Dear Colleagues,

Introduction

It is a great honour to be asked to participate in this important conference on Childhood Immunisation. And I would like to thank the Hungarian EU Presidency for organising the event.

Childhood Immunisation is an important topic and it is inspiring to see so many European experts gathered at this level in the beautiful city of Budapest. The Hungarian EU Presidency is to be congratulated for putting this issue on the health agenda in Europe.

The success of vaccination programmes is an uncontroversial reality – in Europe, as well as worldwide. Vaccinations prevent disease and hospitalisations, and save lives.

I would like to spend the next few minutes to answer three simple questions:

- First, are we happy with the performance of our current immunisation programmes?
- Second, is there anything needed to improve our programmes?
- Third, how can ECDC support the EU vaccination programmes?

Starting with the first question, I dare to say that in the EU countries vaccination programmes are very safe and effective. And thanks to those successful programmes the incidence of many infectious diseases has dropped substantially.

The Success of Vaccination Programmes

The success of vaccination programmes is such that many people born in Europe during the last three decades do not even recognise the names of severe infectious diseases, such as smallpox, poliomyelitis, tetanus and diphtheria.

However, there is also a downside to this success story.

As a paradox, many people are today more worried about alleged adverse side effects than the disease itself. As a result, this may lead to inadequate vaccine coverage levels.

Challenges

As an immediate consequence, Europe just missed the important milestone of measles and rubella elimination by 2010.

And if we look at the epidemiological reports, it is also important to underline that some EU countries are suffering with the highest burden of measles.

In 2010 alone, more than 28,000 measles cases were reported in the EU. During the 2009/2010 outbreak in Bulgaria, 24 children died. This is an unnecessary tragedy.

We are familiar with the use of key performance indicators. And these are very important but can also sometimes be misleading.

To have a vaccination coverage of 95% is good, but only if the remaining 5% of those not vaccinated are spread over a population. Unfortunately, large pockets of susceptible population have been accumulating in many EU countries. Outbreaks may occur earlier and easier when such pockets are concentrated in the same geographical area or belong to the same population group.

Why are these pockets increasing? There are many reasons for this, such as:

- difficult access to services for vulnerable or high-risk populations,
- cultural or religious beliefs,
- vaccine hesitancy due to vaccine safety concerns, or simply due to misleading information, and
- complacency whereby immunisation is considered a low priority with no real perceived risk.

Similar problems became evident during the last influenza pandemic. In many EU Member States reaching sufficient vaccination coverage levels has been really challenging.

Question number 2: How can we improve vaccination programmes?

This is a very complex issue that can only be faced with a strong and coordinated approach by all public health stakeholders.

We need to provide both EU public and health professionals with **transparent and scientifically sound information**.

Effective vaccines

First, we need to provide effective vaccines. But this is only a start. We then need to **clearly communicate** that those vaccines can prevent serious disease, and even death. In the case of measles, this vaccine has an efficiency of 95% in the vaccinated population.

The marketing authorisation process in the EU – through the European Medicines Agency, (EMA) - is very strict and efficient and only good vaccines are marketed in Europe. But this is not enough.

Public health has to prove that also in post-marketing settings those products are effective and are actually reducing the burden of disease. This is not trivial at all. The experience that we are developing with the pneumococcal vaccines is teaching us a lot.

Effective Monitoring

What we are learning from the pneumococcal vaccines is that a strict and constant monitoring of the effect of the vaccination on the disease is paramount.

We need to continuously monitor diseases to know what kind of strains are circulating. And to know whether it is a 7-valent, a 10-valent or a 13-valent vaccine we should offer to parents and their children in the EU for the most effective vaccine in a given situation. This piece of information is also crucial for public health decision-makers and authorities. They need this information for cost-effectiveness and in order to make the decision of introducing a new vaccine.

Safe Vaccines

Even more importantly, we need to provide safe vaccines.

