Final Report on the Survey on AEFI Monitoring Systems in Member States

VENICE Project

Work Package 5

December 2007

Contents

Abbreviations

AEs	Adverse Events
AEFI	Adverse Event Following Immunisation
asap	as soon as possible
BC	Brighton Collaboration
ECDC`	European Centre for Disease Control
EMEA	European Medicines Agency
EEA	European Economic Area
EU	European Union
ICD	International Classification of Diseases
ISS	Istituto Superiore di Sanità
lha	local health authority
lhp	local health personnel
mav	movement against vaccines
MedDRA	Medical Dictionary for Regulatory Activities
MoH	Ministry of Health
MS	Member States
Na	National authority
NIPH	National Institute of Public Health
nk	not known
o	other
PHC	Primary Health Care
PhV	PharmacoVigilance
po	public opinion
p/p	parent/patient
VENICE	Vaccine European New Integrated Collaboration Effort
vp	vaccine personnel
WHO	World Health Organization
WHO-EURO	World Health Organization, Regional Office for Europe
WP	Work Package

ISO 3166-1 Country Codes

AT	Austria
BE	Belgium
BG	Bulgaria
CY	Cyprus
CZ	Czech Republic
DK	Denmark
EE	Estonia
FI	Finland
FR	France
DE	Germany
GR	Greece
HU	Hungary
IS	Iceland
IE	Ireland
IT	Italy
LV	Latvia
LT	Lithuania
LU	Luxembourg
NL	The Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SK	Slovakia
SI	Slovenia
ES	Spain
SE	Sweden
UK	United Kingdom

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INTRODUCTION

Background

One of the greatest achievements in public health has been infectious disease prevention through immunization. Vaccinations have prevented many deaths and diseases. Nevertheless vaccine-related adverse events that are not rapidly and effectively dealt with, can undermine public confidence in vaccinations with potentially dramatic consequences for immunization coverage and disease incidence. The case study of the United Kingdom during the 1970s, when public concern over the risk associated with whooping cough vaccines led to a reduction in vaccination coverage and to an epidemic of over 100,000 cases with death and hospitalizations, is a dramatic example and lesson learned.

In 1999, WHO established the Global Advisory Committee on Vaccine Safety to respond promptly, efficiently, and with scientific rigour to vaccine safety issues of potential global importance and general public concern. In June 1996, the Global Training Network (GTN) was established to provide educational resources to vaccine regulatory and production staff throughout the world, including courses on AEFI surveillance

Although vaccines are now much safer than they were 40 years ago, every year new ones enter the market and information proliferates on the Internet and other communication media, leading to the onset of public concerns about risks and benefits. Hence, immunization programs have a responsibility to address these concerns.

Aim of the VENICE Project

There is a need to improve knowledge on how vaccinations are performed across EU and how the related adverse events are monitored and analyzed in order to agree on indicators for vaccination program monitoring, to collect and share best practices and lessons learned, to define models of decision-taking processes and, finally, to integrate available information identifying gaps and added values.

The VENICE project aims at encouraging collection and dissemination of knowledge related to vaccination and to further develop collaboration and partnership between participating countries.

The project is organized in five Work Packages (WP), which refer to different areas of activity and to the specific objectives of the program:

WP 1 Coordination

WP 2 Dissemination of results

WP 3 Indicators of immunisation programs

WP 4 Priority setting and decision-making

WP 5 Capacity building in monitoring, prevention and management of post-vaccination Adverse Events.

Each Work Package is guided by a *WP leader*. In each country participating in the project, several people of competence in public health institutions are involved: a *gatekeeper* responsible for the project at the national level, three *contact points*, one for each "technical Work Package" (WP3, WP4, WP5); and, an executive board of the *Work Package leaders* ensures that aims and objectives of the project are met.

Twenty-eight national gatekeepers were identified, one from each participating country, at the beginning of the project, on the basis of their participation in other ongoing European vaccination networks (e.g. EUVACNET), as well as through the project sponsor (DG SANCO) and the ECDC advisory forum EU members.

All the data collection is performed with the collaboration of the national gatekeepers and specific issues are addressed and solved using the experience of specific contact points in each country.

Objectives of the project

1.To create an EU vaccination network capable of collecting and collating information on vaccination programs in each MS

2.To create a resource capable of providing advice and support to single member states by integrating available tools and knowledge on various vaccine related issues

3.To create a network capable of providing support in the development of preparedness strategies

4.To define comparable common indicators for monitoring immunisation programs across MS and their constituent regions

5.To provide MS with the necessary information regarding safe vaccination and support capacity building in areas dealing with contraindications and management of Adverse Events Following Vaccination

6.To encourage a rational approach to vaccination policy decision-making processes by providing standardized tools

Namely WP 5 intends to pursue the following specific objectives:

1. to collect information on Adverse Events Following Immunization (AEFI) monitoring systems adopted by all the participating members states (MSs)
2. to establish evidence-based protocols for AEFI monitoring, prevention and management
3. to improve the training for prevention and management of AEFIs
4. to adopt a common procedure for all MSs
5. to improve vaccination safety

Aim and Objective of the Survey

A survey was implemented in order to comply with the project's 5th objective and objective number 1 of WP5 specifically. Continuing from the first survey "Immunisation Programs in Europe" which looked also at AEFIs, this survey expanded further on AEFI monitoring system.

