



## ECDC CORPORATE

# Strategies for disease-specific programmes

2010-2013

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**ECDC** Corporate

## Strategies for disease-specific programmes 2010–2013



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## **Abbreviations**

AMR	Antimicrobial resistance		
CSR	Community Summary Report		
DSN	Dedicated surveillance network		
DSP	Disease-specific programme		
EARSS	European Antimicrobial Resistance Surveillance System		
ECDC	European Centre for Disease Prevention and Control		
EEA	European Economic Area		
EFSA	European Food Safety Agency		
EFTA	European Free Trade Association		
EU	European Union		
EVD	Emerging and vectorborne diseases		
EWGLINET	European Working Group for Legionella Infections Network		
EWRS	Early warning and response		
FWD	Food- and waterborne diseases and zoonoses programme		
HAI	Healthcare-associated infections		
IHR	International Health Regulations		
MS	Member States		
RASFF	The rapid alert system for food and feed		
SMP	Strategic multi-annual programme		
VAESCO	Vaccine Adverse Event, Surveillance and Communication		
VENICE/VENICE II	Vaccine European New Integrated Collaboration Effort		
VPD	Vaccine-preventable diseases		
WHO	World Health Organization		

## **Executive summary**

Based on the European Centre for Disease Prevention and Control's (ECDC's) strategic multi-annual programme (SMP), from 2010 on ECDC will shift its focus from building up the core public health functions (surveillance, scientific advice, preparedness and response, health communication) to disease-specific work.

Over the past several years, ECDC has started building up the basic tools for this task through intensified scientific work, building up specific databases, networks and methodologies. However, as the SMP sets only general objectives for all the disease-specific programmes (DSP), there has been no clarity on the specific long-term objectives of each of these DSPs. This is further complicated in that these six programmes are different; they cover a diverse number of infectious diseases (from tuberculosis to more than 20 in food- and waterborne diseases and zoonoses) and they are in the different stages of development.

Therefore, to further facilitate the development of each of these DSPs in the coming years, DSP coordinators and their teams have worked intensively to develop their long term vision; specifically, where they want to be with their specific programmes by the end of 2013. This process has been facilitated by a small, internal steering group helping the different programmes to find a common, acceptable level of detail for strategy.

This document sets out the strategic priorities for all six ECDC DSPs from 2010 to 2013 based on a short description of the epidemiological background, context in which ECDC works on that specific disease or disease group, and defined gaps that require action at the European Union (EU) level.

The following is a list of the DSPs:

- 1. Antimicrobial resistance (AMR) and healthcare-associated infections (HAI);
- 2. Emerging and vectorborne diseases (EVD);
- 3. Food- and waterborne diseases and zoonoses (FWD);
- 4. Respiratory tract infections (influenza, legionella, and tuberculosis);
- 5. Sexually transmitted diseases, including HIV/AIDS, hepatitis, and other blood borne viruses; and
- 6. Vaccine-preventable diseases (VPDs).

This document follows the structure of ECDC's SMP and the disease-specific strategies that fall under Target 1: *By* 2013, ECDC will have made significant contributions to the scientific knowledge base of communicable diseases and their health consequences, their underlying determinants, the methods for their prevention and control, and the design characteristics that enhance effectiveness and efficacy of their prevention and control programmes.

**Strategy 1.1**: To enhance the knowledge of the health, economic, and social impact of communicable diseases in the EU. This includes all surveillance-related strategies.

**Strategy 1.2**: To improve the scientific understanding of communicable disease determinants. This includes all strategies towards specific and scientific studies.

**Strategy 1.3**: To improve the range of the evidence base for methods and technologies for communicable disease prevention and control. This includes all strategies towards developing guidance.

**Strategy 1.4**: To contribute to the strengthening of programmes for communicable disease prevention and control at EU level and, upon request, in individual Member States. This includes the strategies towards co-ordination, training, monitoring and evaluation, and communication.

It should be kept in mind that ECDC covers a range of diseases for which political priorities at the EU level have impact and that the field of communicable diseases, from a scientific and medical point of view, is in constant evolution. Therefore, although this document is a long-term strategy, it needs sufficient flexibility to be able to follow and adapt to such evolutions in an efficient way.

#### Background

The strategic multi-annual programme 2007-2013 was adopted by the Management Board in June 2007.

This paper 'Strategies for disease-specific programmes 2010–2013' was adopted by the Management Board in November 2009.

## **1 Introduction**

## 1.1 Legal framework to address communicable diseases at European and global levels

The legal basis for community action in the field of public health is stipulated in Article 152 of the Treaty establishing the European Community<sup>i</sup>. Even though there were informal surveillance activities at the Community level since the mid 1980s addressing recognised threats posed by communicable diseases (e.g., HIV/AIDS), it was only in 1999 that the Network of Communicable Diseases started its work (Decision 2119/98/EC<sup>ii</sup>of the European Parliament and the Council). This network builds on the work done together with the EU Member States (MS) and international partners and consists of two pillars: surveillance and early warning and response systems (EWRS). The list of communicable diseases to be covered by the EU-wide surveillance, and the criteria for their selection, was set out in Decision 2000/96/EC<sup>iii</sup>. Early warning and response is a system linking the Commission and public health authorities in the MS responsible for risk management and it is regulated by the Commission Decision 2000/57/EC<sup>iv</sup>. Since November 2007, ECDC supports the Commission by operating this EWRS IT tool.

The Founding Regulation of the  $\text{ECDC}^{\vee}$  sets out the mandate of the Centre as well as the obligations for the MS regarding the provision of data, EWRS collaboration and sharing of resources. The work of the ECDC is also closely linked to legal international instruments; in particular, International Health Regulations (IHR), which are binding in 194 countries globally, including all the EU MS.

Based on the shared competencies in the field of public health, there are also a number of non-binding initiatives (e.g. Council Conclusions, Council Recommendations, Commission Communications) setting the direction of ECDC's disease-specific work. As the development of these initiatives can be started by several sources, they will remain a challenge which will require ECDC to adapt its work, as appropriate, to possible requests.

## **1.2 ECDC stakeholders**

In disease-specific activities, ECDC builds up its operational capacity both through its own resources and existing capacities in the MS through the Competent Bodies<sup>vi</sup>. European Union MS, EU institutions (the European Commission, European Parliament, and other EU Agencies), and the World Health Organization (WHO) European Region are the closest partners for the ECDC. However, as learned societies, private sector and non-governmental organisations are actively involved in the disease specific actions at global and EU level, ECDC has recognised the need to develop a strategy for stakeholder management to facilitate these important interactions.

## 1.3 Disease-specific programmes and the Strategic Multiannual Programme 2007-2013

The European Centre for Disease Prevention and Control was established in 2005 as an EU Agency to strengthen defences against communicable diseases in Europe. After the start-up phase, ECDC was fully operational in 2007, and the Strategic Multi-Annual Programme (SMP) was developed in a close consultation with its governing bodies. This strategic programme provides the vision and sets the goals for the work of the ECDC. The overall goal until the end of 2009 was to strengthen the internal structures, working methods, and core public health functions (surveillance, preparedness and response, scientific advice, and communication) of the Centre. From 2010 onwards, the emphasis will be shifted to building up and further strengthen the disease specific work and this document is the first concrete step to define the way ECDC will develop its Disease Specific Programmes (DSP) for years to come.

- i http://europa.eu/legislation\_summaries/institutional\_affairs/treaties/amsterdam\_treaty/a16000\_en.htm ii http://eur-lex.europa.eu/pri/en/oj/dat/1998/I\_268/I\_26819981003en00010006.pdf
- iii http://eur-lex.europa.eu/pri/en/oj/dat/2000/I\_028/I\_02820000203en00500053.pdf

iv http://eur-lex.europa.eu/pri/en/oj/dat/2000/l 021/l 02120000126en00320035.pdf

v http://eur-lex.europa.eu/pri/en/oj/dat/2004/l\_142/l\_14220040430en00010011.pdf

vi ECDC Competent Bodies are institutions or scientific bodies providing independent scientific and technical advice or capacity for action in the field of the prevention and control of human disease. They have been designated by the Member States' governments and their list has been compiled by the ECDC Management Board in December 2007.

## 1.4 ECDC inheritance of disease-specific work

One of the driving forces behind the establishment of the ECDC was to have a coordinated way to develop and implement communicable disease surveillance in the EU and within Europe at large. Since 1999, the Community Network on Communicable Diseases has been operational and by the time the ECDC was established there were 17 Dedicated Surveillance Networks (DSN), such as EuroTB, EuroHIV, financed partially through the EC Public Health Programme with coordinating hubs across several EU MS.

Over the last several years, ECDC has conducted extensive evaluations of these DSNs and based on these evaluations relevant operations of these networks have been integrated into ECDC's work. This transition will, for some years, have an effect on the activities of the DSPs of the ECDC, and therefore affect the way some of the short/middle-term strategies are set up.

#### 1.5 Future

So far, the disease-specific work of ECDC has been based on the visions, results and architecture of the EU DSNs. This has formed a solid basis for ECDC's work and has guaranteed a seamless continuation of operations in the transition period. However, the strategic approach for the ECDC disease-specific work is a natural shift from the present vertical and fragmentised approach to a truly horizontal and integrated approach, fully integrating all of the core public health functions of the Centre: surveillance, scientific advice, preparedness, response, training, and communication. The work for the second phase should start now with the involvement of all the units of the Centre, relevant networks, and external stakeholders as appropriate.

## 1.6 Structure of this document

This document sets out the strategic priorities for all six ECDC DSPs 2010-2013 based on the short description of epidemiological background, context where ECDC works on that specific disease/disease group, and defined gaps, which need action at the EU level.

