

Immunization highlights

European Vaccine Action Plan
progress report for 2016



Immunization highlights 2016





Abstract

This annual report for 2016 provides an overview of progress made in the WHO European Region towards the vision, goals and objectives of the European Vaccine Action Plan 2015–2020. It covers the progress and challenges of the Member States of the European Region and highlights the support provided to them by the WHO Regional Office for Europe's Vaccine-preventable Diseases and Immunization programme.

Keywords

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Abbreviations

ASU	annual status update
AEFI	adverse event following immunization
BCG	Bacillus Calmette-Guerin
cMYPs	Comprehensive multi-year plans
CRS	congenital rubella syndrome
DTP3	diphtheria-tetanus-pertussis, third dose
ECDC	European Centre for Disease Prevention and Control
ETAGE	European Technical Advisory Group of Experts on Immunization
EVAP	European Vaccine Action Plan
GAPIII	WHO Global Action Plan to minimize poliovirus facility-associated risk
GVAP	Global Vaccine Action Plan
Hib	haemophilis influenza type b
HPV	human papillomavirus
IPV	Inactivated polio vaccine
JCVI	Joint Committee on Vaccines and Immunization
MeaNS	WHO Measles nucleotide surveillance database
mEQA	molecular external quality assessment
MIC	middle-income country
MR LabNet	WHO European Measles and Rubella Laboratory Network
NITAG	national immunization technical advisory group
NRA	national regulatory authority
NVC	national verification committee for measles and rubella elimination
OPV	oral polio vaccine
RCC	European Regional Certification Commission for Polio Eradication
POSE	polio outbreak simulation exercise
RVC	European Regional Verification Commission for Measles and Rubella Elimination
RubeNS	WHO Rubella nucleotide surveillance database
RVC	European Regional Verification Commission for Measles and Rubella Elimination
SAGE	Strategic Advisory Group of Experts on Immunization
SDGs	Sustainable Development Goals
SIA	supplementary immunization activity
TIP	Tailoring Immunization Programmes
UNICEF	United Nations Children's Fund
US CDC	United States Centers for Disease Control and Prevention
V3P	WHO vaccine product price and procurement initiative
VPI	WHO Regional Office for Europe, Vaccine-preventable Diseases and Immunization programme
WPV	wild poliovirus

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Foreword

2016 was a pivotal year in shaping the global health agenda for the coming decade and beyond. As reflected in the 2030 Agenda for Sustainable Development, much has changed in how we view, measure and promote health both as a product and driver of human development. Throughout the global agenda-setting process, recognition of immunization's important role in helping to achieve the Sustainable Development Goals (SDGs) did not waver. Leaving no one behind includes reaching every child or adult with the vaccinations they deserve.

The European Vaccine Action Plan 2015-2020 (EVAP) adopted in 2014 by all Member States of the European Region embodies the principles of equity and empowerment underlying the SDGs. As such it has already laid important groundwork for achieving the SDGs in the European Region.

In reporting on the Region's progress toward the EVAP goals and objectives, I am impressed by the Member States' achievements, and immensely proud of the support provided to them by WHO. While on track for most of our goals, there is still important work to be done by each and every one of us to ensure the Region fulfills its potential and promise. Keeping the people of this Region safe from vaccine-preventable diseases is a shared vision and a stepping stone toward a more sustainable and resilient future.

Dr Zsuzsanna Jakab
WHO Regional Director for Europe



Executive summary

The European Vaccine Action Plan 2015–2020 (EVAP) was endorsed at the 64th session of Regional Committee for Europe, September 2014, to complement, regionally interpret and adapt the Global Vaccine Action Plan (GVAP) in harmony with Health 2020: the European Health Policy for Health and Wellbeing. By placing health at all ages and reduced inequality at the centre of immunization efforts, EVAP set the Region on a course that is fully aligned with the newly established Sustainable Development Goals 3 and 10. This report presents progress made towards the attainment of the vision, goals and strategic objectives of EVAP by the close of 2016.

The WHO European Region remains polio free. In 2016, the European Regional Certification Commission for the Eradication of poliomyelitis (RCC) identified three Member States at high-risk of establishing poliovirus transmission in the event of reintroduction of poliovirus – Bosnia and Herzegovina, Romania and Ukraine. All 20 Member States in the Region that used oral polio vaccine (OPV) successfully switched from trivalent OPV to bivalent OPV or to an inactivated polio vaccine (IPV) only schedule in April 2016, and the Region made substantial progress in implementing the WHO Global Action Plan to minimize poliovirus facility-associated risk (GAPIII).

Member States have made steady progress in measles and rubella elimination, with fewer cases of both disease recorded in 2016 than in any previous year. 51 of the 53 Member States in the Region have established a National Verification Commission for measles and rubella elimination (NVC) and the Regional Verification Commission (RVC) has verified that 42 Member States interrupted endemic transmission of one or both diseases by the end of 2016, compared to 32 in 2014. The number of Member States with endemic measles has dropped from 18 in 2014 to 9 in 2016¹.

The 'Action plan for the health sector response to viral hepatitis in the WHO European Region' was endorsed by the Regional Committee for Europe at its annual meeting in September 2016. This Plan defines hepatitis B immunization targets and priority activities. The process of validation of hepatitis B control in the Region was also initiated, including establishment of a working group within the independent European Technical Advisory Group of Experts (ETAGE) to review HBsAg seroprevalence and vaccine coverage data in the Region.

¹ Report of the Sixth meeting of the European Regional Verification Commission on Measles and Rubella Elimination (RVC)

Progress towards regional vaccination coverage targets has stalled. Coverage with the third dose of diphtheria-tetanus-pertussis vaccine (DTP3) at national and sub-national levels showed no improvement in 2016 compared with 2014 and 2015, with regional coverage actually declining by 1 percentage point over the two-year period. The number of Member States with $\geq 95\%$ national DTP3 coverage decreased from 36 in 2014 and 2015 to 31 in 2016, while the milestone for 2018 is 42 and the target for 2020 is 48. The reported coverage figures at the subnational level show that only 24 Member States have $\geq 90\%$ DTP3 coverage in more than 90% of their districts in 2016. The 2020 target for this indicator is all 53 Member States.

Member States have made significant progress in assuring that evidence-based decisions are made with regard to new vaccine introduction. By 2016, national (independent) immunization technical advisory groups (NITAGs) had been established in 45 Member States. An increasing number of Member States are applying social science research to identify underserved population groups and their barriers to vaccination.

More and more Member States are taking advantage of the significant health gains offered by new and under-utilized vaccines. By the close of 2016, 40 Member States had introduced pneumococcal vaccine, 32 implemented human papillomavirus (HPV) vaccination, and 18 started universal immunization with rotavirus vaccine, helping to tackle diseases that threaten life

at all ages, from pneumonia in infancy to cancer in adulthood.

By 2016, 47 Member States had achieved financial sustainability in procuring vaccines. As reflected in the target for EVAP goal 6, five additional Member States are expected to be financially self-sufficient for procuring routine vaccines by the end of 2020 (Tajikistan and Kyrgyzstan will remain donor dependent).

Nevertheless, financial commitment to immunization is suboptimal in Europe. Member States challenged by competing priorities at home and inaccessibly priced vaccines on the global market experienced several vaccine shortages in 2015–2016, sometimes causing critical disruptions of services. Furthermore, to varying degrees, Member States face difficulties in sustaining programme performance, in part due to poorly understood access and hesitancy issues. These issues are particularly acute in middle-income countries, many of which self-procure vaccines and continue to face significant challenges in achieving financial sustainability of their immunization programmes. Evidence indicates that these Member States pay more for vaccines, have more unstable vaccine supply and require support in securing and ring-fencing domestic funds for vaccines. All of these factors contribute to the particularly concerning declining trend in coverage with all antigens in the southeastern European middle-income countries. In 2016, support from the WHO Regional Office for Europe (Regional Office) to national immunization

programmes included price transparency projects, vaccine safety management and communications capacity building, resource mobilization tool development, dissemination and training to secure domestic financing of immunization programmes and capacity building on specific elements of vaccine demand, such as awareness raising and measurement of vaccine hesitancy. Furthermore, recognizing the need at country level to prepare for and mitigate potential crises in confidence, the Regional Office developed a comprehensive vaccination and trust library and training package. The Regional Office also continues to support Member States in strengthening capacity on vaccine procurement, vaccine cold chain and immunization logistics, injection safety and waste management, causality assessment methodology, cold chain upgrades and evaluations, laboratory accreditation and training on contraindications as part of the holistic improvement of immunization service delivery.