Again, this is the main responsibility of drug producers; the EMA and national pharmacovigilance authorities.

On the other hand, we learned from recent history that alleged adverse events following immunisation can impair any vaccination programme and can seriously harm public health.

We can cite a long list of stories: from MMR and autism, to Hepatitis B vaccine and multiple sclerosis. All those stories have been clarified afterwards and the links between vaccine and adverse event have been rejected after clinical studies have been performed.

The public health sector must intervene with top-class, unbiased expertise. We must assess vaccine safety in the post-marketing setting ruling out any possible conflict of interest.

This is our duty and this is what ECDC is committed to do.

Very recently, Finland and Sweden have reported a higher than expected incidence of narcolepsy among children and adolescents since the beginning of 2010. This suggests a possible association with the pandemic influenza vaccine used in those countries.

The aetiology was unclear but the temporal association with the influenza A (H1N1) pandemic and pandemic influenza vaccination has been reported.

The ECDC, in cooperation with the EMA, is currently assessing this potential association and will come very soon out with results from such scientific studies. Those results will help all of us to communicate with both health professionals and with the public in a transparent and evidence-based way.

Having effective and safe vaccines will be the first pre-requisite to reach high vaccination coverage.

All health professionals in Europe must be confident to comply with national and international recommendations. Health professionals are the main communication channel to the public. They have to be convinced if we, in return, want them to convince their patients.

We should not underestimate the importance of this challenge – otherwise the vaccines remain unused on the shelf.

Hard-to-Reach Groups

We also have to break those barriers to reach the so-called hard-to-reach groups. I would like to elaborate on this.

Very often those are the most vulnerable people that would benefit the most from vaccination.

To do so we need an extraordinary effort by the means of advocacy actions and sharing good practice.

I fully realise that this is not easy. I count on you and really hope that this Conference will come up with some concrete suggestions in this regard.

Cross-border issues

Last, but not least, the EU can improve the impact of vaccination programmes by facilitating some cross-country issues.

These issues are of particular concern to families that are moving across Europe. Many children, moving from one country to another, miss the opportunity to be vaccinated because of the large variability of schedules, vaccine combinations and different national approaches.

In my view, moving towards a more **coordinated approach** is desirable.

In the meanwhile, EU organisations like ECDC can support this initiative by strengthening cooperation and communication between national public health authorities and sharing best practices as well as providing technical tools.

So moving towards the development of a bridging schedule and towards a simple vaccination certificate to be used by any health professional across the EU may be good options.

When I moved to Sweden, I had to vaccinate my cat using a standardised EU vaccination certificate. Why could we not develop one for humans?

Question number 3: What ECDC can do?

In conclusion, I strongly believe that public health has done so far a really good job in

fighting infectious diseases, thanks to strong commitment from every single stakeholder.

But now we are facing new challenges. The risk perception on infectious diseases is changing rapidly. There is no time for complacency. Reducing the incidence of vaccine-preventable diseases through vaccination has to now be a shared responsibility.

ECDC is strongly committed to bring vaccine preventable diseases high on the agenda. And we will fully support WHO to allow Europe to meet the measles and rubella elimination goal.

So far the ECDC has built very strong networks and connections with the best European experts and has established several good platforms for collecting data and information and sharing good practices throughout Europe.

Providing scientifically sound and transparent technical support to Europe is our job.

I know that outside this Conference people are questioning measles vaccination. We need to be able to convince parents about the benefits of vaccination. To stress my point, I would like to show you a brief **CLIP** now.

Watch the video here: <u>http://www.ecpcp.eu/measles_video-english.html</u> (source: European Confederation of Primary Care Paediatricians, ECPCP)

I'm sure that after this movie I do not need to talk longer.

If we act in a coordinated manner our impact will be higher and Europe will be stronger in the fight against infectious diseases.

This is ECDC's mission and we are strongly committed to fulfil it.

ENDS