This document follows the structure of ECDC Strategic Multi-Annual programme and disease specific strategies fall under Target 1: *By 2013, ECDC will have made significant contributions to the scientific knowledge base of communicable diseases and their health consequences, their underlying determinants, the methods for their prevention and control, and the designs characteristics that enhance effectiveness and efficacy of their prevention and control programmes.* 

**Strategy 1.1**: To enhance the knowledge of the health, economic, and social impacts of communicable diseases in the EU. This includes all surveillance related strategies.

**Strategy 1.2**: To improve the scientific understanding of communicable disease determinants. This includes all strategies towards specific and scientific studies.

**Strategy 1.3**: To improve the range of the evidence base for methods and technologies for communicable disease prevention and control. This includes all strategies towards developing guidance.

**Strategy 1.4**: To contribute to the strengthening of programmes for communicable disease prevention and control at the EU level and, upon request, in individual MS. This includes the strategies towards co-ordination, training, monitoring and evaluation, and communication.

The European Centre for Disease Prevention and Control covers a range of diseases for which political priorities at the EU level have impact, and the field of communicable diseases is, from a scientific and medical point of view, constantly evolving. Therefore, although this document is a long-term strategy, it needs sufficient flexibility to be able to follow and adapt to such evolutions efficiently.

## 2 Antimicrobial resistance and healthcareassociated infections programme

## 2.1 Scope and context

Antimicrobial resistance (AMR) and nosocomial infections are two special health issues listed in Annex 1 of Commission Decision of 22 December 1999<sup>i</sup> on the communicable diseases to be progressively covered by the Community network<sup>ii</sup>. Nosocomial infections correspond to infections acquired in hospitals. The term 'healthcare-associated infections' (HAI) is now preferred because it includes not only infections acquired in hospitals, but also in other healthcare settings, e.g., long-term care facilities, nursing homes, and home care.

Antimicrobial resistance, i.e., the property of being resistant to one or several antimicrobials used for therapy or prophylaxis, is not a disease but a characteristic that may apply to each of the microorganisms responsible for the communicable diseases listed in Commission Decision 2000/96/EC and for nosocomial and other HAIs.

The issues of AMR and HAI overlap widely, but are not synonymous. Healthcare-associated infections are often due to antibiotic-resistant bacteria, but not always. Inversely, antibiotic-resistant bacteria, including multidrug-resistant types, are often responsible for HAI but they are also responsible for infections in outpatients and found as part of the flora of healthy individuals, in pet animals and in the environment. They are also responsible for infections, and are isolated from food-producing animals and sometimes from foods.

## 2.2 Epidemiological background

Antimicrobial resistance and healthcare-associated infections are among the most serious public health problems globally and in Europe.

Each year in the EU, approximately four million patients acquire an HAI and approximately 37 000 of them die as the direct result of the infection. The death toll directly attributable to HAI is comparable to that of road accidents. Additionally, it is estimated that HAIs indirectly contribute to a further 111 000 deaths each year.

Many, but not all, of these HAIs are due to multidrug-resistant bacteria such as meticillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *enterococci* (VRE), extended-spectrum beta-lactamase (ESBL)-producing Enterobacteriaceae, multidrug-resistant *Pseudomonas aeruginosa* and *Clostridium difficile*.

There are large inter-country variations in the proportion of resistant bacteria in the EU and these variations, often showing a north-to-south gradient, can be observed for most antimicrobial-resistant bacteria surveyed by the European Antimicrobial Resistance Surveillance System (EARSS). There are also large variations in antibiotic use among EU MS as shown by data from the European Surveillance of Antimicrobial Consumption project. Once controlled for size of population, the MS that use the most antibiotics for outpatients (Greece and Cyprus) use approximately three times more than MS that uses the least (the Netherlands). Levels of antibiotic consumption have been shown to correlate with levels of antibiotic resistance; i.e., the more antibiotics that are being used in a population, the more resistance to antibiotics there will be in bacteria responsible for infections in that population.

In several countries, decreasing trends in AMR are being observed for MRSA. The EARSS Annual Report 2007 indicated that seven MS now report significantly decreasing percentages of MRSA among *Staphylococcus aureus* from bloodstream infections. This is likely due to increased efforts on infection control, hand hygiene, and antibiotic policies in hospitals in these MS, as demonstrated by national data from Slovenia, France and the UK. Despite these encouraging experiences, AMR is still high or increasing in most MS, in particular for common Gramnegative bacteria such *Escherichia coli, Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*.

Because antimicrobial-resistant microorganisms fail to respond to therapy, infections due these microorganisms result in prolonged illness, longer stays in hospitals and a greater risk of death. The number of yearly deaths in the EU directly attributable to five common multidrug-resistant bacteria often responsible for HAI is estimated at 25 000.

Additionally, cases of infections due to bacteria totally or almost totally resistant to antibiotics are currently emerging in the EU. Examples of such bacteria are carbapenemase-producing Enterobacteriaceae (often *Klebsiella pneumoniae*), and multidrug-resistant *Acinetobacter*. There is no rational choice of antibiotic therapy for treating

<sup>&</sup>lt;sup>i</sup> <u>http://eur-lex.europa.eu/pri/en/oj/dat/2000/I\_028/I\_02820000203en00500053.pdf</u>

ii http://eur-lex.europa.eu/pri/en/oj/dat/1998/I\_268/I\_26819981003en00010006.pdf

such patients and treatment often relies on old and toxic antibiotics such as colistin. This new trend is worrying as there are very few compounds in the research and development pipeline that would potentially have activity against these bacteria and could be marketed within the next 5–10 years.

## 2.3 Existing initiatives

In 2001, the European Commission (EC) published the Community strategy against antimicrobial resistance<sup>i</sup>. In November 2001, EU health ministers adopted a Council Recommendation on the prudent use of antimicrobial agents in human medicine with a series of specific measures aimed at containing the spread of antimicrobial resistance<sup>ii</sup>. An evaluation of the implementation of the Council Recommendation was performed by the EC in 2003<sup>iii</sup> and a second evaluation is currently being performed. In June 2008, EU health ministers adopted the Council Conclusions on AMR that reiterated their call for action to contain antimicrobial resistance<sup>iv</sup>. In June 2009, EU health ministers adopted another Council Recommendation on patient safety including the prevention and control of HAI<sup>v</sup>. Finally, the Commission is preparing a staff working paper on AMR to be released before the end of 2009.

In 2001, WHO launched its Global Strategy for Containment of AMR<sup>vi</sup>. Since 2004, WHO has, through its World Alliance for Patients Safety, launched several Global Patients Safety Challenges<sup>vii</sup>. The first challenge, 'Clean Care Is Safer Care', focused on prevention and control of HAI through improving hand hygiene practices. The second and third challenges focus on safer surgery and AMR, respectively.

## 2.4 Major gaps at the EU level

Despite all of these initiatives, there are still several gaps that need to be addressed. Dedicated surveillance networks for AMR, antimicrobial use and HAI do not cover all MS. Additionally the range of infections, microorganisms and antimicrobials covered by these surveillance systems need evaluation to ensure that they still cover current issues in the area of AMR and HAI. For example, there is a need to address emerging microorganisms such as *Clostridium difficile* and bacteria that are totally or almost totally resistant to antibiotics.

There are also gaps in our knowledge about the current state of MS on the determinants of AMR such as over-thecounter use and self-medication of antibiotics, and the use of alcohol-based products for hand hygiene.

Access to evidence-based information on prevention and control of AMR and HAI is often difficult. Although improving, the dissemination of knowledge about prevention and control measures into practice and implementation of the Council Recommendations remain a challenge for many MS. Finally, awareness about AMR issues, prudent use of antibiotics and good hygiene practices among the general public and healthcare professionals are still poor in many MS.

i European Commission. Communication from the Commission of 20 June 2001 on a Community strategy against antimicrobial resistance. <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52001DC0333:EN:HTML</u>

ii Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine (2002/77/EC). <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:034:0013:0016:EN:PDF</u>

<sup>&</sup>lt;sup>iii</sup> Report from the Commission of 22 December 2005 on the basis of Member States' reports on the implementation of Council Recommendation (2002/77/EC) on the prudent use of antimicrobial agents in human medicine. <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0684:FIN:EN:PDF</u>

<sup>&</sup>lt;sup>iv</sup> Council Conclusions on Antimicrobial Resistance (AMR). 2876th Employment, Social Policy, Health and Consumer Affairs Council meeting Luxembourg, 10 June 2008. <u>http://www.consilium.europa.eu/ueDocs/cms\_Data/docs/pressData/en/lsa/101035.pdf</u>

<sup>&</sup>lt;sup>v</sup> Council Recommendation of 9 June 2009 on patient safety including the prevention and control of healthcare associated infections (2009/C 151/01).

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:151:0001:0006:EN:PDF

<sup>&</sup>lt;sup>vi</sup> WHO Global Strategy for Containment of Antimicrobial Resistance (WHO/CDS/CSR/DRS/2001/2/EN) <u>http://www.who.int/entity/csr/resources/publications/drugresist/en/EGlobal Strat.pdf</u>

<sup>&</sup>lt;sup>vii</sup> World Alliance for Patient Safety. <u>http://www.who.int/patientsafety/about/en/index.html</u>

## 2.5 ECDC strategic priorities

By 2013, ECDC should be the reference centre that MS, EEA/EFTA and neighbouring countries consult for information and advice on AMR and HAI, and should have become an essential partner in this area for the EU and other stakeholders worldwide. By providing support to MS, EEA/EFTA countries and neighbouring countries should have made a significant contribution to implementation of the Council Recommendations on the prudent use of antibiotics in human medicine and on patient safety including the prevention and control of HAI.