European Immunization Week in 2016 was actively utilized by national health authorities and civil society throughout the Region. The event's visibility and reach on social media eclipsed all previous years, demonstrating the commitment of Member States to use this event in ever-evolving ways to advocate the importance of immunization among various stakeholders, including parents of unimmunized children.

Introduction

Member States of the European Region consider immunization as a critical tool to reduce health inequality and significantly improve the well-being of populations. These guiding principles are reflected in the European Vaccine Action Plan 2015–2020 (EVAP), the European health policy Health 2020 and the global Sustainable Development Goals. In adopting EVAP in 2014, the 53 Member States of the European Region made an unprecedented commitment to these principles by pledging to ensure the sustainable and predictable investment in immunization and political commitment needed to achieve six goals:

- sustain the European Region’s polio-free status;
- eliminate measles and rubella;
- control hepatitis B infection;
- meet regional vaccination coverage targets at all administrative levels throughout the Region;
- make evidence-based decisions about introduction of new vaccines;
- achieve financial sustainability of national immunization programmes.

EVAP proposes innovative strategies to meet these goals, by defining five strategic objectives, priority action areas and a framework to evaluate and monitor progress towards them.

Guided by this comprehensive Plan, Member States are working toward the vision of “a Region free of vaccine-preventable diseases, where all countries provide equitable access to high-quality, safe, affordable vaccines and immunization services throughout the life course.”

This report presents activities and progress made towards attainment of the vision, goals and strategic objectives of EVAP in 2016.

Fig. 1. The European Vaccine Action Plan 2015–2020 (EVAP) is the operational framework for the Vaccine-preventable Diseases and Immunization programme of the WHO Regional Office for Europe

Guided by the vision of "a European Region free of vaccine-preventable diseases, where all countries provide equitable access to high-quality, safe, affordable vaccines and immunization services throughout the life course",

... the activities of the Vaccine-preventable Diseases and Immunization programme of the WHO Regional Office for Europe supports Member States to...



Progress towards EVAP goals

A woman with long, curly hair and a tattoo on her left arm is shown in profile, looking towards a young boy. She has her hand on the boy's shoulder. The boy is looking towards the camera. The entire image is overlaid with a semi-transparent pink filter.



EVAP goal 1:

Sustain polio-free status

2018 target: No wild poliovirus transmission re-established in the Region (to be confirmed by the Regional Certification Commission at its meeting in 2019)

Progress: On track

In June 2002, the European Regional Certification Commission for Poliomyelitis Eradication (RCC) declared the WHO European Region polio free, with the last case of poliomyelitis having been reported in Turkey in 1998. In June 2017, the European Regional Certification Commission convened its 31st meeting to review the annual status updates of the 53 Member States and concluded that, based on the available evidence, no wild poliovirus was circulating in the WHO European Region in 2016.

Despite this success and the tremendous progress made towards global polio eradication in recent years, the European Region continues to be at risk for the introduction of wild polioviruses and the emergence of vaccine-derived polioviruses.

In 2015–2016, the Region's polio-free status was threatened by an outbreak of circulating vaccine-derived poliovirus in Ukraine. The Regional Office and other Global Polio Eradication Initiative Partners provided technical support to the response in Ukraine, including the initial outbreak coordination, supplementary immunization planning and monitoring, outbreak response assessments, surveillance strengthening, communications and polio surveillance activities. In April 2016, the outbreak was declared over following the 6-month assessment. The Regional Office continues to provide technical support for polio activities in Ukraine to build preparedness and programme resilience.

The third round of a polio immunization campaign in Ukraine began in January 2016, targeting all children aged under 10.





Until global polio eradication is achieved, the European Region will need to continually assess and mitigate risks to ensure that it maintains its polio-free status. Consequently, the RCC uses the annual status update reports to assess each country's level of risk and the degree to which it is undertaking corresponding mitigation activities. To assess risk, the RCC reviews immunization coverage, polio surveillance activities, planning activities and outbreak response capacity. This approach is in line with the anticipated collection and collation of evidence that will be needed to certify global eradication.

In its 2016 risk assessment, the RCC concluded that Bosnia and Herzegovina, Romania and Ukraine continue to be at high risk for sustained transmission following an importation or emergence of a vaccine-derived poliovirus. This is mainly due to suboptimal performance of routine immunization programmes resulting in low population immunity and a large number of susceptible individuals. A more stringent application of all of the components of the risk assessment in 2016 resulted in Greece, Iceland, Italy and San Marino being provisionally assessed as at high risk for the first time, based on inadequate information provided in their 2016 annual status reports.

Risk mitigation and preparedness are an important focus for the Regional Office. Over the past five years, the Regional Office has supported Member States in the development and implementation of Polio Outbreak Simulation Exercises (POSEs). These exercises provide them with the opportunity to test their ability to respond to a polio outbreak at national and international levels. The exercises have been tailored to address specific risks identified in different Member States and geographic areas of the Region, and they

will continue to be an important part of regional mitigation activities through 2020.

As the number of circulating wild polioviruses decreases globally, the main risk for the WHO European Region could come from a containment breach at a vaccine manufacturer or research facility. Containment activities, as outlined in the third edition of the WHO Global Action Plan to minimize poliovirus facility-associated risk (GAPIII), continued throughout the Region in 2016.

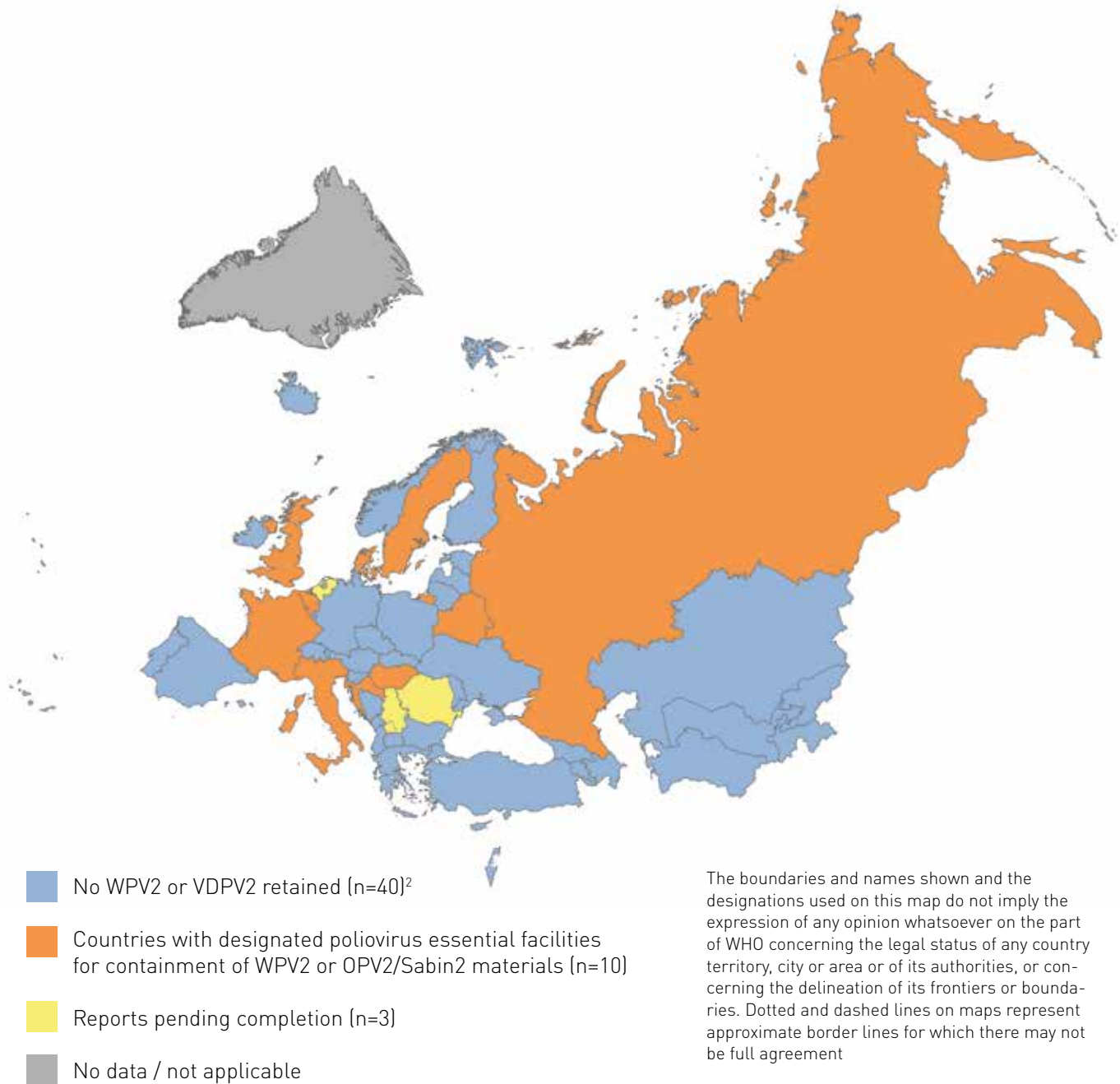
Due to the large number of vaccine manufactures and research facilities in the Region, containment activities have focused on minimizing poliovirus facility-associated risk. Several rounds of high-level communication as well as technical assistance have been provided to ensure support for poliovirus containment activities in all Member States.