The objectives of the survey in detail are:

a) to have a structured description of different AEFI monitoring systems
b) to identify similarities and heterogeneities of the different systems
c) to collect background information on different aspects of the AEFI reporting, investigation, prevention, management and training

METHODS

The AEFI Monitoring System Questionnaire is the result of several discussions and meetings at different levels and it was piloted in six countries (Bulgaria, France, Ireland, Italy, Spain, The Netherlands) before full scale administration. Thereafter, the gatekeepers/contact points of the participating countries were asked to enter the reserved members' area of the VENICE website and complete the questionnaire online by June 2007. Participating countries are 28 of which 26 belonging to the European Union (EU – Austria, Bulgaria, Belgium, Czech Republic, Cyprus, Denmark, Finland, France, Greece, Hungary, Republic of Ireland, Italy, Estonia, Germany, Latvia, Lithuania, Luxembourg, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, The United Kingdom) and 2 to the European Economic Area (EEA – Iceland and Norway).

The AEFI questionnaire is based on 36 questions grouped in 6 different sections. It was filled by 26/28 countries except for Cyprus and Luxembourg. As for the latter two last countries and for the interpretation of some main findings we have utilized the answers reported in the first general questionnaire on national immunization programs (March 2007). The 6 different sections are the following:

- Generic (not specific) information (2 questions)
- Political commitment (3 questions)
- Identification (15 questions)
- Investigation/Causality assessment (9 questions)
- Prevention and Treatment (2 questions)
- Communication and Information (3 questions)
- Vaccination campaign (1 question)
- Training (1 question)

The questionnaire included a vast majority of multiple choice questions and very few open answer questions.

Data were then input into Microsoft Excel file for subsequent analysis.

EXECUTIVE SUMMARY

This report is the result of a survey carried out by a web-based specific questionnaire on AEFI surveillance, prevention and treatment systems put in place in 28 European countries, in the context of different activities implemented by VENICE Project. This report follows a previous one that provided a general description for each national immunization program (April 2007) and another one on vaccination coverage (May 2007). The main conclusions of the first general survey about AEFIs were that adverse events are reported to the institutions/bodies with responsibility for AEFIs in all participating countries, additional (specific) systems are in place in 8/28 countries, feedback of AEFIs between vaccinators and public occurs in 19/28 and, finally, a compensation scheme for vaccine damage exists in 14/28 countries.

The administered questionnaire is the result of several discussions and meetings at different levels. It is based on 36 questions and was filled in by 26/28 countries. We have utilized answers reported in the first general questionnaire and the interpretation of selected main findings for the two excluded countries, Cyprus and Luxembourg.

Generally speaking, the picture of the main findings seems difficult to understand and there appears to be a gap between the political commitment, or the different designed systems put in place, and the quantity/quality of effective output in terms of "service deliveries" useful for the population and effective prevention and treatment of AEFIs
The following main findings are reported:

- All countries report AEFIs, the majority (67% - 18/27) has developed a specific system, a bit more than 30% (9/28) has put it in place in addition to PharmacoVigilance (PhV), but considering the data reported in the questionnaire on the number and seriousness of AEFIs, it seems that to develop a specific system is not essential to collect quantitative information about AEFIs.
- In 21/26 countries there are mandatory rules or laws in order to report and investigate AEFI. Namely reporting and investigation are mandatory in 18 and 12 of 25 countries respectively. It seems there is a gap between reporting and investigation.
- Usually a doctor is in charge of filling in an AEFI report in 80% (21/26) of countries, a nurse in 45% (12/26) patient or parent in 7,5% (2/26 – Denmark and United Kingdom) and other categories in 20% (5/26). The case of United

Kingdom, where any person can report AEFI, should be taken under consideration for a more in depth analysis.

- Of 24 countries 17 (71%) state to have adopted a AEFI classification: 20 (83%) report criteria for AEFI classification and only 9 (38%) have adopted AEFI case definitions. These considerations highlight a gap between the availability of data and their comparability: the different kinds or absence of a AEFI classification or case definitions make very difficult to compare or to aggregate data of different countries.
- Almost all countries (92%, 23/25) can report the number of AEFIs, but few of them perform case studies (32%, 8/25). Data are analyzed with a different frequency: 36% (9) yearly, 28% (7) monthly, 24% (6) with other frequencies. Finally the connection with EMEA (88%) and with one or more EU networks about AEFI surveillance seems very strong.
- 20/25 countries are used to investigate AEFIs to establish a causal relationship,15 systematically and 5 when needed. In 2/3 of the countries where AEFIs are systematically investigated the process is mandatory, but only 5 countries have a procedure for clinical and laboratory investigation for AEFI identification and follow up. In 12 of 19 countries national health authority is in charge of investigating and assessing causality, in 10 a local health authority and in 7 both the authorities are responsible.
- As partially stated above, all the countries record AEFIs, 80% of them has mandatory rules or laws to report and investigate AEFIs, 60% investigates and has a system/network for identifying and analysing them, 36% (9/25) has large – linked databases available and suitable for vaccine safety studies but only 6 countries use these databases.
- Some countries do not know or report the number of serious AEFI or AEFI with permanent sequelae and a significant proportion (11 countries) doesn't know the quantity of vaccine doses administered or sold
- Only 36% (9/25) of the countries have a counselling service for pre- and post-vaccination AEFI prevention: 2 countries have developed a protocol for AEFI management and none for reducing their frequency. The case of Green Channel experience adopted in the Veneto Region, Italy, should be taken under consideration for a more in depth analysis.