The European Centre for Disease Prevention and Control should be regarded as the institution coordinating AMR and HAI activities in the EU and promoting the exchange of experiences and best practice among MS in this field. This will be achieved through close collaboration with key partners, such as MS and their competent bodies, the Commission and other relevant international bodies and networks in order to achieve the following goals:

- 1 To enhance the knowledge of the health, economic, and social impact of communicable diseases in the EU via the following concrete steps:
  - maintaining and improving surveillance of AMR and of antimicrobial consumption (short/medium term);
  - maintaining and improving surveillance of HAI and implement surveillance of infection control indicators (short/medium term);
  - contributing to the standardisation of AMR, HAI, antimicrobial consumption and infection control monitoring (medium term); and
  - assessing and reporting on AMR and HAI threats (medium term).
- 2 To improve the scientific understanding of communicable disease determinants by documenting and reporting on AMR and HAI determinants (long term).
- 3 To improve the range of the evidence base for methods and technologies of communicable disease prevention and control by ensuring the following:
  - providing evidence-based guidance on prevention and control of AMR and HAI (short term);
  - providing scientific opinions and contributing to inter-agency collaboration on AMR and HAI (short term); and
  - monitoring and report on upcoming AMR and HAI issues (medium term).
- 4 To contribute to the strengthening of programmes for communicable disease prevention and control at EU level and, upon request, in individual MS via the following methods:
  - contributing to coordination of AMR and HAI prevention and control activities in MS through regular meetings of National Focal Points (short term);
  - providing country support on AMR and HAI upon request from MS and neighbouring countries, in particular through country visits (short term).
  - providing training on surveillance, prevention and control of AMR and HAI (medium term).
- 5 To improve awareness of the general public and healthcare professionals about AMR, prudent use of antibiotics and hand hygiene (medium term), including a European Antibiotic Awareness Day campaign.

## 3 Emerging and vectorborne disease programme

### 3.1 Scope and context

The emerging and vectorborne disease (EVD) programme is working towards the development of a wide range of timely and topical assessments of the risks that emerging and vectorborne diseases pose to EU citizens. The following list of major diseases is ranked by primary source of exposure.

#### 3.1.1 Vectorborne disease

- Tickborne diseases (e.g., tickborne encephalitis, Lyme disease, Crimean-Congo haemorrhagic fever, rickettsioses).
- Mosquito-borne diseases (e.g., Chikungunya, Dengue, West Nile, malaria).
- · Sandflyborne diseases (e.g., leishmaniasis)

#### 3.1.2 Zoonotic disease

- · Rodentborne diseases (e.g., Hantavirus, arenavirus, Cowpox virus).
- Diseases from other mammals (e.g., rabies, SARS, plague, *Nipahvirus, Hendravirus, filovirus, poxvirus*).

Only some of the following diseases are under EU-level surveillance covered by Decision 2119/98 (amended 2003/534/EC)<sup>i</sup>: malaria, rabies, Q fever, West Nile, and viral hemorrhagic fevers (VHF). The VHF group includes yellow fever, dengue, Crimean-Congo haemorrhagic fever, *filoviruses* (Ebola and Marburg), *arenaviruses* (Lassa) and *hantaviruses* (Puumala or Sin Nombre). However, the range of diseases has been extended to communicable diseases that may lead to potential emergencies of international concern identified according to Annex 2 of the IHR<sup>ii</sup>.

## 3.2 Epidemiological background

Some emerging and vectorborne diseases are present in Europe and of importance to the EU MS. Several thousand cases of tickborne encephalitis and haemorrhagic fever with renal syndrome (*hantavirus* infection) are reported in Europe each year. The burden of Lyme disease in Europe is unknown, and Leishmaniasis is present in southern Europe. There have been few cases of West Nile fever in humans in the last decade (e.g., in Italy, Romania and Hungary in 2008 and 2009) highlighting the risk of transmission by blood donations or organ transplants. Crimean-Congo haemorrhagic fever is present in the Balkans; in 2008, human cases were reported in Bulgaria and, for the first time, in Greece. It remains a major public health concern in Turkey, with 1315 cases and 63 deaths in 2008. In 2007, the first outbreak of Chikungunya virus outside tropical countries (Italy) clearly indicated that Europe is at risk. Diseases linked to the spread of the *Aedes albopictus* mosquito have increased in Europe since the 1990's. Hundreds of cases of malaria or dengue are imported each year by tourists and travellers from endemic countries. Plague is absent in Europe but regularly identified in Africa, Madagascar, and USA.

The emergence of SARS in 2003 in south-east Asia and its rapid spread in North America and Europe is an example of the risks that emerging diseases represent. Rabies is still present in a few European countries; several re-introductions by pets from endemic regions (e.g., North Africa) have been notified in the recent years. Pet rats transmit cowpox to humans as observed in Germany and France in January 2009. Imported viral haemorrhagic diseases with risk of HAI, such as Lassa fever in patients returning from West Africa, have been reported (UK 2009). In September 2008 a new arenavirus, called the Lujo virus, was discovered in South Africa in a patient from Zambia with several fatal cases of healthcare associated transmission. The discovery of Ebola-Reston in pigs in the Philippines at the end of 2008 is a further example of a communicable disease of potential public health importance, even if clinical disease in humans has not been identified. Other diseases transmitted by vectors, such

<sup>&</sup>lt;sup>1</sup> Commission decision of 17 July 2003 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions for communicable diseases (notified under document number C(2003) 2301). <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:184:0035:0039:EN:PDF</u>

<sup>&</sup>lt;sup>ii</sup> Commission decision of 18 December 2007 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions (notified under document number C(2007) 6355) <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:344:0048:0049:EN:PDF</u>

as Chaga's disease from South America, are under the programme's scope which is important due to the possibility of transmission via blood transfusion. Concerns about other arthropods (e.g., bedbugs, lice) are increasing.

## 3.3 Existing initiatives

The EVD programme contributes to strengthening EU-wide preparedness and response by providing MS with access to expertise, the latest scientific knowledge, and a wide range of other tools to support decision making. A coordinated multi-disciplinary approach is required to cover EVD as this approach involves environmental, entomological and behavioural studies. It links between veterinarians, physicians, and a wide range of laboratory expertise and academic research for a better understanding of the mechanisms leading to resurgence of EVD, and to bring to bear appropriate measures for prevention and control.

To achieve the set goals, the programme is pursuing a networking approach through which ECDC will play a central role in establishing and maintaining specific European networks of expertise: laboratory experts for outbreak assistance and support; clinical experts in tropical and travel medicine; and entomology and public health experts providing information on arthropod-borne surveillance for public health. Based on this network, generic tools will be developed to support MS in strengthening preparedness and response actions and which may even be applicable to other diseases with similar vectors/hosts.

Additionally, the programme needs to collaborate in an integrated manner with European research projects such as emerging diseases in a changing European environment (EDEN), the International Network for Capacity Building for the Control of Emerging Viral Vector Borne Zoonotic Diseases (ArboZooNet) or the Network for Excellence for Epizootic Disease Diagnosis and Control (Epizone), all of which work on specific diseases<sup>1</sup>. Equally, the programme needs to work closely with other European agencies (e.g., European Environmental Agency (EEA), European Food Safety Agency (EFSA)). Nevertheless, collaboration should not be limited to Europe but should be strengthened at the international level with international organisations (e.g., WHO, the World Organization for Animal Health (OIE), the Food and Agriculture Organization of the United Nations (FAO)) or non-governmental organisations.

## 3.4 Major gaps at the EU level

The spectrum of diseases covered by the programme requires a wide range of expertise and involvement from many stakeholders for a better understanding of the factors of emergence and spread. The integration of environmental factors and behavioural changes are essential. A large variety of diseases are zoonoses and links with veterinary medicine, primarily at the EU level, need to be reinforced.

One specific challenge for the programme is the risk of a fragmented approach when dealing with multiple stakeholders. For this reason, the development of an integrated process would provide added value from a public health perspective at the EU level. For example, the objectives of project EDEN are to describe, explain and predict the impact of environmental changes on human health. Core scientific expertise within the programme would need to be reinforced.

In terms of vectorborne diseases, WHO has developed new strategies for prevention and control that emphasise 'integrated vector management' as an approach that reinforces links between health and environment in an attempt to optimise benefits to both. A coordinated approach on pest control issues by European agencies— potentially involving ECDC, the European Medicines Agency (EMEA), the European Chemicals Agency (ECHA), EEA and the EC—would be suitable in determining ECDC's possible role in vector control issues.

## 3.5 ECDC strategic priorities

- 1 To enhance the knowledge of the health, economic, and social impact of communicable diseases in the EU through the following measures:
  - setting up joint surveillance of EVDs with WHO and other international key stakeholders with a clear division of work;
  - setting up information systems to collect standardised data on EVDs; and
  - assisting MS assess the burden of these diseases.
- 2. To improve the scientific understanding of communicable disease determinants by improving knowledge of determinants—including environmental changes—that favour the emergence and spread of these diseases.

<sup>&</sup>lt;sup>i</sup> <u>www.eden-fp6project.net, www.arbo-zoo.net</u>, <u>www.epizone-eu.net</u>

This will be accomplished by enhancing liaisons with research projects on these diseases at EU and international levels.

- 3 To improve the range of the evidence base for methods and technologies for communicable disease prevention and control through the following suggestions:
  - setting up an evidence database to help MS in the decision making process regarding EVDs;
  - developing specific tools (e.g., risk assessment tool for West Nile fever) to support MS strengthen preparedness and response actions applicable to other EVDs.
- 4 To contribute to the strengthening of programmes for communicable disease prevention and control at the EU level and, upon request, in individual MS by implementing the following concepts:
  - strengthening collaboration and networks through the development and coordination of a wellconnected European network of experts in the field of EVDs;
  - prioritising diseases that are the most important for Europe in terms of prevention and control, and on that basis identifying the main gaps for a rational European EVD prevention and control strategy;
  - ensuring regular updates of ECDC's website on EVDs for the general public and health professionals.
     developing the means to support the communication of key public health messages (short/medium term).

From 2010 to 2012, the programme will prioritise activities regarding tickborne diseases, focusing primarily on Lyme disease, tick-borne encephalitis and Crimean Congo haemorrhagic fever, and secondarily on rickettsioses.

