarters
14:00-15:00	Session 6: Update on NITAGs ⁺	Dr Liudmila Mosina
	- Update on NITAGs in the WHO European Region	WHO Europe
	- SIVAC ^ε Resource & Training Centre	•
		Dr Kamel Senouci
		SIVAC Initiative/AMP
15:00-15:30	Session 7: Regional meeting on cervical cancer prevention	Dr Liudmila Mosina WHO Europe
15:30-16:00	Coffee	
16:00-16:30	Session 8: Updates in Vaccine Preventable Diseases & Immunization - VPI Strategic Plan 2012-2016 - EIW 2011 - Decade of Vaccines	Dr Rebecca Martin WHO Europe
	- Discussion	
16:30-17:15	Conclusions and recommendations	Dr Ray Sanders
	Closing remarks	Rapporteur

⁺ NITAGs - National Immunization Technical Advisory Groups

ETAGE Chairperson

 $^{^\}epsilon$ SIVAC - Supporting National Independent Immunization and Vaccine Advisory Committees Page ${\bf 22}$

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ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ **ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО**

11th meeting of European Technical Advisory Group of Experts for Immunization (ETAGE)

17-18 March - Copenhagen, Denmark

14 March 2011

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