- Out of 24 countries, 7 give communication on AEFIs only to vaccine personnel and public opinion is informed about AEFIs in 12 countries. In almost all the countries (23/25) a national health authority is in charge of giving information on AEFI to communication media and in 7 of them also the local health personnel is in charge. In 10 (40%) of the countries an annual report is released.

Finally, considering all the countries included in this survey, the general picture does not show a great variety between the different areas. In particular, the following actions should be taken to reach a more homogeneous EU pattern:

- All the activities related to connection with EU networks, availability and use of databases should be implemented mainly in Southern Europe
- The AEFI prevention-related activities should be improved in all the regions
- The overall training component is not considered a priority and should be potentiated.

<u>From the following tables (1a, 1b, 1c and 1d) it is possible to get a general overview of almost all of the answers to the questionnaire.</u>

Table 1 – General overview *														
Table 1a – General overview (Austria – Ireland)														
	AT	**BE**	**BG**	**CY**	**CZ**	**DE**	**DK**	**EE**	**FI**	**FR**	**GR**	**HU**	**IS**	**IE**
(1) Countries with a specific safety monitoring system for AEFIs developed	■		■			■	■		■			■	■	
(2) AEFI monitoring system in addition to the pharmacovigilance system						■			■			■	■	
(35) Different surveillance system planned during mass vaccination campaigns	■								■	■				■
(4) Mandatory rules or laws in order to report and investigate AEFIs	■		■		■	■	■	■	■	■		■	■	■
(5) Compensation system for vaccine-related damage	■					■	■		■	■		■	■	
(5) Reported No. of people economically and socially supported in at least 1 year (2004 – 2005)														
(6) Form for a AEFI report developed	■		■			■	■	■	■			■		■
(7) AEFI report form filled in or written only by a doctor			■					■				■		■
(8) Mandatory AEFI reporting	■		■			■	■	■				■	■	
(9) Mandatory AEFI reporting for all events			■									■		
(10) Formal procedure and reporting time in order to communicate AEFI	■		■		■									
(14) AEFI classification adopted	■		■		■	■	■		■			■	■	
(16) List of case definitions developed	■		■		■									
(11) Reported No. of AEFIs in at least 1 year (2003 – 2005)	■		■		■	■		■	■	■		■	■	■
(13) AEFIs analysis at national level with a monthly interval	■							■						■
(13) AEFIs analysis at national level with a yearly interval			■		■				■			■	■	
(20) Attached flow chart of AEFI reporting	■		■			■						■		
(21) AEFIs systematically investigated	■		■			■			■			■		
(22) Mandatory AEFI investigation	■		■						■			■		
(23) National health authority in charge of investigating, assessing the causality and filling in the final AEFI investigation form			■			■			■			■	■	
(23) Local health authority in charge of investigating, assessing the causality and filling in the final AEFI investigation form			■			■				■				
(24) System/network for identification and analysis of AEFIs in place	■		■					■	■	■		■		
(24) Group of experts at national level in charge of identifying and analysing AEFIs	■		■					■	■	■		■		
(24) Group of experts at local level in charge of identifying and analysing AEFIs														

(25) Procedure for clinical and laboratory investigation for AEFI identification and follow up														
(27) No. of serious AEFI reported in at least 1 year (2003 – 2005)														
(28) No. of serious AEFI with permanent sequelae reported in at least 1 year (2003 – 2005)														
(29) No. of vaccines administered/sold reported in at least 1 year (2003 – 2005)														

Table 1b – General overview (Austria – Ireland)

	AT	BE	BG	CY	CZ	DE	DK	EE	FI	FR	GR	HU	IS	IE
(12) AEFI reports communicated to EU organizations														
(18) Connection with EU networks for AEFI surveillance and/or pharmacovigilance														
(26) Large-linked databases available in the country and suitable for vaccine safety studies														
(26) Use of large-linked databases available in the country and suitable for vaccine safety studies														
(17) Case studies on AEFIs performed														
(32) Giving information on AEFIs to parent/patient														
(32) Giving information on AEFIs to vaccine personnel														
(32) Giving information on AEFIs to public opinion														
(32) Giving information on AEFIs to Movements against Vaccines														
(33) National authority in charge of giving information on AEFIs to communication media														
(33) Local health personnel in charge of giving information on AEFIs to communication media														
(34) AEFI annual report released														
(30) National/local protocol developed to reduce the frequency of AEFIs														
(31) National/local protocol developed for AEFI management														
(19) Counselling service for pre- and post-vaccination AEFI prevention														
(36) Training program/manual developed for health staff on prevention, identification and treatment of AEFIs														