## 4 Food- and waterborne diseases and zoonoses programme

## 4.1 Scope and context

The food- and waterborne diseases and zoonoses (FWD) programme contains 20 diseases covered by EU level surveillance. Additionally, norovirus infection is included in the programme to address the need for guidance in the prevention and control of it at the EU level. Diseases under the programme will be divided into four groups based on the pathogen types and characteristics. This division allows more efficient planning and enables addressing activities in different areas, and it also ensures the consideration of all diseases when planning annual work programmes according to the strategy. The four groups are as follows:

- Common food- and waterborne bacterial diseases, including the following:
   salmonellosis, campylobacteriosis, STEC/VTEC infection<sup>i</sup>, shigellosis, listeriosis, yersiniosis;
- Parasitic diseases, including the following:
   Cryptosporidiosis, giardiasis, echinococcosis, toxoplasmosis, trichinosis;
- Rare food- and waterborne diseases and zoonoses, including the following:
   Anthrax, botulism, brucellosis, cholera, variant Creutzfeldt Jacob disease(vCJD) and other transmissible spongiform encephalopathies (TSE), leptospirosis, tularaemia;
- 4 Viral enteric pathogens, including the following:
  Hepatitis A and norovirus.

Due to the nature of the programme—covering 21 diverse diseases—the strategy needs to have a stepwise approach. In the coming years, to further guide the development of this strategy and other priorities, appropriate actions at the EU level and expected outcomes will be assessed systematically through a thorough consultation process.

## 4.2 Epidemiological background

**Common food- and waterborne bacterial diseases** constitute the majority of all reported food- and waterborne diseases in the EU. The reported cases of salmonellosis are decreasing due to intensified prevention and control programmes in the EC farms, but campylobacteriosis still remains the most frequently reported food- and waterborne disease in the EU. Until 2006, the number of reported listeriosis cases had increased in many MS, particularly among the elderly, with high reported case fatality ratios around 20%. Incidence of STEC/VTEC infections has decreased substantially since 2004. After several years of declining shigellosis notification, rates turned upwards in 2007 and a newly recognised potential threat—via fresh vegetables imported from third countries—was identified. After several years of decline, reported yersiniosis cases increased in 2007, requiring further analyses of the potential cause.

**Parasitic diseases:** In general, the number of reported parasitic diseases has been in decline for several years. Since 2007, however, after two new MS joined the EU, the total number of reported giardiasis cases increased substantially. In 2006, there was a sharp peak of notified toxoplasmosis cases at the EU level. Echinococcosis and trichinosis are still reported in relatively high numbers (100–300 cases annually) in some MS, although the parasites that cause these diseases have been mainly detected in wild animals.

**Rare food- and waterborne diseases and zoonoses** is a mixed group of diseases with low notification rates in the EU MS. However, reporting by geographical areas may vary; e.g., brucellosis is much more common in some of the Mediterranean countries than in other parts of Europe. The numbers of brucellosis cases are declining in the EU but countries that have non-official *Brucella* free (non-OBF) status still experience outbreaks caused by contaminated food products; e.g., cheese. Since 2001, vCJD has become very rare due to intensified prevention and control measures at the Community level<sup>ii</sup>. However, blood transfusions have now been identified as a new mode of transmission.

**Viral enteric diseases**: Notified hepatitis A cases have reduced steadily for several years, although foodborne outbreaks, sporadic travel-related cases and nationwide outbreaks among injecting drug users (IDU) are still reported. Norovirus infections cause large outbreaks in settings with frequent close contact between persons in

<sup>&</sup>lt;sup>i</sup> Shiga-toxin producing Escherichia coli/Verocytotoxinogenic Escherichia coli

<sup>&</sup>lt;sup>ii</sup> Regulation EC No 999/2001

hospitals, schools, and community gatherings. New waves of norovirus infections occur throughout the year due to regular antigen shifts, high person-to-person transmission rates, and the capability of the virus to survive a long time in the environment. Norovirus has also a remarkable potential to cause foodborne outbreaks.

## 4.3 Existing initiatives

Due to the major modes of transmission via food, water and animals, several stakeholders outside the public health field play essential roles in the prevention and control of food- and waterborne diseases. At the Community level, the Commission has initiated several baseline studies to assess the prevalence of *Salmonella* and *Campylobacter* in farm animals since 2004. The European Food Safety Authority plans and leads the execution of these studies in the MS in close collaboration with the Commission. Based on the results of the baseline studies, reduction targets have been set up for the MS and harmonised monitoring of *Salmonella* and *Campylobacter* prevalence at the primary production level has been performed since 2007. In addition, regulation 2073/2005<sup>1</sup> lays down microbiological criteria for food providing harmonised prevalence data on *Salmonella* and *Campylobacter* in food safety authorities, allowing quick warning of risk for exposure via contaminated food in other EU countries and outside of the EU. The Commission has established several veterinary Community Reference Laboratories for specific pathogens; e.g., *Salmonella, Campylobacter, Listeria,* and VTEC. Based on the Council Directive<sup>ii</sup>, the Commission monitors outbreaks of defined animal diseases through the Animal Disease Notification System and a new Animal Disease Information System, which is still in development.

The Zoonoses Directive<sup>iii</sup> provides an important legislative framework requiring MS to report data on specified zoonoses at the EU level. Based on this data, EFSA produces an annual Community Summary Report (CSR) on selected zoonoses together with ECDC. The jointly prepared CSR links human data with food and animal data and thus allows the assessment of public health impact of measures taken by food and veterinary authorities. Based on the Zoonoses Directive, MS are also obliged to report foodborne outbreaks to the Community. The European Food Safety Authority is responsible for producing an annual Community report on foodborne outbreaks.

## 4.4 Major gaps at the EU level

A common feature for food- and waterborne diseases is that only a small proportion of human infections are captured by national surveillance systems. This is mainly due to the variations in infrastructures (e.g., access to healthcare) and reporting systems (i.e., only a small proportion of diagnosed cases are reported). Therefore, there is a need to develop new tools to assess the true incidence of these diseases and the current level of under-reporting. Some other essential areas to improve are laboratory diagnostics and data quality (standardisation of methods, coordination of development of typing methods for surveillance, external quality assurance etc.), including completeness of reporting, comparability of data, and support to national surveillance systems. These form the basis for invaluable analyses of data, particularly when combined with information from other sources like the existing monitoring and control programmes at the farm level and in the whole food chain, as well as with the environmental/socio-demographic data collected by Eurostat. Thus, joint analyses with EFSA and Eurostat are to be enforced. The data collected through other existing systems, like ECDC's urgent inquiry network and EFSA's foodborne outbreak reporting need to be further utilised, and this information should be combined with analysed surveillance data in the annual reports. Outputs from surveillance data need to be developed to provide timely information for the public and experts.

Food and animal trade plays an important role in the spread of zoonotic diseases. Intensified multidisciplinary collaboration is a prerequisite for effectively combating food- and waterborne diseases at the EU level and in the MS. Good collaboration between food, veterinary, and public health authorities is essential for detection of and response to multinational dispersed clusters and outbreaks that spread in the EU through contaminated imported food or animals. Existing alert systems in the EU, ECDC's urgent inquiry network (formerly Enter-net activity), EWRS, RASFF and EFSA's new Emerging Risks Unit, need to be linked in an effective and meaningful way to ensure timely and appropriate information exchanges to prevent and halt the spread of diseases. Appropriate typing methods need to be integrated into the surveillance to enable early detection of dispersed clusters and outbreaks caused by distribution of contaminated food. Member State reporting of foodborne outbreaks should be further supported through typing in order to assess the attribution of the source of infection to different types of food.

<sup>&</sup>lt;sup>i</sup> Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

<sup>&</sup>lt;sup>ii</sup> Council Directive 82/894/EEC on the notification of animal diseases within the Community

<sup>&</sup>lt;sup>iii</sup> Directive 2003/99/EC of the European Parliament and of the Council on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC

Norovirus causes an enormous disease burden in different community settings and therefore efforts are needed to assess appropriate measures in the prevention and control of these events. Another area where further efforts are required are with CJD and other transmissible spongiform encephalopathies; EU level guidance on prevention is needed, particularly in the healthcare settings.

## 4.5 ECDC strategic priorities

The ECDC FWD programme has the following general objectives: to improve the surveillance system in the EU; to increase the scientific knowledge regarding aetiology, risk factors and the burden of food- and waterborne diseases; to facilitate cooperation between public health, veterinary and food safety sectors; to strengthen the capacity of the EU MS to respond to and prevent food- and water-borne diseases; and to improve early detection of and coordinated response to food- and waterborne disease outbreaks with an EU dimension. The specific goals of these objectives include the following:

- 1 To enhance the knowledge of the health, economic, and social impact of communicable diseases in the EU by ensuring the following steps occur:
  - establishing enhanced surveillance for food- and waterborne diseases where appropriate;
  - supporting harmonisation of methods and procedures in surveillance; particularly looking for harmonisation of laboratory methods with food and animal laboratories, where appropriate;
  - developing molecular surveillance for food- and waterborne diseases to support early detection of dispersed clusters and outbreaks and to support a multidisciplinary response to multinational foodand waterborne diseases events; and
  - enhancing linkage and analysis of data from different sources to surveillance data.
- 2 To improve the scientific understanding of communicable disease determinants through the following activities:
  - promoting joint studies with EFSA and Eurostat;
  - promoting the use of novel techniques to assess the burden of food- and waterborne diseases; and
  - promoting collaboration between the nominated experts within the food- and waterborne disease surveillance network.
- 3 To improve the range of the evidence base for methods and technologies for communicable disease prevention and control through the following procedures:
  - performing feasibility studies related to the development of surveillance for food- and waterborne diseases (e.g., assessing the usefulness of laboratory methods and techniques); and
  - producing guidance for the prevention and control of diseases, where appropriate.
- 4 To contribute to the strengthening of programmes for communicable disease prevention and control at the EU level and, upon request, in individual MS via the following methods:
  - supporting existing Community control programmes for food- and waterborne diseases;
  - evaluating national surveillance systems for food- and waterborne diseases;
  - evaluating EU-wide food- and waterborne disease surveillance systems; and
  - providing focused training on specific needs identified in the MS or required to support the development of molecular surveillance.