By the end of 2016, significant progress was made toward achieving phase I, part A of GAPIII, namely:

- preparation for the containment of all type 2 polioviruses in certified polio essential facilities in accordance with GAPIII requirements; and
- destruction of all type 2 poliovirus materials in all non-essential facilities.

Special training on GAPIII bio-risk management was organized to ensure compliance with containment procedures.

Fig. 2. Progress on completion of GAPIII, Phase 1, Part A, WHO European Region, 2016



² WPV2=wild poliovirus type 2; VDPV2=vaccine-derived poliovirus type 2

EVAP goal 2: Measles and rubella elimination

2018 target: Measles and rubella elimination by all Member States verified by the RVC

Progress: Off track

The European Region has seen a dramatic overall decline in measles and rubella over the past two decades, and recorded the lowest-ever number of measles and rubella cases in 2016. However, several measles outbreaks that started in 2015 and 2016 grew into large-scale outbreaks that exposed gaps not only in the vaccination of children, adolescents and adults, but also in countries' ability to prevent and respond to such outbreaks. The lack of quality rubella surveillance in many Member States also remains a significant challenge.

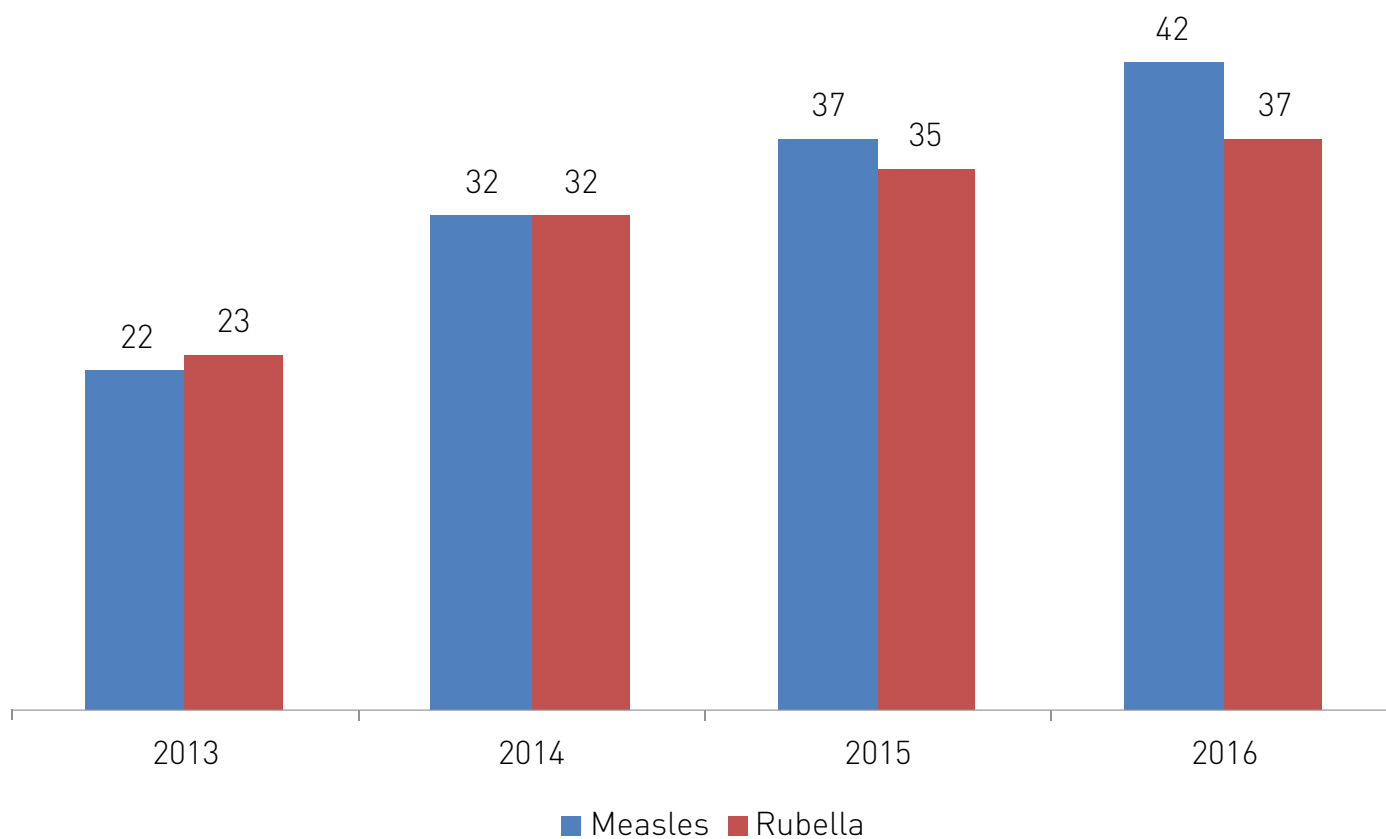
Interrupting endemic measles and rubella transmission is one of the top immunization priorities of the European Region. Following the 2010 decision by the Region's Member States to initiate the process of verifying elimination, the European Regional Verification Commission for Measles and Rubella Elimination (RVC) was established in 2011. The RVC meets every year to evaluate the status of measles and rubella elimination in the Region based on documentation

submitted by each Member State's National Verification Committee (NVC). The verification process was modified in late 2014 to enable assessment of the elimination status of individual Member States instead of the Region as a whole.

The RVC convened its sixth meeting in June 2017 to evaluate each Member State's status for 2016. After reviewing the 2016 annual status reports prepared by the NVCs, the RVC concluded (pending receipt of further documentation from one Member State) that 42 and 37 of the 53 Member States in the Region had demonstrated interruption of endemic transmission of measles and rubella, respectively³.

³ Report of the Sixth meeting of the European Regional Verification Commission on Measles and Rubella Elimination (RVC)

Fig. 3. Number of Member States that interrupted endemic measles and rubella transmission ≥ 12 months, WHO European Region, 2013–2016



Source: RVC meeting reports, 2014–2017

Compared to the 2014 baseline of 32 for each, this shows incremental progress towards achieving the regional goal.