Table 1c – General overview (Italy – United Kingdom)														
	IT	LV	LT	LU	NL	NO	PL	PT	RO	SK	SI	ES	SE	UK
(1) Countries with a specific safety monitoring system for AEFIs developed	■	■	■		■	■	■		■	■	■	■	■	
(2) AEFI monitoring system in addition to the pharmacovigilance system		■	■		■				■	■				
(35) Different surveillance system planned during mass vaccination campaigns					■									■
(4) Mandatory rules or laws in order to report and investigate AEFIs	■	■	■			■	■		■	■	■	■	■	
(5) Compensation system for vaccine-related damage	■			■		■					■		■	■
(5) Reported No. of people economically and socially supported in at least 1 year (2004 – 2005)						■			■					■
(6) Form for a AEFI report developed	■	■	■			■	■		■	■	■		■	■
(7) AEFI report form filled or written only by a doctor		■	■						■	■	■			
(8) Mandatory AEFI reporting	■	■	■			■	■	■	■	■	■	■	■	
(9) Mandatory AEFI reporting for all events	■						■		■		■	■		
(10) Formal procedure and reporting time in order to communicate AEFI		■	■				■		■		■		■	■
(14) AEFI classification adopted	■		■		■	■	■		■		■		■	■
(16) List of case definitions developed	■	■	■		■				■				■	
(11) Reported No. of AEFIs in at least 1 year (2003 – 2005)	■	■	■		■	■	■	■	■	■	■	■	■	■
(13) AEFI analysis at national level with a monthly interval		■					■		■				■	
(13) AEFI analysis at national level with a yearly interval			■		■	■				■				
(20) Attached flow chart of AEFI reporting	■	■	■			■	■	■				■		■
(21) AEFIs systematically investigated	■	■	■		■	■		■	■			■	■	■
(22) Mandatory AEFI investigation		■	■				■	■	■		■		■	■
(23) National health authority in charge of investigating, assessing the causality and filling in the final AEFI investigation form	■		■		■		■	■				■	■	■
(23) Local health authority in charge of investigating, assessing the causality and filling in the final AEFI investigation form		■	■				■		■	■		■		■
(24) System/network for identification and analysis of AEFIs in place	■	■	■		■	■			■			■	■	■
(24) Group of experts at national level in charge of identifying and analysing AEFIs		■			■							■	■	■
(24) Group of experts at local level in charge of identifying and analysing AEFIs		■				■						■		
(25) Procedure for clinical and laboratory investigation for					■	■								■

AEFI identification and follow up														
(27) No. of serious AEFI reported in at least 1 year (2003 – 2005)														
(28) No. of serious AEFI with permanent sequelae reported in at least 1 year (2003 – 2005)														
(29) No. of vaccines administered/sold reported in at least 1 year (2003 – 2005)														

Table 1d – General overview (Italy – United Kingdom)

	IT	LV	LT	LU	NL	NO	PL	PT	RO	SK	SI	ES	SE	UK
(12) AEFI reports communicated to EU organizations														
(18) Connection with EU networks for AEFI surveillance and/or pharmacovigilance														
(26) Large-linked databases available in the country and suitable for vaccine safety studies														
(26) Use of large-linked databases available in the country and suitable for vaccine safety studies														
(17) Case studies on AEFIs performed														
(32) Giving information on AEFIs to parent/patient														
(32) Giving information on AEFIs to vaccine personnel														
(32) Giving information on AEFIs to public opinion														
(32) Giving information on AEFIs to Movements against Vaccines														
(33) National authority in charge of giving information on AEFIs to communication media														
(33) Local health personnel in charge of giving information on AEFIs to communication media														
(34) AEFIs annual report released														
(30) National/local protocol developed to reduce the frequency of AEFIs														
(31) National/local protocol developed for AEFI management														
(19) Counselling service for pre- and post-vaccination AEFI prevention														
(36) Training program/manual developed for health staff on prevention, identification and treatment of AEFIs														

* The questions n° 3 and n° 15 are not included in this table because of their complexity: the first one is an open answer question and the second one is a multiple choice question

RESULTS

Findings

Questionnaires were downloaded 2 times. The first time was between the last week of June (on June 25th) and first 2 weeks of July (on July 8th and 11th). The second time was on July 31st. Generally speaking, the questionnaire was returned from all the countries (**28**), but one of them was largely incomplete (Belgium) and those from Cyprus and Luxembourg completely unfilled. For these last two countries, some data have been extracted from the first general questionnaire administered and returned in the period between September and October 2006.

The results of this survey were grouped in different chapters after a brief introduction and explanation of each topic. The data were summarized in the subsequent tables, followed by comments.

General considerations

Adverse events are reported to the institutions/bodies with responsibility for Adverse Events Following Immunization (AEFIs) in all participating countries. The latter countries were asked

- If a specific safety monitoring system has been developed and
- If the system in place is in addition to the pharmacovigilance system

The answers are summarized in the following tables:

Table 2 - European countries with a specific safety monitoring system for AEFI - 2007*		
Yes	**Not**	**TOTAL**
18	**9**	**27**
* Data for Luxembourg are not available and for Cyprus were extracted from the first general questionnaire "Immunization Programs in Europe".		

Table 3 - European countries with a specific safety monitoring system for AEFI in addition to the pharmacovigilance system - 2007*		
Yes	**No**	**TOTAL**
9	**19**	**28**
* Data for Cyprus and Luxembourg are extracted form the first general questionnaire.		

Table 4 - European countries with a specific safety monitoring system for AEFI and reported data on number of AEFIs in at least one year - 2007*	
With specific safety monitoring system	**With reported data on number of AEFIs**
18	**17**
* Data for Luxembourg are not available	

Table 5 - European countries without a specific safety monitoring system for AEFI and reported data on number of AEFIs in at least one year - 2007*	
Without specific safety monitoring system	**With reported data on number of AEFIs**
8**	**6**
* Data for Luxembourg are not available ** Cyprus is not included in this table because reported data on number of AEFIs are not available in the returned questionnaire	

Comments

The majority (67% - Table 2) of the countries has developed a specific system but 32% (Table 3) has put it in place in addition to pharmacovigilance system. Among 18 countries with a specific safety monitoring system one country did not report data on the number of recorded AEFIs (Table 4), while 8 countries without a specific system only 2 did not report data (Table 5). Therefore, it seems that the existence of a specific system is not essential to collect quantitative information about AEFIs. The not questioned and missing information about which year the system has been developed and/or put in place is a point of weakness for the interpretation of the unreported data about the number of AEFIs in the country.