## **5 Respiratory tract infections programme**

The ECDC respiratory tract infections programme covers three diseases: influenza, legionellosis, and tuberculosis.

## 5.1 Scope and context

#### 5.1.1 Influenza

The ECDC influenza activities cover seasonal influenza, pandemic preparedness and animal (avian) influenzas in close liaison with the vaccine preventable diseases (VPD) programme.

The most effective countermeasures against influenza are annual vaccinations with seasonal vaccines and personal hygiene measures. Current policies on vaccination in Europe focus on immunising the elderly and those with chronic medical and physical conditions but this will need to be reviewed in the light of experience with the 'new' seasonal influenza following the 2009 pandemic. Few countries have a formal control or immunisation programme and there are major differences in use of vaccines across Europe. In 2007, the likelihood of an older person being immunised varied 40 fold between countries, from 2 to 80%. At the same time, influenza can be expected to become burdensome and immunisation more worthwhile in Europe with its aging population and larger numbers of people living with well controlled chronic illnesses. Pandemic preparedness is more standardised across Europe, but the experience of the 2009 pandemic has revealed country- and topic-specific deficiencies, and priorities for strengthening preparedness will need to be reviewed following evaluations.

One key aim for ECDC Influenza activities is to reduce the burden of seasonal influenza in Europe during interpandemic periods by supporting MS, the Commission, and the WHO in implementing the 2009 EU recommendation on seasonal influenza vaccination.<sup>i</sup> Another aim is to improve European pandemic preparedness and response, providing evidence-based analyses and lessons to improve pandemic response to the current and future pandemics.

#### 5.1.2 Legionellosis

The surveillance of Legionnaires' disease at the European level and the monitoring of travel-associated cluster response activities are carried out by the European Working Group for Legionella Infections Network (EWGLINET), one of the last dedicated surveillance networks that are still outsourced. As of 1 April 2010, ECDC will have fully integrated the coordination of the network and its activities. The surveillance focus on travel-associated cases and clusters of Legionnaires' disease is particularly relevant as many clusters consist of single cases from different countries and would have never been detected without a European surveillance scheme. The ageing population in most of Europe and their continued propensity to travel lends additional importance to the surveillance of a disease that tends to be associated with old age and travel accommodation sites in classical tourist destination countries. The day-to-day search for Legionnaires' disease clusters, in conjunction with the rigorous monitoring of local response activities and public risk communication (offender site list), has been shown to prevent subsequent cases. Maintaining this important public health impact beyond mere case counting will be the major challenge faced by ECDC after completing the transition of EWGLINET.

#### 5.1.3Tuberculosis

The incidence of tuberculosis (TB) has declined steadily over the past decades in the EU. Figures from the 27 MS are among the lowest in the world, although higher than in other industrialised countries like the USA and Australia. Nevertheless, there is no room for complacency as a similarly favourable epidemiological situation was described in several countries decades ago, resulting in a decrease in awareness and the reduction of resources and services for TB prevention and control. Consequently, there was a re-emergence of the disease fuelled by the HIV epidemic, the development of multi-drug resistant TB (MDR TB), and the aggregation of burden among vulnerable populations.

As a result, renewed efforts in control programmes and activities to ensure early diagnoses, availability of appropriate therapy, and completion of treatments are required. It also prompts actions targeted at specific groups and settings. The ECDC TB team operates within this context, aiming at providing support and expertise in recognised key areas for optimising TB control in the EU.

<sup>&</sup>lt;sup>i</sup> Council of the European Union. Council Recommendation of 22 December 2009 on seasonal influenza vaccination. 2009/1019/EU. Official Journal of the European Union. 2009. L 348/71. <u>http://eur-lex.europa.eu/Lex.UriServ.Lex.UriServ.do?uri=OJ:L:2009:348:0071:0072:EN:PDF</u>

## 5.2 Epidemiological background

#### 5.2.1 Influenza

Epidemics of seasonal influenza take place each winter season in Europe and ECDC estimates that these have caused up to 40 000 additional deaths per year in EU and EEA/EFTA countries. There are no estimates for total morbidity each year, but the estimates are that influenza results in some illness in around 5 to 10% of the population each season with higher rates in younger people.

#### 5.2.2 Legionellosis

For the past few years, travel-associated Legionnaires' disease has annually accounted for almost 1000 cases and approximately 100 clusters in the countries participating in EWGLINET. The case-fatality rate has been around 5%. A large majority of cases and clusters have occurred in France, Italy and Spain. The total annual number of travel-associated and non-travel-associated cases of Legionnaires' disease that are reported retrospectively amounts to about 6000 cases or 1 per 100 000 population, although incidence rates vary considerably between countries. Generally, the trend in numbers of travel-associated cases and clusters of Legionnaires' disease is increasing in Europe while the average size of clusters appears to be decreasing. Known risk factors for acquiring Legionnaires' disease are old age, smoking and immunodeficiency.

#### 5.2.3 Tuberculosis

Despite the global progress that has been made over the past decade, the elimination target of less than one TB case per 1 000 000 population is still far from being achieved. The overall decline in EU and EEA/EFTA countries has been sustained in recent years. Currently, EU data reflect the heterogeneity of the TB situation with three distinct epidemiological groups of countries:

- 1 Low-incidence countries, with cases increasingly aggregating in the immigrant population and other vulnerable groups;
- 2 Countries with relatively moderate to high notification rates that are in decline, with MDR TB still uncommon;
- 3 Countries with relatively high notification rates and with a high proportion of MDR TB cases, but again with declining overall TB rates.

Overall, several epidemiological indicators, such as age distribution, notification of paediatric TB cases and TB meningitis trends, seem to suggest that the downward trend is real and, over the past five years, sustained. Additionally, TB mortality rates remain comparatively low.

Multi-drug resistance remains a major epidemiological feature within the EU. Despite some progress shown in the decline of mainly relapsed and re-treated cases of MDR TB, this remains a substantial challenge. The proportion of MDR TB remains high in the Baltic states, and trends need to continue to be carefully monitored to assess the evolution of the epidemic. The MDR TB picture is further complicated by the fact that monitoring for MDR TB (and consequently, extensively drug-resistant (XDR) TB) is not systematic across the rest of the EU countries.

## 5.3 Existing initiatives

#### 5.3.1 Influenza

Currently, there are several key EU and global initiatives. The World Health Assembly in 2003<sup>i</sup> Recommendation suggested raising levels of seasonal influenza immunisation coverage among elderly people and estimating the burden of influenza in MS. This can be expected to be revised during the planning period. Concerning pandemic preparedness, there is a specific communication from the Council<sup>ii</sup> of 2005 on improving pandemic preparedness and a WHO Global Action Plan<sup>iii</sup> to increase the production and use of influenza vaccines. Revisions to the WHO Pandemic Plans and Guidance are ongoing and will continue in 2010 and beyond.

<sup>III</sup> WHO Global pandemic influenza action plan to increase vaccine supply. WHO Geneva Immunization, Vaccine and Biologicals. Epidemic and Pandemic Alert and Response. September 2006.

http://www.who.int/csr/resources/publications/influenza/WHO\_CDS\_EPR\_GIP\_2006\_1/en/index.html

<sup>&</sup>lt;sup>i</sup>World Health Assembly Resolution: Prevention and control of influenza pandemics and annual epidemics WHA 2003. 56:19 <u>http://apps.who.int/gb/archive/pdf\_files/WHA56/ea56r19.pdf</u>

<sup>&</sup>lt;sup>ii</sup> Communication from the Commission to the Council, the European Parliament, the European economic and social committee and the committee of the regions on pandemic influenza preparedness and response planning in the European Community.

Some important EU projects include I-Move, which provides estimates of vaccine effectiveness, Vaccine European New Integrated Collaboration Effort project (VENICE and VENICE II), an annual survey on seasonal influenza vaccine policies, practices and coverage, and the Vaccine Adverse Event, Surveillance and Communication (VAESCO) project, which develops guidelines and sustainable infrastructure to support work by the European Medicines Agency and national agencies for post licensure vaccine safety assessment in the EU, including safety assessment of the newly licensed pandemic flu vaccines.

European surveillance is carried out within the European Influenza Surveillance Network, which is the follow-up to the former EISS<sup>i</sup> network. Since the spring of 2009, surveillance is carried out jointly together with WHO Europe.

#### 5.3.2 Legionellosis

The surveillance of Legionnaires' disease at the EU level, and the monitoring of travel-associated cluster response activities, are currently carried out by EWGLINET and will be transferred to ECDC by 1 April 2010.

#### 5.3.3 Tuberculosis

Several relevant initiatives have been ongoing at the EU level over the past decades. The following initiatives are of key importance to ensure synergy and concerted action in TB control in the EU:

- 'A Framework Action Plan to Fight TB in the EU'<sup>ii</sup>, drafted in 2007, defines the strategy for TB control in the EU and provides the basis for the development and updating of national plans. The European Centre for Disease Prevention and Control has initiated preparatory work in support of the follow-up and implementation of the plan;
- In recognition of the importance of a multi-disciplinary approach towards TB control, two recent Council Conclusions on antimicrobial resistance and migrant health<sup>iii</sup> have called for increased attention to TB control in the context of drug resistance prevention and improvement of the health of migrants, respectively;
- In 2007, the 53 WHO European Region MS signed the Berlin Declaration on Tuberculosis<sup>iv</sup> and committed themselves to providing more political support and resources to control the disease. The Declaration is an important milestone in providing renewed impetus and commitment to the progress towards TB control and elimination in the EU and region-wide.