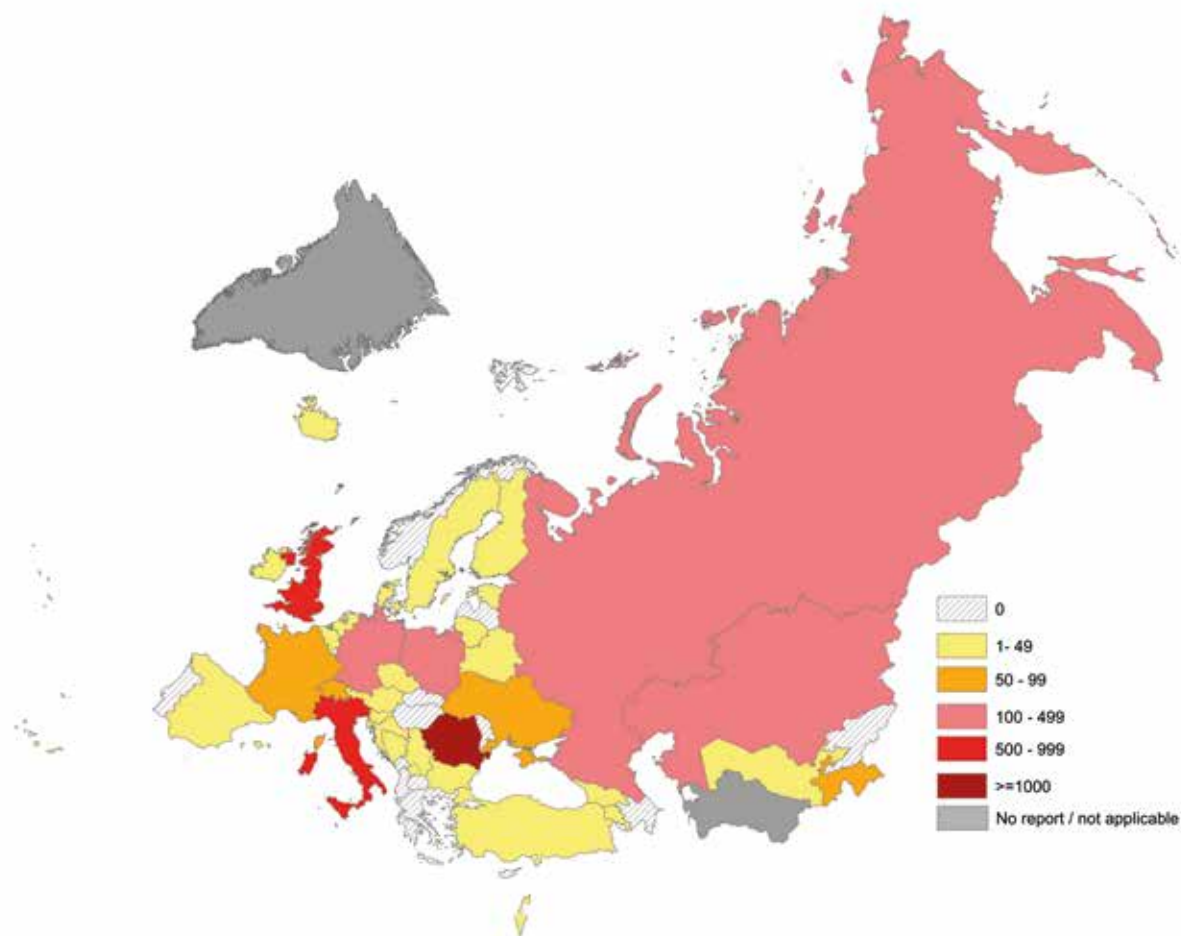
As of the end of 2016, 11 Member States were considered to be endemic for measles or had not provided the RVC with adequate documentation to demonstrate interruption, and 16 were either endemic or had not demonstrated interruption for rubella⁴. Substantial efforts – at the regional and national levels, in vaccination delivery and disease surveillance, by parents, politicians and health workers – will be needed to achieve the goal of elimination in every Member State.

The Regional Office continued to provide technical support to Member States throughout 2016 for the elimination of measles and rubella. The team focused its efforts on helping the remaining Member States to achieve interrupted status. Activities included country missions to support outbreak response, measles and rubella case-based surveillance activities, regional and national reference laboratory accreditation, and quality improvements in annual status updates documentation. Updating of standard operating procedures and guidelines for measles/rubella case-based surveillance and reporting is ongoing. Joint technical missions were conducted between the Regional Office's disease surveillance and laboratory teams as well as other activities within the Measles/Rubella Laboratory Network workplan. (See also EVAP strategic objective 4).

⁴ Report of the Sixth meeting of the European Regional Verification Commission on Measles and Rubella Elimination (RVC)



Fig. 4. Measles cases, WHO European Region, 2016

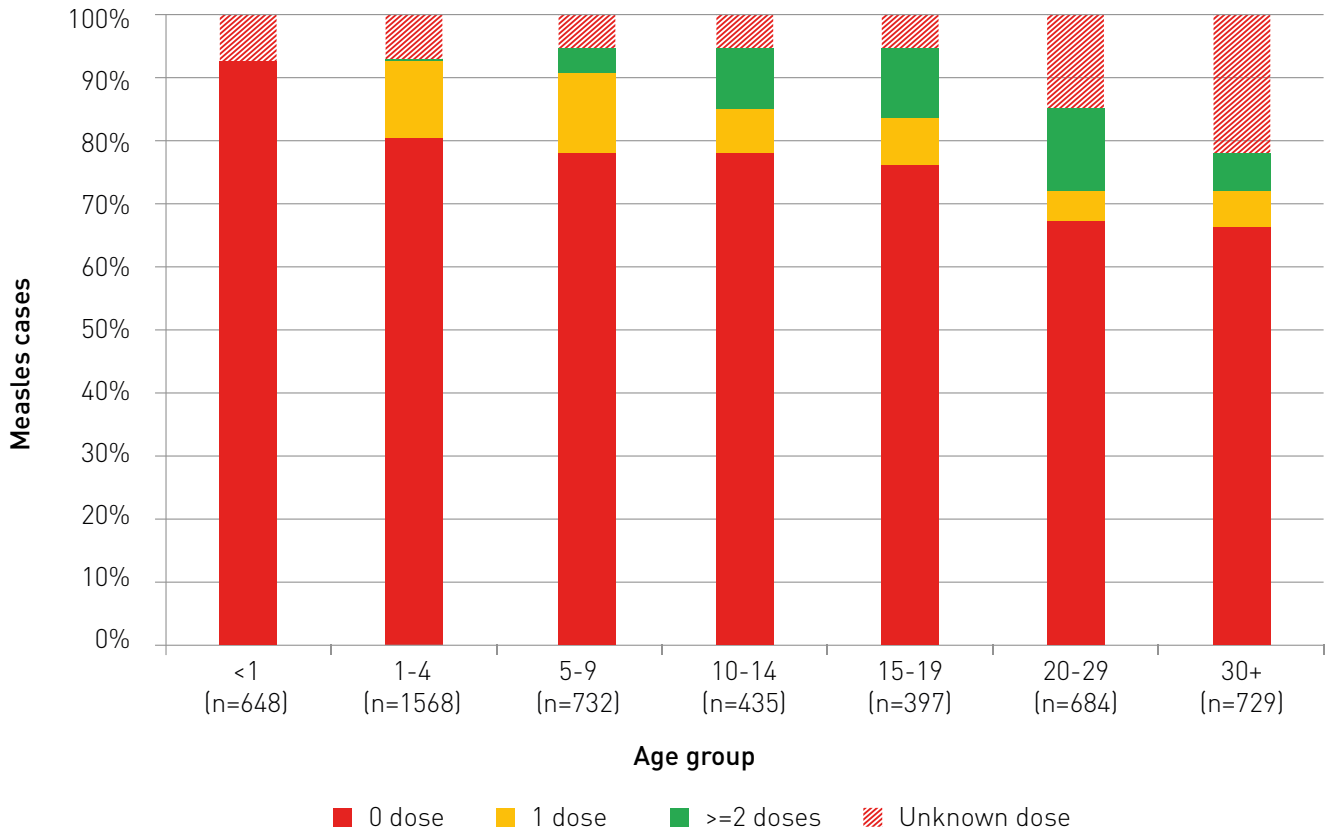


Data as of: 1 August 2017

Source: Monthly reporting by countries to the WHO Centralized Information System for Infectious Diseases (CISID)

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Fig. 5. Age and vaccination status of measles cases, WHO European Region, 2016



Data as of: 1 August 2017

Source: Monthly reporting by countries to the WHO Centralized Information System for Infectious Diseases (CISID)

EVAP goal 3: Control hepatitis B infection

2016 milestone: Regional hepatitis B control goal established
2020 target: To be established

Progress: On track

In unanimously adopting EVAP, Member States instructed the Regional Office to guide action against hepatitis B. In line with this mandate, hepatitis B control targets, priority activities and indicators were presented in the 'Action plan for the health sector response to viral hepatitis in the WHO European Region' to the 66th session of the Regional Committee for Europe, and endorsed on 14 September 2016.