As detailed in the last chapter, of 25 countries asked about a surveillance system during mass vaccination campaign only 6 (24% - Table 34) state to plan a different system during mass vaccination campaign.

Political commitment

Countries were asked

- to define name and functions of the national regulatory political and technical authority, body or committee in charge of the AEFI surveillance
- if there are mandatory rules or laws in order to report and investigate AEFI and
- if there is a compensation system for vaccine-related damage and the number of people supported.

Table 6 - European countries with mandatory rules or laws in order to report and investigate AEFI - 2007*		
Yes	**No**	**TOTAL**
21	**5**	**26**
* Data for Cyprus and Luxembourg are not available.		

Table 7 - European countries with a compensation system for vaccine-related damage and reported data in 2004 and 2005 about people economically and socially supported - 2007*						
Yes	*2004 reported*	*2005 reported*	*2004 Not known*	*2005 Not known*	**No**	**TOTAL**
13	*2*	*3*	*10*	*10*	**15****	**28**
* Data for Cyprus and Luxembourg are extracted from the first general questionnaire. ** The answer of The Netherlands is contradictory with the answer to the same question given in the general questionnaire about Immunization Programs implemented in the last year 2006						

Comments

Twenty-one out of 26 (80%) of the countries (21/26) have mandatory rules or laws to report and investigate AEFIs, but less than a half (46% or 13/28) has put in place a compensation system for vaccine-related damage (Tables 6 and 7). Moreover only 3 countries (23%, 3/13 - Table 7) reported some information about the number of vaccine-related damaged people and were really supported through the compensation system. Also in this case the missing information on when (the year) the compensation system was put in place is a point of weakness for the interpretation of the unreported data.

Identification

AEFI reporting

In this paragraph the issues about AEFI reporting (form and people in charge of filling in it, process and time of communicating a report) are highlighted. Participating countries were asked:

- if a form for AEFI reporting has been developed
- who is in charge of filling in it
- about the juridical framework of AEFI reporting
- about formal procedure and reporting time in order to communicate an AEFI

The results are summarized in different tables and comments:

Table 8 - European countries with a form for AEFI reporting - 2007*			
Yes	*Upload or fax*	**No**	**TOTAL**
18	*13 ** *	**9**	**26**
* Data for Cyprus and Luxembourg are not available. ** The form of Estonia has been sent by fax			

Comments

- There is a positive correlation in almost 77% of the countries (20/26) between the statement of developing or not a specific safety monitoring system (Table 3) and developing or not a form for AEFI reporting (Table 8). The negative correlation recorded in 6 countries is in both meanings: 3 countries declared to have developed a specific system but not a specific form (Iceland, The Netherlands and Spain),and 3 countries declared the opposite (Estonia, Ireland and United Kingdom).
- There is also a positive correlation in 80% of countries (21/26) between the statement of developing or not a form for AEFI reporting (Table 8) and who is in charge for filling in it (Table 9). The negative correlation recorded in 4 countries (Czech Republic, Iceland, Portugal and Spain) is only in one aspect: these countries report that there is some category in charge for filling in the form, but they did not develop any specific form to be filled. In these countries it is supposed that AEFI reporting is developed without any standard form. 4 countries (Belgium, France, Greece and The Netherlands) reported not to have developed any form for AEFI reporting

Table 9 - Categories in charge of filling in the AEFI report form in European countries – 2007 *						
PH Physician	**Nurse**	**PC Physician/ Paediatrician**	**Hospital doctor**	**Patient/ Parent**		
17	**12**	**21**	**21**	**2**		
Other						
Manufacturer	**Holder of marketing authorization**	**Physicians**	**Pharmacists**	**PH officer**	**Relatives**	**Any person**
1	**1**	**1**	**1**	**1**	**1**	**1**
* Data for Cyprus and Luxembourg are not available. Belgium, Czech Republic, Greece, Iceland, The Netherlands, Portugal and Spain haven't developed any filling form for AEFIs. France has developed an AEFI report specific for mass immunization campaigns.						

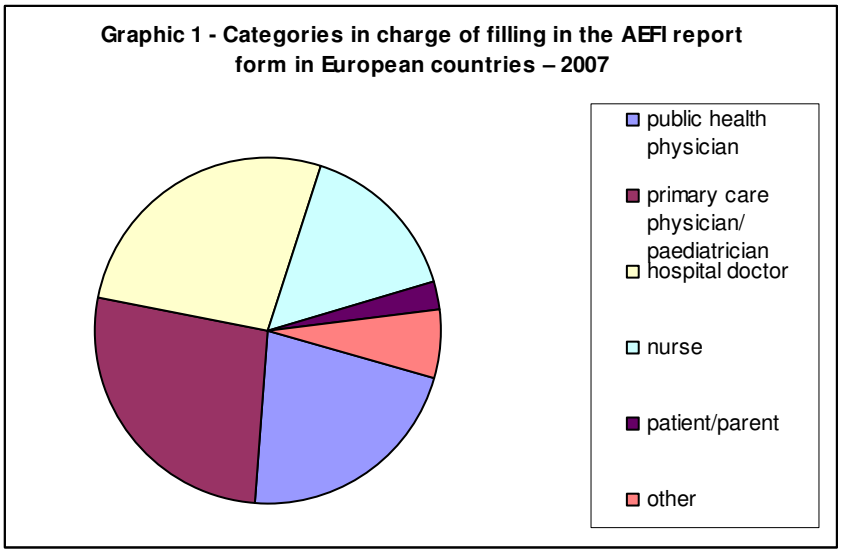

Table 10 - European countries with medical category only in charge of filling in the AEFI report form - 2007*		
Physician category only	**Different categories (including physician category)**	**TOTAL**
9**	**13**	**22**
* Data for Cyprus and Luxembourg are not available. ** Bulgaria, Estonia, Hungary, Ireland, Latvia, Lithuania, Romania, Slovakia, Slovenia		