Surveillance is done jointly with WHO and ECDC within the Euro-TB network.

## 5.4 Major gaps at the EU level

#### 5.4.1 Influenza

Even though the impact of seasonal influenza vaccination programmes in Europe is evident, there are still major gaps in the knowledge, control and prevention of influenza. Surveillance of severe disease and deaths is mostly lacking. Vaccine coverage is poor overall, coverage data are not yet collected in a standardised way and a lack of comparability makes evaluations impossible using this basic indicator. There are uncertainties over the need to immunise children and pregnant women. While the circulating viruses are reviewed annually by WHO's Global Influenza Surveillance Network, informing decisions on the composition of the annual vaccine, there has been no method for evaluating vaccine effectiveness. The Council Recommendation on seasonal influenza vaccination and the WHO Global Action Plan will facilitate the closure of existing gaps; however, this will still need several years of vigorous implementation.

Although preparations in the EU and EEA/EFTA countries by ECDC, the Commission, WHO and the MS themselves have paid off, the experience of the 2009 influenza pandemic has revealed major weaknesses in clinical care and the provision and use of specific pandemic vaccines. Lessons learned will inform the response to the pandemic in 2010 as it moves over to a new seasonal influenza pattern in 2010–2011, strengthening pandemic assessment procedures and improving the response to the next pandemic in Europe.

http://ecdc.europa.eu/en/publications/Publications/0803 SPR TB Action plan.pdf

<sup>&</sup>lt;sup>i</sup> European Influenza Surveillance Scheme

<sup>&</sup>lt;sup>ii</sup> A Framework Action Plan to Fight TB in the EU,

<sup>&</sup>lt;sup>iii</sup> Council Conclusions on Antimicrobial Resistance and Migrant Health <u>http://www.eu2008.si/en/News\_and\_Documents/Council\_Conclusions/June/0609\_EPSCO-AMR.pdf</u> <u>http://register.consilium.europa.eu/pdf/en/07/st15/st15609.en07.pdf</u>

<sup>&</sup>lt;sup>iv</sup> Berlin Declaration on Tuberculosis, <u>http://www.euro.who.int/document/e90833.pdf</u>

#### 5.4.2 Legionellosis

In order to achieve the real added European value from the surveillance of legionellosis, and in particular the travel associated cases, there are still issues that need to be addressed in the coming years.

Many countries in the EU do not report travel-associated cases of Legionnaires' disease for various reasons, such as national data protection issues, lack of awareness among clinicians or insufficient laboratory capacity. Most clusters are only defined epidemiologically by place and time. Full outbreak investigation, including the molecular matching of environmental and human isolates, fails because cases are diagnosed by urinary antigen test and clinical strains are not available.

Finally the capacity of a European surveillance scheme to investigate outbreaks and to protect Europeans travelling outside of Europe remains very limited.

#### 5.4.3 Tuberculosis

Although the epidemiological picture within the EU is generally favourable, diverse problems need to be addressed.

**Heterogeneous strategic requirements:** The strategic approach to control and finally eliminate TB in the EU requires a tailored procedure that recognises the diversity of the epidemiological and control settings among MS. The strategies in the countries nearing the elimination threshold should focus on the following: preventing new infections; sustaining technical expertise to keep up case detection and appropriate care; maintaining awareness among professionals, policy makers and the general public; and addressing actions to vulnerable. In other countries, where TB incidence remains unacceptably high, resistance to the most effective TB drugs (MDR and XDR TB) is a problem and public health capacity needs further investment. They should target their strategies at controlling the disease by strengthening the fundamentals of TB control.

**Vulnerable populations:** These include immigrants from countries with a high TB incidence, prisoners, HIVseropositive persons and the socially and economically disadvantaged. The most vulnerable and excluded groups are the ones that carry the most significant burden of disease and which have the poorest access to services. The evidence around interventions tailored to vulnerable populations requires further assessment in order to develop and implement effective strategies for TB control among these groups. Communication around these strategies needs to be developed on the basis of solid evidence in order to avoid stigmatisation of the affected populations. Enhanced surveillance needs to be improved and should pay particular attention to identifying and describing TB vulnerable populations.

**Optimisation of laboratory network:** The optimisation of laboratory networking is of key importance for a truly region-wide and efficient approach to TB control. Despite the high quality of TB laboratories throughout the EU, further strengthening of networking capacity is needed, particularly in controlling TB drug resistance.

**Case management and treatment monitoring:** Successful TB case management is at the core of any successful programme. Despite advanced health systems available throughout the EU, poor case management remains a key issue. Overall treatment outcome monitoring requires further strengthening in view of the sub-optimal number of countries reporting outcome data and the sub-target level of success rate (<85%).

**Implementation of new tools:** All partners in the EU are involved in continuing efforts to create synergies and encourage innovation through research and development of new vaccines, drugs and diagnostic facilities for TB. However, it is recognised that the integration of new tools in a systematic manner at the programme level is lagging. Furthermore, innovation should be sought in enhancing the operational components of TB control, optimising accessibility to quality TB care for all strata of the EU population.

## 5.5 ECDC strategic priorities

#### 5.5.1 Influenza

- 1 To enhance the knowledge of the health, economic, and social impact of communicable diseases in the EU by implementing the following measures:
  - maintaining and improving influenza surveillance in Europe (short/medium term);
  - managing and monitoring the EU-wide influenza sequencing database (medium/long term); and
     continuing the coordination of the Community Network of Reference Laboratories (medium/long term).
- 2 To improve the scientific understanding of communicable disease determinants via the following methods:
  - producing evidence-based advice for seasonal influenza immunisation with the 'new' seasonal influenza, notably in children and pregnant women across the EU (short term); and

- continuing the Surveillance and Studies in a Pandemic (SSiaP) project (short/medium term).
- 3 To improve the range of the evidence base for methods and technologies for communicable disease prevention and control through the following procedures:
  - providing estimates of 2009 pandemic influenza A(H1N1) vaccine effectiveness and subsequent seasonal vaccines in the EU (short/medium term);
  - coordinating the 'studies' portion of the SSiaP project (short/medium term); and
  - exploring behavioural aspects of influenza control relevant to both the 2009 pandemic and improving seasonal influenza control (short term).
- 4 To contribute to the strengthening of programmes for communicable disease prevention and control at EU level and, upon request, in individual MS through the following methods:
  - supporting the Commission in updating the 2005 Communication on pandemic preparedness and the Member States and the Commission in the implementation of the Council Recommendation on seasonal influenza immunisation;
  - contributing to European Medicine Agency and national systems for monitoring and assessing influenza pandemic vaccine safety specific issues (medium term);
  - piloting a monitoring and evaluation tool for seasonal influenza vaccination programmes (short term);
  - annually monitoring national seasonal influenza vaccine policies, practices and coverage (short/medium term);
  - determining lessons learned from the pandemic in order to provide recommendations on the future strategy for pandemic preparedness activities in the EU along with supporting their implementation (short/ medium term); and
  - developing the means to support the communication of key public health messages (short/medium term).

#### 5.5.2 Legionellosis

- 1 To enhance the knowledge of the health, economic, and social impact of communicable diseases in the EU by implementing the following measures:
  - maintaining surveillance of Legionnaires' disease and enhanced surveillance of travel-associated cases and clusters; and
  - encouraging molecular matching of clinical and environmental *Legionella* isolates in cluster investigations.
- 2 To improve the scientific understanding of communicable disease determinants through the following methods:
  - adding 'risk factors' to surveillance data and monitoring trends in their distribution; and
  - studying associations of certain Legionella sequence types with known risk factors.
- 3 To improve the range of the evidence base for methods and technologies for communicable disease prevention and control through the following procedures:
  - establishing the validity of the currently used epidemiologic travel-associated Legionnaires' disease cluster definition.
- 4 To contribute to the strengthening of programmes for communicable disease prevention and control at the EU level and, upon request, in individual MS by the following methods:
  - maintaining the publication of offender sites and notification of tour operators;
  - supporting standardisation of Legionella diagnostic and typing methods across MS;
  - supporting laboratory investigations of selected community clusters of Legionnaires' disease in MS;
  - supporting training for public health experts from MS; and
  - producing tools for outbreak investigations and making them available online.

#### 5.5.3 Tuberculosis

The overall strategy of the TB work is in line with the following key principles of the TB Action Plan: ensuring prompt and quality TB care for all; strengthening health systems; developing and assessing of new tools; building partnerships and international collaboration; along with being in line with the eight areas of action described in the Plan. The follow-up to the Action Plan, with the identification of key indicators and areas of responsibility, will represent the basis for monitoring progress towards TB elimination in the EU. In particular, the ECDC TB work will aim at addressing the following priorities in the framework of the overall ECDC strategy:

- 1 To enhance the knowledge of the health, economic, and social impact of communicable diseases in the EU by implementing the following measures:
  - maintaining and improving TB surveillance in Europe; and

- analysing and forecasting the impact of social and economical developments on TB epidemiology and control in the EU.
- 2 To improve the scientific understanding of communicable disease determinants through analysing social and environmental determinants of TB in the EU to guide control strategies.
- 3 To improve the range of the evidence base for methods and technologies for communicable disease prevention and control through the following procedures:
  - developing guidance for the introduction of new tools for TB control;
  - launching and coordinating an EU MDR/XDR TB scientific consultation group;
  - evidence assessing of TB control among TB vulnerable populations; and
  - establishing a basis for the start-up of molecular surveillance of TB in the EU.
- 4 To contribute to the strengthening of programmes for communicable disease prevention and control at EU level and, upon request, in individual MS via the following methods:
  - developing the follow-up of the TB Action Plan, including monitoring the implementation plan;
  - coordinating TB surveillance for EU and EEA/EFTA countries;
  - fully developing guidance for support of national TB control plans;
  - coordinating and strengthening the EU TB Laboratory Network (TB-ERLN); and
  - developing the means to support the communication of key public health messages (short/medium term).