The Action plan sets the following targets to be achieved by Member States by 2020:

- 0.5% HBsAg prevalence in vaccinated cohorts;
- 95% coverage with three doses of hepatitis B vaccine in infants;
- 90% coverage with hepatitis B birth dose vaccine or 90% coverage with hepatitis B screening of pregnant women and 95% coverage with post-exposure prophylaxis of newborns.

A WHO Hepatitis B Advisory Group made up of technical experts within and outside of WHO met in December 2016 to establish a regional process for validating hepatitis B control. As part of this process an independent working group of the European Technical Advisory Group of Experts (ETAGE) was established to annually review all submitted HBsAg seroprevalence and vaccine coverage data and validate whether a country has achieved the control targets. The validation will be reported to ETAGE and published on the Regional Office website. The ETAGE working group will meet for the first time in September 2017.

Validation will occur at both the country and regional levels. Once all Member States have been validated as having met the control goals, the Region can be certified to have achieved its regional goal. The Regional Office will provide support to Member States in strengthening hepatitis B control and demonstrating the achievement of control targets. Priority

activities will include improvement in timeliness of hepatitis B birth dose; evaluation and improvement of coverage with screening during pregnancy and post-exposure prophylaxis of newborns; increasing and sustaining high coverage with three doses of hepatitis B vaccine; and conducting serosurveys to demonstrate the impact of hepatitis B vaccination.



EVAP goal 4:

Meet regional vaccination coverage targets at all administrative levels throughout the Region

2016 milestone: 42 of 53 Member States with $\geq 95\%$ coverage with three doses of DTP-containing vaccine at national level

2020 target: 48 of 53 Member States with $\geq 95\%$ coverage with three doses of DTP-containing vaccine at national level

Progress: Stalled

When the Global Vaccine Action Plan (GVAP) was adapted to the regional context, owing to consistently high reported vaccination coverage in the Region, European Member States set the bar high in the EVAP by establishing regional coverage targets that exceeded those of GVAP. Measles outbreaks along with cases of diphtheria and pertussis and mumps in 2016 clearly indicate gaps in immunization programme performance.

Coverage with the third dose of diphtheria-tetanus-pertussis vaccine (DTP3) at national and sub-national levels showed no improvement in 2016 compared with 2015 and 2014, with the average regional

coverage in 2016 actually declining by 1 percentage point over the two-year period.

The number of Member States with $\geq 95\%$ national DTP3 coverage decreased from 36 in 2015 to 31 in 2016. Stepped-up action will be needed to regain the Region's momentum and reach the 2020 target of 48 Member States with $\geq 95\%$ DTP3 coverage. According to the available subnational-level data, only 24 Member States had $\geq 90\%$ DTP3 coverage in more than 90% of districts in 2016. The 2020 target is for all 53 Member States to achieve this subnational coverage target.

WHO-UNICEF vaccination coverage estimates for 2016 show considerable variation in national DTP3 coverage rates and trends across the Region:

- 31 Member States achieved $\geq 95\%$ DTP3 coverage in 2016;
- 5 Member States with coverage below 95% in 2016 showed an increase in coverage from 2014 to 2016;
- 10 Member States with coverage below 95% in 2016 reported either no change or up to a 2 percentage point decrease in coverage compared to 2014;
- 7 Member States with coverage below 95% in 2016 showed a steep decline in coverage from 2014 to 2016 (Fig. 6). Of these, 4 are middle-income countries.

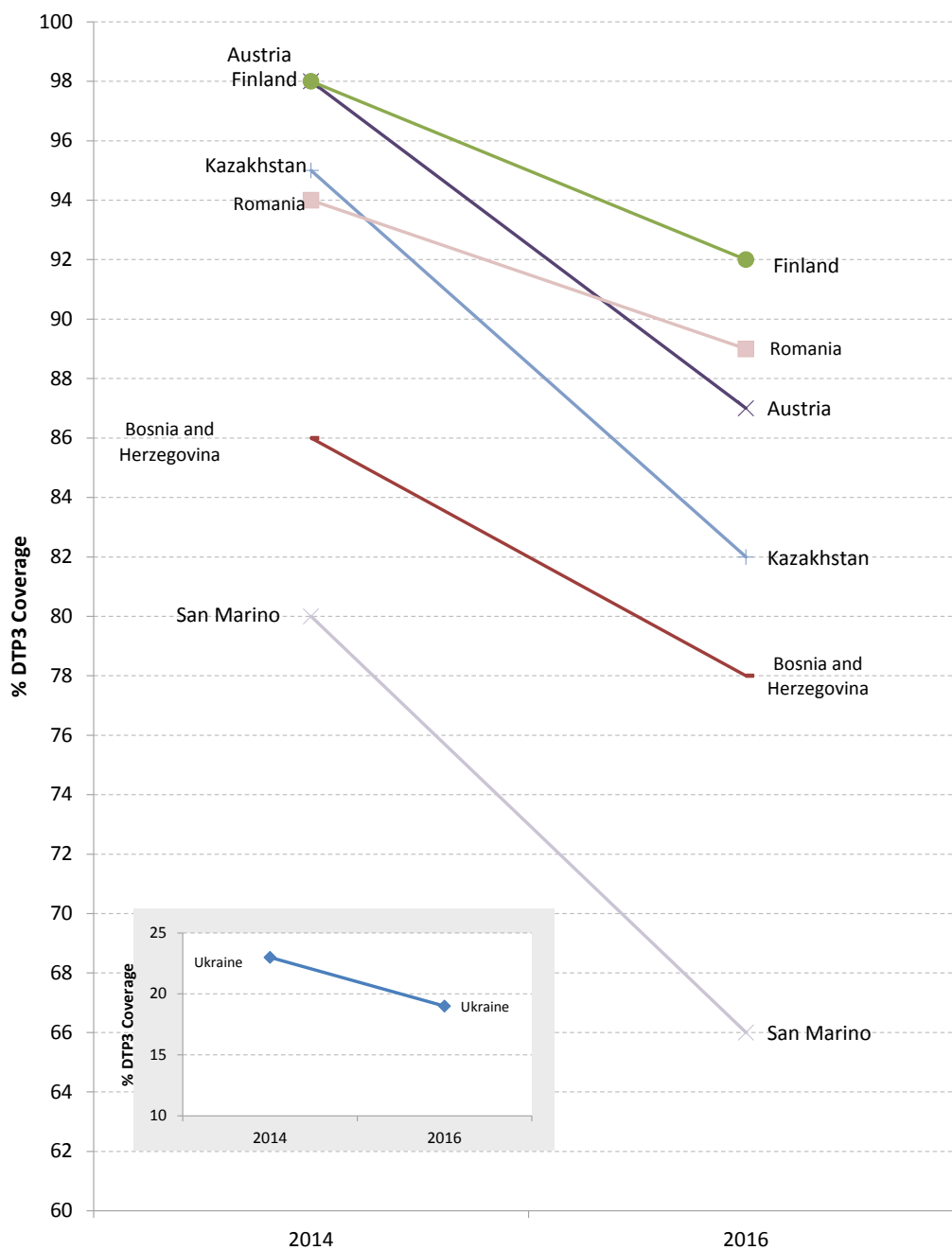
DTP3 coverage data for all 53 Member States (2014–2016) is provided in Annex 1.

Middle-income country challenges (not limited to Goal 4: vaccine coverage target attainment).

The declining trend in coverage with all antigens in most middle-income countries (MICs) (particularly in the southeastern European subregion) is concerning. This decline is exacerbated by complacency in translation of political commitments into action at the country level. The challenges that MICs face include a lack of adequate financial resource commitment to immunization due to competing priorities, non-eligibility for external funding (i.e. Gavi, the Vaccine Alliance), difficulty in accessing vaccines at affordable and optimum prices, global supply shortages for vaccines and a growing anti-vaccine agenda and visibility.

MICs, many of which self-procure vaccines and rely solely on their domestic financial resources, continue to face significant challenges in expanding their immunization programmes through introduction of new vaccines and sustaining performance of their programmes. These challenges are apparent in the table below. The MIC Member States which receive no Gavi support bear the burden of the highest number of unvaccinated children in the Region and have introduced the lowest number of new vaccines. The Region is committed to support these Member States through development of a more cohesive strategy to address the identified challenges.