Comments

Usually a doctor (Public Health Physician, Primary Care Physician, Paediatrician and Hospital doctor) is in charge of filling in an AEFI report in 80% (21/26) of countries, a nurse in 45% (12/26), patient or parent in 7,5% (2/26) and other categories in nearly 20% (5/26) of the countries (Table 9 and Graphic 1). In the category "other" are included: manufacturer, holder of marketing authorization, pharmacist, public health officer (not necessarily a physician), relatives, any person. We think that the case of United Kingdom, where any person can now report suspected side effects to vaccines and/or medicines, is to be taken under consideration for a more in depth analysis. In 41% (9/22 – Table 10) of the countries only a doctor is in charge for filling in or writing an AEFI report form.

Table 11 - Kind of procedure for AEFI reporting in European countries – 2007*			
Mandatory	**Recommended**	**Voluntary**	**TOTAL**
18	**3**	**4**	**25**
* Data for Belgium Cyprus and Luxembourg are not available.			

Table 12 - Kind of AEFIs which report is mandatory for in European countries – 2007*			
All events	**Serious events**	**Other**	**TOTAL**
7	**9****	**6*****	**18****
* Data for Cyprus and Luxembourg are not available. ** 3 countries state as mandatory reporting both for serious events and other *** 1 for new and increased events, 2 for unexpected or unlisted events, 2 according with list accepted by national entities (MoH, Cabinet) and 1 according with European legislation			

Comments

The great majority of the countries (72%, 18/25 – Table 11) states AEFI reporting as mandatory, for all events with a rate of 39% (7/18), serious events with a rate of 28% (5/18), both serious and other events with a rate of 16,5% (3/18) and, finally, only other events with the same rate of 16,5% (3/18 – Table 12). The answers for France, Czech Republic and Ireland were not included in the current analysis because they seem contradictory where AEFI reporting is defined as voluntary (France) or recommended (Czech Republic and Ireland) and all events (France and Ireland) or serious events are defined as mandatory for reporting. 4 countries define AEFI

reporting as voluntary (Greece and United Kingdom) or recommended (Finland and The Netherlands).

Table 13 - European countries with a formal procedure and reporting time in order to communicate an AEFI to the health authority - 2007*							
Yes	*Time interval*					**No**	**TOTAL**
	*Asap or immediately***	*12 h*	*24 h*	*Days*	*Nk*		
10	*2*	*1*	*5*	*3*	*1*	**14**	**24**
* Data for Cyprus, Italy, Luxembourg and Spain are not available. **Slovenia reports immediately for serious events and with a not known time for other events, Austria as soon as possible (asap) for serious events and new/increased events, Lithuania 24 h by phone and 15 days by e mail for all events adopted by MoH and Latvia 12 h for all events adopted by Cabinet							

Comments

Ten of 24 countries (42% - Table 13) have a formal procedure and reporting time in order to communicate an AEFI to the health authority. 8 of 10 countries have a reporting time of 24 hours or less with an AEFI reporting mandatory. Comparing data from tables 11 and 13, it seems unusual that 9 countries with an AEFI reporting mandatory do not refer any reporting time in the questionnaire. Finally data from Table 12 and Table 13 show us that 5 of 8 countries with a reporting time of 24 hours or less have a mandatory report for all events o events included in a list defined by a national authority and in the remaining countries (3/8) the reporting time is mandatory only for serious, new or unlisted events

AEFI Classification, case definitions and counselling service

The next step has been to know

- if the countries have adopted, if any, a classification of AEFI and which kind
- which criteria are used for classification and
- if a list of case definitions has been developed

- if the countries have a counselling service for pre- and post-vaccination AEFI prevention

The results are summarized in the tables 14, 15 and 16:

Table 14 - European countries adopting a classification of AEFIs, and relative criteria of classification - 2007*						
Yes	*WHO*	*Other*	*Not defined*	**No**	**Not Known**	**TOTAL**
17	*6*	*5***	*6*	**7**	**1**	**24**
Causality	*Seriousness*	*Type of vaccine*	*Other*			***TOTAL***
10	*18*	*15*	*2****			***21****
* Data for Belgium, Cyprus, Greece and Luxembourg are not available. ** Kind of classification: MedDRA medical dictionary, Brighton, ICD-10, own national classification and EU scheme *** Number of countries which reported different kinds of criteria adopted for classifying AEFIs **** Criteria for classification according to EMEA and type of event						

Table 15 - European countries which developed/adopted a list of case definitions for AEFIs, and, in case, which ones - 2007*						
Yes	*WHO*	*Brighton collaboration*	*Other*	**No**	*Upload or fax*	**TOTAL**
9	*7*	*2*	*2*	**15**	*2*	**24**
* Data for Belgium, Cyprus, Greece and Luxembourg are not available.						