## 6 Sexually transmitted infections, including HIV/AIDS and bloodborne viruses

## 6.1 Scope and context

In the EU, several populations are severely affected by the following group of diseases: HIV/AIDS, infections with *Chlamydia trachomatis* (including lymphogranuloma venereum (LGV)), gonorrhoea, syphilis, congenital syphilis and bloodborne viruses (hepatitis B, hepatitis C). The European Centre for Disease Prevention and Control will play a role in the monitoring and evaluation of the communication and subsequent action plan supporting the EU Commission.

## 6.2 Epidemiological background

HIV/AIDS is a significant public health problem in EU and EEA/EFTA countries, although the situation has markedly changed since the beginning of the epidemic in the 1980s. The HIV/AIDS epidemic displays significant heterogeneity across Europe despite some similarities in main trends. In the early 1990s the epidemic was relatively stable in many MS and even showed evidence of decrease. However, most recent trends show a steady increase in new HIV cases reported; e.g., in western EU countries among men having sex with men (MSM) and, among heterosexually acquired HIV cases, in migrants from countries with generalised epidemics. In eastern Europe, the number of reported cases increased sharply since 1994, peaked in 2001, and remains at a high level mainly due to unsafe injecting drug use. HIV morbidity and mortality (mainly due to AIDS) is decreasing in most EU/EEA countries, except in eastern European countries due to the availability of antiretroviral treatment.

Trends in STI show a similar picture: After a period of decreasing incidence in the late 1980s, incidence of most STIs is increasing in Europe and remains a major public health problem. This has been most visible in outbreaks of syphilis and LGV in MSM in several European countries, many of whom are living with HIV<sup>1</sup>. For other STIs, the situation is more complex and STI and HIV can show diverging trends in risk groups. Cases of gonorrhoea and syphilis have increased in many countries and antimicrobial resistance in gonorrhoea has increased significantly in recent years. Trends in chlamydia are difficult to interpret because they are dependent on levels of testing and only a few countries have implemented comprehensive national control programmes. However, it is believed that chlamydia is the most prevalent bacterial STI in Europe. Limited information is available about trends in congenital syphilis and burden of disease.

Hepatitis B and C virus (HBV, HCV) infections cause acute and chronic hepatitis and are the leading causes for hepatic cirrhosis and cancer. Hepatitis and HIV can be transmitted through blood, and screening of blood products and prevention of IDU-associated transmission are top priority public health activities. For hepatitis B, sexual transmission is a significant contributor to transmission. There is a distinct geographical variation in the HBV and HCV incidence and prevalence in EU and EEA/EFTA countries. Both diseases are concentrated in subpopulations, especially in IDU—with 10–100 times higher prevalence than in the general population—and in some migrant and minority populations. Hepatitis B and C viruses cause treatable infections, but a preventive vaccine is only available for HBV. Hepatitis surveillance systems vary across countries and limit the possibilities for measurement of disease burden and impact forecasting. The actual size of infected populations throughout the EU is unknown and uncertainty will remain even if all major transmission modes have been identified. The cost-effectiveness of generalised screening for hepatitis among subpopulation groups and injection equipment exchange among IDU has not been comprehensively evaluated.

## 6.3 Existing initiatives

Heads of State have signed the United Nations General Assembly Special Session on HIV/AIDS (UNGASS) Declaration in 2001 and committed themselves to follow-up on the declaration. Important political declarations on HIV were issued in 2004<sup>ii,iii</sup> and 2007<sup>iv</sup>. A five-year plan to combat HIV in the EU and its neighbouring countries

<sup>&</sup>lt;sup>i</sup>van de Laar MJ. HIV/AIDS and other STI in men who have sex with men – a continuous challenge for public health. Euro Surveill. 2009;14(47):pii=19423. Available online: <u>http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19423</u> Date of submission

<sup>&</sup>lt;sup>ii</sup> Dublin Declaration. <u>http://www.eu2004.ie/templates/meeting.asp?sNavlocator=5,13&list\_id=25.</u>

<sup>&</sup>lt;sup>III</sup> Vilnius Declaration. <u>http://ec.europa.eu/health/ph\_threats/com/aids/docs/ev\_20040916\_rd03\_en.pdf</u>.

<sup>&</sup>lt;sup>iv</sup> Bremen Declaration. <u>http://www.eu2007.de/en/News/download\_docs/Maerz/0312-BSGV/070Bremen.pdf.</u>

was adopted by the EC in 2005<sup>i</sup>, followed by a European parliamentary resolution on early diagnosis and early care of HIV/AIDS in 2008<sup>ii</sup>. At the end of 2009, it is foreseen that the Commission will release a new Communication on the fight against HIV/AIDS in the EU and neighbouring countries. The European Centre for Disease Prevention and Control is expected to play a role in the monitoring and evaluation of the communication and subsequent action plan in order to support the EU Commission.

Enhanced HIV/AIDS surveillance is done jointly with WHO Euro within the European network for HIV/AIDS surveillance. Enhanced surveillance of STIs is set up within the European network for STI surveillance consisting of both epidemiological and microbiological experts.

## 6.4 Major gaps at the EU level

Good quality data from enhanced surveillance programmes are needed for priority setting and long-term responses. Improved compatibility, coverage, and timeliness of reporting are essential for the planning of public health activities and burden of disease estimates. For HIV/AIDS, with long-standing EU-wide surveillance, the challenge is to improve the completeness and accuracy of reporting. For STIs and hepatitides B and C, the challenges are to extend the scope and content of surveillance to obtain comparable data across EU and EEA/EFTA countries. Outbreak investigation, resistance surveillance, laboratory-quality support for STI, and an enhanced surveillance system for hepatitides B and C need to be developed and implemented. Prevention targeting would benefit from behavioural surveillance related to HIV and STI. As wide expertise in this field is already available in the EU and EEA/EFTA, the challenge is to harmonise the processes and to support individual countries.

Concerning the control of HIV, STI and hepatitis, prevention efforts need to be enforced and, in some areas, new and innovative methods need to be developed and evaluated. Prevention strategies and methods at national and international levels need to be adjusted to changing epidemiological situations and target groups. New methods for prevention have to be integrated in strategies and policies. The challenge is to examine the impact, effectiveness and outcome of prevention and intervention measures and to disseminate evidence-based knowledge with respect to control, prevention and intervention measures as guidance.

With respect to responses at national and international levels and given the political commitments in the field of HIV/AIDS, the challenges are to develop a flexible, meaningful and comparable system for monitoring and evaluation (M&E) at the European level and to support building national capacities where necessary. The added value would be that M&E systems would be harmonised and streamlined at both national and international levels and that it will improve compliance in the EU to international responses.

## 6.5 ECDC strategic priorities

The overall strategy is to build capacity at ECDC to ensure that it becomes both a key player in Europe with respect to HIV/AIDS, STIs and hepatitis epidemiology, surveillance, risk assessment and communication to guide, monitor, and evaluate prevention and control programmes, and the reference centre for these activities for all MS in the EU. This will also be achieved through close collaboration with key partners, like MS and their competent bodies, the EC and other relevant international bodies and networks. In particular, ECDC work will aim at addressing the following priorities in the framework of the overall ECDC strategy:

- 1 To enhance the knowledge of the health, economic, and social impact of communicable diseases in the EU by implementing the following measures:
  - maintaining and improving HIV and AIDS surveillance in Europe (short/medium term);
  - implementing enhanced surveillance for STI (short/medium term);
  - developing and implementing enhanced surveillance for hepatitides B and C by establishing a new network for hepatitis surveillance (short/medium term); and
  - forecasting and modelling the HIV/AIDS epidemic (including national HIV prevalence estimates (medium term), undiagnosed fraction of HIV (medium term), and life expectancy and burden of disease (long term).

<sup>&</sup>lt;sup>i</sup> Communication from the Commission to the Council and the European Parliament on combating HIV/AIDS within the European Union and in the neighbouring countries, 2006-2009 COM(2005) 654 final. http://ec.europa.eu/comm/health/ph\_threats/com/aids/docs/com\_2005\_654\_en.pdf.

<sup>&</sup>lt;sup>ii</sup> European Parliament resolution of 20 November 2008 on HIV/Aids: early diagnosis and early care. P6\_TA(2008)0566. <u>http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2008-0566&language=EN</u>

- 2 To improve the scientific understanding of communicable disease determinants through the following methods:
  - supporting MS to implement behavioural surveillance related to HIV and STI by developing toolkit and pilot studies (medium term); and
  - addressing increased risks in vulnerable, marginalised, and socially disadvantaged population groups for HIV and hepatitis (long term).
- 3 To improve the range of the evidence base for methods and technologies for communicable disease prevention and control through the following procedures:
  - providing evidence-based guidance for key prevention interventions, including HIV testing guidance, prevention in MSM and IDU, control of hepatitis.
- 4 To contribute to the strengthening of programmes for communicable disease prevention and control at the EU level and, upon request, in individual MS via the following methods:
  - assessing and evaluating national prevention and control programmes for HIV and STI (long term);
  - developing a flexible M&E system to monitor political commitments at national and international levels (medium term);
  - coordinating support laboratory activities with respect to STI (resistance surveillance in gonococci (short term), diagnostics (long term)) and HIV (HIV incidence, HIV resistance (medium term)); and
  - developing the means to support the communication of key public health messages (short/medium term).

## 7 Vaccine-preventable disease programme strategies

## 7.1 Scope and context

The aim of the vaccine-preventable disease (VPD) programme is to fill the existing knowledge, control and prevention gaps in order to allow an equal access to vaccination programmes of a high quality standard in the EU. The programme provides evidence-based information, along with knowledge and technical support (including support to laboratory activities necessary to monitor vaccine-preventable diseases and impact of vaccine programmes on circulating strains) to help the decision making process and strengthen immunisation programmes. It supports MS, in collaboration with the European Medicine Agency (EMEA) and other relevant partners, to set up reliable systems for evaluating vaccination coverage investigating factors for low coverage and monitoring, and investigating and assessing vaccine safety in the EU in a comparable way. It also supports MS to improve vaccination coverage and to reach elimination goals set in Europe.