Fig. 6. Member States in WHO European Region with steep decline in DTP3 coverage, 2014–2016



Source: WHO/UNICEF estimates on national immunization coverage

Table 1. Characteristics of Member States in European Region by income level^a

Income level category	Average no. of antigens accommodated/ country	Average no. of new vaccines introduced/ country	Coverage with DTP3 [population weighted average]	Unvaccinated infants (DTP3)		Coverage with MCV1 ^c [population weighted average]
				% of Region	# of infants	
HIC ^b (n=33)	12.5	2.0	96.5%	24.7%	182,250	94.2%
MIC^b (no Gavi support) (n=13)	10.4	0.5	88.7%	70.2%	518,850	91.8%
MIC (Gavi support) (n=7)	13.0	2.6	97.3%	5.1%	37,270	97.9%
Regional average or total #	11.9	1.6	93.4%		738,370	93.6%

Source: WHO/ UNICEF Joint Reporting Form, 2015 data

^aAccording to 2015 GNI, World Bank

^b MIC=middle-income countries, HIC= high-income countries

^c MCV1=first dose of measles-containing vaccine

EVAP goal 5:

Make evidence-based decisions on the introduction of new vaccines

2016 milestone: 45 of 53 Member States have established a NITAG

2020 target: At least 48 of 53 Member States with NITAGs have made an informed decision on a defined set of new vaccines, following the review of the relevant evidence by their NITAGs

Progress: On track

By close of 2016, 45 Member States had officially established a national immunization technical advisory group (NITAG) to provide scientific advice to ministries of health on immunization policy and practice. This signifies a steady increase since 2014 when 39 NITAGs had been established, and 2015 when 42 NITAGs had been established.

Evidence-based NITAG recommendations have helped ministries of health make informed decisions on introduction of new vaccines. By the end of 2016, 40 countries had introduced a pneumococcal conjugate vaccine in their routine immunization schedules, 32 introduced vaccination against human papillomavirus (HPV) and 18 against rotavirus. Four more middle-in-

come countries will introduce HPV vaccines with Gavi support in 2017.

The recently established NITAGs in 10 middle-income countries conducted self-evaluations using a standardized questionnaire. The NITAG representatives discussed the evaluation results and defined future steps to improve NITAG performance at the WHO Regional Meeting for NITAGs on 14 October 2016.

The Republic of Moldova conducted an HPV vaccine cost-effectiveness study to obtain local economic evidence and incorporate it in the decision-making process. The study results demonstrated that introduction of HPV vaccination in this country will be highly cost effective. In line with the NITAG's recommendation, the

Ministry of Health decided to introduce the vaccine in 2017, through the Gavi demonstration project modality. Collaboration between national and regional advisory bodies continued in 2016. Representatives of NITAGs from middle-income countries participated in meetings of ETAGE and the Global Strategic Advisory Group of Experts on Immunization (SAGE). The Joint Committee on Vaccines and Immunization (JCVI), a well-established NITAG in the United Kingdom, supported the recently established NITAG in Albania by hosting its representatives at the 2016 JCVI meeting and by sharing information on the JCVI Secretariat's experience and decision-making processes.

All 45 NITAG chairs are to attend the Regional Office's Immunization Programme Managers Meeting in October 2017 in Montenegro, to share experiences, information and upcoming vaccine decision-making deliberations and meetings with each other. The WHO Regional Director will also be engaging with Member States that do not currently have a NITAG to encourage them to establish one.

EVAP goal 6:

Achieve financial sustainability of national immunization programmes

2016 milestone: 46 of 53 Member States have achieved financial sustainability

2020 target: At least 51 of 53 Member States (except two low-income countries as of 2012) are financially self-sufficient for procuring routine vaccines (domestic resources)

Progress: On track

Financial sustainability of immunization programmes is critical for the Region's long-term success in controlling the spread of vaccine-preventable diseases. By the end of 2016, 47 Member States had achieved financial sustainability in procuring vaccines. The Republic of Moldova gained its financial self-sufficiency in 2016 and started successfully funding all vaccines in its routine schedule from domestic resources. Armenia, Azerbaijan and Georgia are expected to follow in 2017, as they transition from donor support. Uzbekistan will be the next country to achieve financial self-sufficiency during the life cycle of EVAP (2015–2020). Only

Kyrgyzstan and Tajikistan will continue to receive donor support for procurement of programme vaccines beyond 2020.

For those programmes that still relied on external financial resources in 2016, the Regional Office continued to provide multi-dimensional programmatic and financial support, and assisted in updating comprehensive multi-year plans (cMYPs). The cMYPs provide a road map for the coming five years, guiding programme strengthening and outlining the steps and measures needed to achieve full financial self-sufficiency. Costing components of the cMYPs provide

guidance to decision-makers at the government level on the resources required for their programme to achieve targets set for the planned period. They present an assessment of available funding as well as the predicted funding gap to be filled. The cMYPs are also leveraged as an advocacy tool in ensuring increased and/or sustained funding for national immunization programmes.

For Member States transitioning from donor support, the Regional Office provided support in developing national 'transition plans'. These plans address the challenges the programmes face or expect to face in achieving financial sustainability and ensuring sustained programme performance, after donor support. Transition plans also include intensification of resource mobilization efforts to increase domestic funding for the programmes. In 2016, high-level multi-partner advocacy visits were conducted to all transitioning countries to help ensure sustained political commitment to national immunization programmes, with particular emphasis on financial sustainability. European Immunization Week in April 2016 was used as a platform to maximize ongoing advocacy efforts in all Member States to maintain sustainability of their immunization programmes and to move towards financial self-sufficiency where donor support is utilized to achieve programme targets.

A photograph of a person sitting on a wooden bench outdoors. A bicycle is leaning against the bench. The person is wearing dark shorts and sneakers. The entire image is overlaid with a semi-transparent teal color. The text 'Progress towards EVAP strategic objectives' is written in white serif font in the upper left quadrant.

Progress towards EVAP strategic objectives



EVAP strategic objective 1:

All countries commit to immunization as a priority

Important reflections of political commitment to immunization include long-term immunization plans that are integrated in broader health plans, evidence-based decision-making incorporating the recommendations of an independent NITAG, financial sustainability of the immunization programme, legislation that anchors in law sustainable funding for immunization and policies at programme level that facilitate equitable access to vaccines. Together these factors point to a generally high level of political commitment to immunization in the European Region. More will be needed, however, to achieve all EVAP targets, including measles and rubella elimination in all 53 Member States (EVAP goal 2).

All cMYPs and transition plans due for development in 2016 were completed with WHO technical assistance. Such plans provide strategic guidance to policy-makers and programme management staff on how to

achieve programme objectives, which in turn contribute to achievement of regional goals and objectives. Endorsement of these plans at the highest political level reflects the consensus built in Member States to protect their citizens against vaccine-preventable diseases.

45 of the 53 Member States in the European Region now have a functioning NITAG. The number of countries introducing new vaccines based on NITAG recommendations increased in 2016 (see EVAP goal 5), and significant improvements in financial sustainability were also realized (see EVAP goal 6). Nearly all Member States utilized European Immunization Week 2016 to demonstrate government commitment to immunization and to sustain high public demand for vaccines (see EVAP strategic objective 2).



Her Royal Highness The Crown Princess of Denmark and WHO Regional Director for Europe visited Republic of Moldova, on 23–25 November 2016 focusing on immunization among other topics. The Crown Princess: “Immunization saves lives. Apart from safe drinking-water, no other health intervention has reduced diseases and mortality as effectively and safely as vaccination.”



Immunization legislation is a potentially powerful tool in support of sustainable immunization financing. Legislative action can provide a legal commitment to public funding of immunization, which can help secure adequate financing and promote accountability and transparency. In the European Region, immunization legislation varies across Member States. Some have separate immunization laws; others legislate immunization through provisions within general health acts or public health laws. In 2016, the Regional Office began mapping the legislative environment across the Region and started to review and present best and promising legislation and policy in 2017. This work is ongoing and is being conducted in collaboration with WHO headquarters and the Sabin Vaccine Institute.