Comments

Only 71% (17/24 – Table 14) of the countries states to have adopted a classification of AEFIs of different kinds (38% WHO and 62% other or not specified) but, if the answers about criteria are analysed in depth, the countries that report criteria for classification of AEFI are 20: Portugal, Slovakia and Spain state to have not adopted any AEFI classification but at the same time mention some criteria of AEFI classification in their questionnaire. Nonetheless taking into account all the 20 countries (Table 14), criteria of seriousness, type of vaccine and causality are included respectively in 90%, 75% and 50% of different classification adopted or assumed to be adopted by the countries. Finally very few countries (38%, 9/24 – Table 15) adopted a classification of case definitions for AEFIs . Out of 9 countries 7 have adopted the WHO classification and 2 a combination of Brighton and other not

specified. It would be useful to track, analyse and compare the experience that the countries gained from using different kind of classifications.

These considerations highlight a gap between the availability of data and their comparability: the different kinds or absence of a AEFI classification or case definitions make very difficult to compare or to aggregate data of different countries.

Table 16 - European countries with a counselling service for pre- and post-vaccination AEFI prevention - 2007*		
Yes	**No**	**TOTAL**
9 **	**16**	**25**
* Data for Belgium, Cyprus and Luxembourg are not available. ** The experience of Veneto region, Italy, Green Channel is not included		

Comments

Only 36% (9/25 – Table 16) of the countries have a counselling service for pre- and post-vaccination AEFI prevention without including the regional experience (Veneto) of Italy, so called "Green Channel"

AEFI analysis and case studies

The countries were asked

- to report the number of AEFI for all vaccines in the years 2003 - 2005
- to specify the frequency of AEFI analysis performed and
- to indicate if case studies on AEFI were performed

Table 17 - Countries reporting absolute number of AEFIs according the different years considered - 2007*									
Reported			**Not reported**			**Not known**			**Total**
2003	*2004*	*2005*	*2003*	*2004*	*2005*	*2003*	*2004*	*2005*	**25**
21	**23**	**23**	**1**	**1**	**1**	**3**	**1**	**1**	
* Data for Belgium, Cyprus and Luxembourg are not available.									

Table 18 - Frequency of AEFI analysis at national level in European countries included in the survey - 2007*					
Monthly	**6 months**	**Yearly**	**Other**	**Not known**	**TOTAL**
7	**0**	**9**	**6****	**3**	**25**
* Data for Belgium, Cyprus and Luxembourg are not available. ** frequency of AEFI analysis every week (1), 3 months (1), 2 years (1), on need (2), continuously on web database basis with open access (1)					

Table 19 - European countries which have performed case studies on AEFIs - 2007*				
Yes	**No**	**Not known**	*Upload or fax*	**TOTAL**
8	**15**	**2**	*1*	**25**
* Data for Belgium, Cyprus and Luxembourg are not available.				

Comments

Almost all countries (92%, 23/25 – Table 17) can report the number of AEFIs. Nevertheless 2 countries can't report it, the first one (Denmark) with and second one without (Greece) a developed specific safety monitoring system for AEFI, and some of them perform case studies on AEFIs (32%, 8/25 – Table 19): however, only 1 country uploaded its own case study (Ireland about BCG).

Data are analyzed at different intervals: 36% (9) yearly, 28% (7%) monthly, 24% (6) with other intervals (every week, 3 months, 2 years, on need, continuously on web database basis with open access) and 12 % (3) with a not known frequency (Table 18).

AEFI and European Union network

Countries were asked about EU organizations which the AEFI reports are communicated to and connection with EU networks for AEFI surveillance and/or pharmacovigilance

Table 20 - EU organization which AEFI report is communicated to by European countries - 2007*				
EMEA	**None**	**Other**	**Not known**	**TOTAL**
22	**1**	**0**	**2**	**25**
* Data for Belgium, Cyprus and Luxembourg are not available.				

Table 21 - European countries connected with EU networks* for AEFI surveillance and/or pharmacovigilance - 2007**					
Yes	*EUDRA vigilance*	*WHO*	*Brighton Collaboration*	**No**	**TOTAL**
17	*13*	*11*	*1*	**7**	**24**
* Except for EMEA ** Data for Belgium, Cyprus, Greece and Luxembourg are not available.					

Comments

Almost European countries (88%, 22/25 – Table 20) communicate AEFI report to EMEA and a bit lower proportion (70%, 17/24 – Table 21) has some connection with one or more EU networks about AEFI surveillance and/or pharmacovigilance issues: Eudra vigilance (13 countries, 54%), WHO (11 countries, 46%) and Brighton collaboration (1 country, 4%).

Investigation/Causality Assessment

Investigation and causality assessment process

In this paragraph the aim is to understand how much the process of investigating an AEFI is structured. The countries were asked:

- If AEFIs are systematically investigated to establish a causal relationship
- In that case which causality assessment is adopted
- Which the juridical framework of AEFI investigating
- Who is in charge of investigating, assessing the causality and filling in the final AEFI investigation form
- If there is a procedure for clinical and laboratory investigation for AEFI identification and follow up

Table 22 - Countries with AEFIs systematically investigated to establish a causal relationship and kind of causality assessment classification adopted - 2007*				
Yes	**When needed**	**No**	*Upload or fax*	**TOTAL**
15	**5**	**5**	*2*	**25**
WHO	*Other*	*None*	*Not known*	***TOTAL***
14	*4*	*0*	*0*	***18***
* Data for Belgium, Cyprus and Luxembourg are not available.				