The programme covers the following diseases: diphtheria, invasive bacterial diseases (including meningococcal, pneumococcal and *Haemophilus influenzae* infections), measles, mumps, pertussis, poliomyelitis, rabies, rubella, and tetanus. Rotavirus disease, human papilloma virus (HPV) infections and varicella are also targeted by the programme even if not included on the list of Annex I of Decision 2119/98 as new vaccination programmes against diseases that have been started in some EU MS. The programme also addresses vaccination issues related to diseases covered by other programmes at ECDC like influenza, tickborne encephalitis, tuberculosis and viral hepatitis. Generic issues related to immunisation, such as vaccine coverage, effectiveness, and safety, are also dealt within the VPD programme.

## 7.2 Epidemiological background

Vaccination, together with overall socioeconomic improvements, has had a dramatic impact on the infectious disease burden in the EU as in other industrialised countries. Polio has been eliminated, tetanus and diphtheria are under control, the incidence of pertussis has decreased tenfold after vaccine introduction, and measles and congenital rubella are targeted for elimination. However, vaccination has become a victim of its own success. In fact, the virtual disappearance of severe VPDs like polio, tetanus and diphtheria has meant that vaccines now evoke a mixed and often confused response from the public. Frequently, perception of risk has shifted from the disease to the vaccine. When assessing the burden of a VPD it is always important to keep in mind that the observed burden is the result of decades of immunisation activities and that those diseases would still have an enormous potential burden in the absence of a vaccination programme. The following table presents an overview of the current epidemiological situation of VPDs in the EU.

#### Table 1: Overview of the current epidemiological situation of VPDs in the EU.

Disease	severity level	disease incidence	mortality level	level of control in the
		level in the EU	in the EU	EU
diphtheria	very high	very low	very low	close to elimination
Haemophilus influenzae invasive disease	very high	low	low	good
human papilloma virus infections	high	high	high	very poor control
measles	moderate	high	very low	targeted to elimination
meningococcal invasive disease	very high	low	low	acceptable
mumps	moderate	high	very low	low
pertussis	moderate	high	very low	acceptable
pneumococcal invasive disease	very high	moderate	low	low
poliomyelitis	very high	zero	zero	eliminated
rabies (human)	very high	zero	zero	very good
rotavirus disease	moderate	high	very low	no control
congenital rubella	high	low/very low	very low	targeted to elimination
tetanus	very high	very low	very low	very good
varicella	moderate	high	very low	no control

#### Legend

Severity level*:	moderate high very high	moderate case- fatality ratio OR moderate number of sequelae OR moderate hospitalisation rate high case-fatality ratio OR high number of sequelae OR high hospitalisation rate high case-fatality ratio AND high number of sequelae AND/OR high hospitalisation				
		high hospitalisation rate				
Tale						
Disease incidence level (on annual basis):	very low	<1 per 100,000				
, , , , , , , , , , , , , , , , , , ,	low	1-10 per 100,000				
	moderate	1-10 per 10,000				
	high	>1 per 1,000				
Mortality level (on annual basis):		<1 per 100,000				
	low	1-10 per 100,000				
	high	>1 per 10,000				

\* Case-fatality is a ratio between incidance and mortality level. Evaluation of sequelae and hospitalisation rate has been purely qualitative.

## 7.3 Existing initiatives

In 2008, the EC launched an initiative aimed at delivering a proposal for a Council Recommendation on childhood immunisation. The proposal focused on a broad range of topics related to childhood immunisation (including vaccine coverage monitoring, vaccine safety, risk communication, etc.) promoting a series of activities aimed at improving the overall quality level of childhood immunisation in the EU.

The World Health Organization has designated 2010 as the year when measles, rubella and congenital rubella should be eliminated in the European Region. This target is far from being reached and the ECDC, together with other EU institutions, is strongly committed to supporting the WHO and the MS to succeed in this challenge.

The now ECDC-funded Vaccine European New Integrated Collaboration Effort (VENICE and VENICE II) projects promote and share knowledge and best practices regarding vaccination among European states. VENICE II will also provide information on the impact of newly introduced vaccinations in selected MS and will also collect

information at the sub-national level for selected vaccines. The ECDC-initiated VAESCO project develops guidelines and a sustainable infrastructure for postlicensure vaccine safety assessment in the EU (including the newly licensed pandemic flu vaccines) using linkage of large computerised clinical databases and immunisation registries.

European Union surveillance of VPDs is carried out by ECDC and builds on several previous dedicated surveillance networks (DSNs): European Union Invasive Bacterial Infections Surveillance Network (EU-IBIS), which deals with invasive diseases caused by *H. influenzae* and *N. meningitidis*; European surveillance network for vaccine-preventable diseases (EUVACNET), which deals with the surveillance of measles, rubella, pertussis, mumps and varicella; and the Diphtheria Surveillance Network (DIPNET), which covers diphtheria.

### 7.4 Major gaps at the EU-level

Even though the impact of vaccination programmes in Europe is evident, there are still major gaps in the knowledge, control and prevention of VPDs.

Surveillance of 'classical' VPDs (i.e., tetanus, diphtheria, polio, measles, etc.) is, on average, well established in the EU MS. The availability of new vaccines, however, poses new challenges. This is the case for vaccines against invasive bacterial infections (*S. pneumoniae and N. meningitidis*), rotavirus-associated gastroenteritis, and varicella-zoster and human papillomavirus infections. Introducing a new vaccine in established vaccination programmes without knowing the baseline burden of disease is a strategic error that leads to difficulties in evaluation of the programme itself. A harmonised approach to surveillance of 'new' vaccine-preventable diseases is needed at the EU level. Moreover, additional efforts are needed to support the WHO polio eradication initiative.

Vaccine coverage data are not yet collected in a standardised way in EU MS. Lack of comparability makes evaluations impossible using this basic indicator.

Measles, rubella and congenital rubella elimination is a real challenge in the EU. Low vaccine coverage of measles, mumps and rubella, lack of scientific evidence for effective control strategies to respond to measles outbreaks, and lack of effective communication strategies to ensure a high level of vaccine coverage of measles mumps and rubella are some of the gaps that should be addressed at the EU level.

Concerns about vaccine safety are some of the main reasons for low vaccine coverage. Assessing vaccine safety during pre-authorisation trials is not enough to rule out rare adverse events. Wide post-marketing surveillance of adverse events after immunisation (AEFI) is necessary for this scope. To be able to detect rare AEFIs, larger populations need to be monitored and EU-level coordination is therefore essential. An accurate and standardised monitoring, investigation and assessment of AEFI is needed in order to provide EU MS with reliable data on vaccine safety and to facilitate communication activities with up-to-date information. In addition, the routine pharmaco-vigilance based on spontaneous reporting is known to be under-reported. Complementary systems actively looking for adverse events in large medical databases linked to immunisation registries could improve the sensitivity.

Introduction of new vaccines in immunisation programmes or even small changes in vaccination schedules usually require a long process in MS. Occasionally, this process can be facilitated by an effective information exchange at the EU level. An EU platform for exchanging good practice experiences will avoid much duplication at the MS level.

Most immunisation programmes focus on prevention of disease in children (paediatric immunisation programmes) or the elderly (seasonal flu vaccination). However, all immunisation programmes ought to aim for lifelong protection. Few countries have this lifelong protection perspective, even for the vaccines introduced many years ago and, to a lesser extent, all new vaccines. This necessitates repeated studies of immunogenicity and effectiveness.

## 7.5 ECDC strategic priorities

- 1 To enhance the knowledge of the health, economic, and social impact of communicable diseases in the EU by implementing the following measures:
  - strengthening an enhanced EU passive surveillance for VPDs previously belonging to DSN (medium term);
  - setting up EU-wide epidemiological and microbial strain surveillance and data collection to evaluate the burden of the 'new' VPDs (medium/long term); and
  - exploring innovative ways to collect information on VPDs that are not covered by routine surveillance (medium/long term).
- 2 To improve the scientific understanding of communicable disease determinants through the following methods:

- improving knowledge on adolescent and adult immunisation programmes and assessing the impact of vaccination programmes on aging societies (medium term); and
- coordinating scientific studies to investigate effectiveness of control strategies during vaccinepreventable diseases outbreaks, with special reference to measles. Special efforts will be implemented in order to study social determinants (short term).
- 3 To improve the range of the evidence base for methods and technologies for communicable disease prevention and control through the following procedures:
  - setting up an evidence base to help EU MS in the decision making process related to vaccination programmes (short term);
  - setting up a public document repository on vaccination programmes aimed at improving information sharing at the MS level (short term); and
  - investigating methods for an evidence-based assessment and monitoring of vaccination programmes (medium/long term).
- 4 To contribute to the strengthening of programmes for communicable disease prevention and control at EU level and, upon request, in individual MS via the following methods:
  - supporting the set up of information systems to collect standardised data on vaccine coverage in all EU MS (long term);
  - setting up, in collaboration with EMEA and other relevant partners, EU-wide complementary systems for AEFI monitoring and assessment (medium term);
  - exploring innovative ways for private/public cooperation in the field of vaccination and advocating them among EU partners and MS (medium/long term);
  - developing the means to support the communication of key public health messages (short/medium term);
  - facilitating the development of communication strategies to target different groups of vaccinationsceptics/opponents and other hard-to-reach groups in support of WHO elimination/eradication strategies (short term);
  - harmonising the laboratory capacities in MS for IBI and pertussis as well as reinforcing the collaboration between laboratories and public health institutes in EU (medium term); and
  - supporting training activities in vaccine-preventable diseases at national and international levels (short term).