Two additional work streams were initiated in 2016 to begin defining and uncovering the dimensions of ‘equity’ and ‘life-course’ within the context of the vaccination programmes of the European Region, from a policy perspective. This work will be complemented by parallel enquiry and study on the concepts of ‘sustain-

ability’, ‘integration’ and ‘citizen-centred’. The overall goal is to have a stronger shared understanding of how policy supports such objectives/concepts and how the immunization community, through policy and planning, can better accommodate more integrated, sustainable, equitable, and citizen-centred immunization services, throughout the life course.

Increasing domestic expenditure for routine vaccines per newborn is another strong indicator of commitment to immunization as a priority. This indicator will be calculated using a dedicated study planned in early 2018 so that it can be used as an additional measure of progress towards EVAP strategic objective 1 as part of the EVAP mid-term review in 2018.

EVAP strategic objective 2:

Individuals understand the value of immunization services and vaccines and demand vaccination

Individuals will demand vaccination as their right and responsibility only if they have confidence in the value and safety of vaccines and in the system that provides them. Member States report that maintaining this confidence has become increasingly difficult, due to a general mistrust of public institutions, strong influence of online communications and, in line with these, the growing strength and visibility of anti-vaccine voices. In this changing context, immunization programmes, including those with strong resources and capacities, face new challenges they may not be prepared for. Outbreaks of vaccine-preventable diseases and declining immunization coverage in some countries have confirmed the need for greater public and health worker resilience to vaccine safety scares and increased

capacity building within immunization programmes to respond in the event of a vaccine-safety-related event.

In adopting EVAP, Member States acknowledged that immunization programmes need to monitor public attitudes, knowledge and behaviour towards immunization and take action to sustain high demand for vaccines. Preparation is key, and 14 Member States reported having a communication plan in place by 2015 to respond to any vaccine safety-related event with the potential to erode confidence in vaccines. This number will serve as the baseline for future assessment of progress toward this strategic objective.

In addition, Armenia, Georgia and Republic of Moldova have conducted target group research as part of preparations for HPV introduction, and England (in the United Kingdom) continues to closely monitor public opinion to enable a quick response to any relevant signals that may arise. Other Member States have stepped up communication efforts in response to a crisis, such as Denmark and Ireland, which faced a drop in HPV coverage, and Romania where a large-scale measles outbreak began in 2016. European Immunization Week was also utilized across the Region as an opportunity to raise awareness among public, policy-makers, health workers and journalists.

The Regional Office works with Member States to sustain vaccine confidence and demand by providing guidance and training on responding to anti-vaccine lobbyists, preparing for and responding to crises in confidence, identifying barriers to immunization and tailoring immunization programmes to address them, preparing for new vaccine introductions and targeting communications to sub-populations. In addition to developing new publications and communication tools on these topics in 2016, WHO trained representatives from five Member States to respond to vocal vaccine deniers in public, participants from 15 Member States to communicate effectively about vaccine safety and conducted communication reviews in two Member States.

EVAP strategic objective 3:

The benefits of vaccination are equitably extended to all people through tailored, innovative strategies

Despite relatively high regional vaccination coverage, outbreaks and deaths caused by vaccine-preventable diseases in both the eastern and western parts of the Region in 2016 bear witness that not everyone benefits from the protection of vaccination. Inequitable extension of vaccination services may affect any population subgroup; however, the consequences of not being protected against diseases often affect the poorer and marginalized groups more seriously.

An increasing number of Member States are applying social science research to identify underserved population groups and their barriers to vaccination, particularly with the WHO Tailoring Immunization

Programmes (TIP) approach. These processes unravel complex barriers, often related to system challenges and less accessible or user-friendly services, including among marginalized population groups. The insights gained in countries allow immunization programmes to tailor their systems and services to the needs of the unprotected.

Taking stock of TIP implementation and health impact, an external committee of six leading global experts conducted an evaluation in June to December 2016, informed by country assessments in Bulgaria, Lithuania, Sweden and the United Kingdom, a review of national and regional documents

and an online regional survey. The evaluation committee concluded that there is strong demand in the European Region for research to understand enablers and barriers to vaccination in susceptible population groups.

Barriers to vaccination are indeed poorly understood in many settings, and challenges persist to identify underserved populations. Integrated electronic immunization registries have great potential to close this gap by identifying individuals or groups that are not being reached. Their use should therefore be actively encouraged.



EVAP strategic objective 4:

Strong immunization systems are an integral part of a well- functioning health system

Strong health systems are needed to deliver and scale-up the use of new vaccines and to improve immunization coverage and equity. Inadequate infrastructure, lack of trained healthcare workers, interruption in the supplies of essential commodities, lack of data to track and manage progress and limited capacity to store vaccines represent critical barriers to achieving sustainable progress in immunization. With WHO support, all Member States are building or maintaining the necessary capacities to ensure high-quality and sustainable surveillance and vaccine delivery.

A comprehensive health system strengthening support portfolio, financed through Gavi, was finalized in 2016 for Kyrgyzstan, Tajikistan and Uzbekistan. The Regional Office will facilitate and deliver key deliverables as part

of these work packages. The duration and activities of the country projects are aligned with EVAP strategic objectives, providing an opportunity to resolve Member States' health system constraints in a comprehensive manner through a closer technical assistance partnership with the United Nations Children's Fund (UNICEF) and the World Bank.

A strong immunization system includes a fully functional national monitoring and reporting system for vaccine safety and a system that can deal with public concerns and rapidly evaluate the risk to public safety when adverse events following immunization (AEFI) occur. In 2016, 15 of 21 middle-income Member States worked to upgrade their capacities for AEFI surveillance, causality assessment and communications.

WHO training and support focused on classification of AEFI cases, sharing of best practice, review of WHO guidance and tools, self-assessment of national vaccine pharmacovigilance systems and developing action plans to address country-specific challenges and build minimum capacity for vaccine pharmacovigilance. Member States were also supported in developing effective vaccine management improvement plans (Romania, Uzbekistan) to strengthen immunization supply chains. Advocacy and technical assistance to institutionalize best vaccine management practices through policy, regulatory frameworks and quality management systems was provided to countries transitioning from Gavi support (Armenia, Georgia, Republic of Moldova). Georgia strengthened the temperature monitoring system in the immunization supply chain at national and subnational level using cloud-based technology. Kyrgyzstan and Uzbekistan conducted comprehensive cold chain inventories and needs assessment, developed cold chain rehabilitation plans, and identified funding opportunities for Cold Chain Equipment Optimization Platform support.

Highly proficient and well-integrated reference laboratories are an essential component of surveillance systems, playing a critical role in monitoring the achievements of immunization programmes against EVAP targets. A desk review of the performance of the 67 national and subnational laboratories of the European Measles and Rubella Laboratory Network (MR Labnet) was conducted in 2016 with 64 laboratories fully accredited and the remaining 3 provisionally accredited. The annual quality assurance programme for MR Labnet laboratories was upgraded with the implementation of the first round of the new molecular External Quality Assurance (mEQA) for 34 laboratories of the network.

The WHO Regional Polio Laboratory Network (Polio Labnet), the largest component of the global network, consists of 47 laboratories in 37 Member States. All laboratories underwent a process of WHO annual accreditation and were fully accredited in 2016. Four laboratories had difficulties with the most recent virus isolation proficiency panel and will require technical assessment and follow up in 2017. By the close of 2016, all polio laboratories in the Region had transitioned fully to the new WHO virus isolation diagnostic algorithm in accordance with the regional implementation plan. Throughout 2016, the network in Europe was preparing to upgrade to poliovirus intratypic differentiation capacity. All laboratories that implement this technique and successfully pass a proficiency test will be able to differentiate between wild, vaccine and vaccine-derived polioviruses in their own laboratories.

In 2016, seven Member States in the European Region (Armenia, Azerbaijan, Georgia, Republic of Moldova, Tajikistan, Ukraine and Uzbekistan) participated in the WHO-coordinated Global Rotavirus Sentinel Surveillance Network (GRSN). Five Member States in the European Region (Armenia, Azerbaijan, Georgia, Ukraine and Uzbekistan) participated in the WHO-coordinated Global Invasive Bacterial Vaccine-preventable Diseases (IB-VPD) Surveillance Network (GISN), which gathers demographic, clinical and laboratory data on children under 5 years of age hospitalized for bacterial meningitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* or *Neisseria meningitidis*. Four of these (Armenia, Azerbaijan, Georgia, and Uzbekistan) have introduced pneumococcal conjugate vaccine in their national immunization programme. All five have introduced Haemophilus influenzae type b (Hib) vaccine.

EVAP strategic objective 5:

Immunization programmes have sustainable access to predictable funding and high-quality supply

Shortages of vaccines were reported by 28 Member States in 2015 and by 21 Member States in 2016, sometimes causing critical disruptions of services. Multiple vaccines were involved, including Bacillus Calmette–Guérin (BCG), DTP, acellular-pertussis-containing vaccines and IPV. Member States have expressed their concerns to the Regional Office and partners, and requested more information and solutions in order to mitigate the effects of vaccine shortages and prevent them in future. Collaborative efforts with partners at regional and global levels to address global cross-cutting vaccine procurement challenges included inputs to the SAGE discussion on pre-empting and responding to vaccine supply shortages in April 2016,

which was followed in June 2016 by the World Health Assembly (WHA) resolution “Addressing the global shortage of medicines and vaccines” (WHA 69.25). This resolution calls for specific actions from Member States, manufacturers and WHO.

Vaccine costs are an important element of health budgets and vaccine price is a major factor in deciding when to adopt and whether to sustain new vaccines. Vaccine price transparency, with the aim of increasing affordability, has expanded in the Region, with 34 Member States having shared vaccine price information through the WHO Vaccine product price and procurement (V3P) initiative by the end of 2016. Review

of the price trends for the available 3-year datasets show encouraging progress and a potential impact of vaccine pricing transparency: in the period since data have been collected through this project, large discrepancies between vaccine prices paid by individual countries have begun to decrease, and an overall trend of declining vaccine prices has been observed for a range of products. Lessons learned from establishing the regional vaccine price transparency mechanism were shared with ETAGE and national health product procurement experts (WHO Workshop on strategic procurement of new medicines) in 2016.

The first successful inter-country joint vaccine procurement in the Region took place in 2016. A partnership agreement on joint procurement and lending of medicinal products and medical devices signed by health authorities of Estonia, Latvia and Lithuania resulted in joint procurement of rotavirus vaccine by Latvia and Estonia and in securing vaccine supply and gaining important cost savings. It was preceded by improvements in the procurement process, expansion of the supplier base by harmonizing procurement, programmatic and market authorization requirements, and strengthening purchasing power by improving knowledge on vaccine market and product prices (using the V3P website) as well as by improving predictability of demand through multi-year contracting.

National regulatory authorities (NRAs) also play a critical role in ensuring sustainable access to quality-assured vaccines in Member States, particularly in terms of their market authorization (vaccine registration) and pharmacovigilance (AEFI surveillance system) functions. WHO provided technical assistance to priority Member States to strengthen their national regulatory mechanism through implementation of NRA improvement plans through 2016. Workshops and assessments were also conducted to help strengthen regulatory mechanisms, market authorization and licensing of medicinal products, including registration of vaccines.

Publications

and meeting reports





Publications and meeting reports



Best practice guidance: How to respond to vocal vaccine deniers in public

Basic, broad principles for a spokesperson of any health authority on how to respond to vocal vaccine deniers.



Immunization Highlights 2015

The WHO/Europe annual report on its immunization activities in 2015 provides an overview of the support provided to Member States of the WHO European Region in pursuing the goals and objectives of the European Vaccine Action Plan 2015–2020 (EVAP).



European Immunization Week 2016 Narrative Report

Summary of the activities and materials that made European Immunization Week visible across the European Region in 2016.

Meeting reports

- Meeting of the Polio Laboratory Network, June 2016.
- 30th Meeting of the European Regional Certification Commission for Poliomyelitis Eradication, October 2016.
- 5th meeting of the European Regional Verification Commission for Measles and Rubella Elimination, October 2016.
- 16th meeting of the European Technical Advisory Group of Experts (ETAGE), October 2016.

WHO EpiBrief and WHO EpiData

Periodical reports and monthly surveillance data for selected vaccine-preventable diseases.

All publications are available at www.euro.who.int/vaccines

Vaccination and trust library

Recognizing the need at country level to prepare for and mitigate potential crises in confidence, the Regional Office developed a comprehensive Vaccination and trust library and training package. A theoretical background document presents the scientific evidence behind WHO's recommendations on building and restoring confidence in vaccines and vaccination, both in ongoing work and during crises. Drawing on laboratory research and fieldwork within psychology and communication, it examines how people make decisions about vaccination; why some people are hesitant about vaccination; and the factors that drive or mitigate a crisis. The background document is accompanied by a series of support documents with practical guidance for specific situations, such as preparing a press release and planning an immediate media response.

The package was pilot tested through training events in 2016 and launched online in 2017

www.euro.who.int/vaccinetrust



Vaccination and trust

Theoretical background and evidence plus practical guidance for national immunization programmes to prepare for and respond to potential crises in vaccine confidence.

Supporting documents

Programme planning and coordination

- 4 critical elements in the ongoing work to build confidence
- Stakeholder management
- Terms of reference for a vaccine communication working group
- Crisis communications plan template
- New vaccine: checklist for communication and advocacy

Crisis preparedness and response capacity

- Checklist : Are you prepared?
- 4 immediate steps when responding
- How to ensure a context-specific response

Media – ongoing relations and crisis response

- Setting the media agenda
- Safety events: the immediate media response
- Tips for spokespersons
- The questions journalists always ask in a crisis
- Strategies used by journalists
- How to prepare a press release

Messaging and reaching out to the public

- How to prepare a message map
- How to monitor public opinion
- Key principles for presenting data
- How to respond to concerns
- Vaccine safety messages (frequency of AEFIs)
- Societal benefits of immunization
- Myths and facts about immunization
- Risk scales: benefits of vaccines

Annex 1

WHO/UNICEF DTP3 coverage estimates by Member State, WHO European Region, 2014–2016

Country	2014	2015	2016
Albania	98	99	98
Andorra	97	97	98
Armenia	93	94	94
Austria	98	93	87
Azerbaijan	94	96	97
Belarus	97	99	98
Belgium	99	99	98
Bosnia and Herzegovina	86	82	78
Bulgaria	88	91	92
Croatia	95	94	93
Cyprus	99	97	97
Czech Republic	97	97	96
Denmark	94	93	94
Estonia	93	93	93
Finland	98	97	92
France	98	98	97
Georgia	91	94	92
Germany	95	95	95
Greece	99	99	99
Hungary	99	99	99
Iceland	90	92	91
Ireland	96	95	95
Israel	95	95	94
Italy	95	93	93
Kazakhstan	95	98	82
Kyrgyzstan	96	97	96
Latvia	92	95	98
Lithuania	93	93	94

Luxembourg	99	99	99
Malta	99	97	97
Monaco	99	99	99
Montenegro	91	89	89
Netherlands	96	95	95
Norway	93	95	96
Poland	98	98	98
Portugal	98	98	98
Republic of Moldova	90	87	89
Romania	94	89	89
Russian Federation	97	97	97
San Marino	80	76	66
Serbia	93	95	92
Slovakia	97	96	96
Slovenia	95	95	94
Spain	97	97	97
Sweden	98	98	98
Switzerland	96	97	97
Tajikistan	97	96	96
The former Yugoslav Republic of Macedonia	95	91	95
Turkey	96	97	98
Turkmenistan	98	99	98
Ukraine	23	23	19
United Kingdom of Great Britain and Northern Ireland (the)	95	96	94
Uzbekistan	99	99	99
Regional average	93	93	92

Notes:

- Data source: WHO-UNICEF DTP3 coverage estimates;
http://www.who.int/immunization/monitoring_surveillance/data/en/
- Highlighted cells indicate DTP3 coverage level less than the target of $\geq 95\%$

The WHO Regional
Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

Member States

Albania
Andorra
Armenia
Austria
Azerbaijan
Belarus
Belgium
Bosnia and Herzegovina
Bulgaria
Croatia
Cyprus
Czechia
Denmark
Estonia
Finland
France
Georgia
Germany
Greece
Hungary
Iceland
Ireland
Israel
Italy
Kazakhstan
Kyrgyzstan
Latvia
Lithuania
Luxembourg
Malta
Monaco
Montenegro
Netherlands
Norway
Poland
Portugal
Republic of Moldova
Romania
Russian Federation
San Marino
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
Tajikistan
The former Yugoslav
Republic of Macedonia
Turkey
Turkmenistan
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