Table 23 - Countries where AEFI investigation is mandatory and kind of events which investigation is mandatory for - 2007*			
Yes	**No**		**TOTAL**
12	**13**		**25**
All events	*Serious events*	*Other*	***TOTAL***
6	*5***	*3***	***12***
* Data for Belgium, Cyprus and Luxembourg are not available.			

** The category "Other" includes: list of AEFIs, unlisted events and events whenever the risk-benefit may be compromised. In 2 countries investigation is mandatory both for serious events and other events

Table 24 - People and/or authority in charge of investigating, assessing the causality and filling in the final AEFI investigation form in European countries - 2007*			
Local health authority	**National health authority**	**Other**	**TOTAL**
10**	**13****	**5*****	**19**

* Data for Belgium, Cyprus and Luxembourg are not available.
** In 6 countries both national and local authority are in charge
*** In the category other are included: Bundesamt für Sicherheit im Gesundheitswesen, regional epidemiologists and Members of National expert committee, physicians, manufacturer, Regional Centers for PharmacoVigilance, Staff at NIPH. In 2 countries both national/local authority and other authority/institution are in charge

Comments

80% (20/25) of the countries included in this survey are used to investigate the AEFIs to establish a causal relationship. Where investigation is performed, 15 of them carry it systematically AEFI investigation and 5 when needed (Table 22).

In 12 countries (a bit less than 50%, 12/25 – Table 23) the investigation is mandatory. Matching data about mandatory investigation (Table 23) with data about systematic investigation of AEFIs (Table 22) it results that in 2/3 of the countries (10/15) investigation is mandatory and systematically performed.

When mandatory (12 countries), investigation is performed for all events in 6 countries, serious events in 5 countries and other events (list of AEFIs, unlisted events and events whenever the risk-benefit may be compromised – Table 23) in 3 countries. In 2 countries investigation is mandatory both for serious events and other events. National health authority is in charge of investigating, assessing causality in 13 of 19 countries, local health authority in 10 countries and other authorities (mainly at regional level) are in charge in 26% (5/19) of the countries (Table 24). In 7 countries there is a combination of authorities at different level (local, national and other) in charge of investigating AEFIs.

Table 25 - Countries with a system/network for identification and analysis of AEFIs in Europe - 2007*			
Yes	**No**	**Not known**	**TOTAL**
15	**9****	**1**	**25**

* Data for Belgium, Cyprus and Luxembourg are not available.

** Portugal and Germany don't have a system for identification and analysis of AEFIs that are systematically investigated

Table 26 - People in charge of identifying and analysing AEFIs in Europe - 2007*			
At national level			
Group of experts	***None***	***Other****	**TOTAL**
11	**0**	**3**	**14**
At local level			
Group of experts	***None***	***Other*****	**TOTAL**
3	**4**	**5**	**12**

* Data for Belgium, Cyprus and Luxembourg and Romania are not available.
** National network for PharmacoVigilance (Italy), Centre for communicable diseases prevention and control (Lithuania) and Dedicated staff at Norwegian Institute of Public Health (Norway)
*** Regional epidemiologists & team specialists in charge of PHC (Bulgaria), network of 31 regional PV centres which collect and analyze AEs (France), National network for PhV (Italy), Public health centers (Lithuania), AEFIs reporter (health care professional, member of the public - UK)

Table 27 - Countries with procedure for clinical and laboratory investigation for AEFI identification and follow - up in Europe - 2007*			
Yes	**No**	*Upload or fax*	**TOTAL**
5**	**20**	***3***	**25**

* Data for Belgium, Cyprus and Luxembourg are not available.
** Portugal and Germany don't have a system for identification and analysis of AEFIs that are systematically investigated

Comments

Comparing data extracted from tables 22 and 25, 13 of 15 countries (87%) systematically investigate AEFIs and have put also in place a system/network for identification and analysis of AEFIs in Europe. The 2 countries that systematically investigate AEFIs without a system/network for identifying and analysing them are Portugal and Germany. One country (France) has a system in place and AEFIs are systematically investigated when needed. Answers from Estonia are difficult to be interpreted: the country has a system/network for the identification and analysis but AEFIs are nor systematically investigated.

When in place, the system network is implemented at national level in all the countries (14/14, Romania has not been included in the analysis because did not give any detail about the system in place – Table 26). In 8 out of 14 countries the system is both at national and local level. Six countries (Austria, Estonia, Finland, Hungary, The Netherlands and Sweden) have a single system at central level supported by a group of experts. At local level AEFIs are identified and analyzed by a group of experts (3 countries – Table 26), through the network of pharmacovigilance (2 countries), PHC (1 country) and Pubblic health (1 country) and by a "AEFI reporter" (healthcare professional or member of the public, e.g. parent or carer).

80% (20/25) of the countries included in this survey are used to investigate the AEFIs to establish a causal relationship (60% systematically and 20% when needed – Table 22), but only 20% (5/25 – Austria, France, The Netherlands, Norway, United Kingdom – Table 27) has a procedure for clinical and laboratory investigation for AEFIs identification and follow – up.

Analysis and safety studies

They mainly focused on serious events. Some questions of the questionnaire try to gather about the end points of these events.

In this context the countries were asked

- If there are large-linked databases available for vaccine safety studies and about their utilization
- How many serious AEFI/year (absolute number and rate) with and without permanent sequelae were attributed to vaccine in the years 2003 – 2005 and
- How many vaccine doses were administered / sold in the years 2003 - 2005

Table 28 - Countries with large – linked databases available and suitable for vaccine safety studies and their utilization in Europe - 2007*

Yes	*Do you use them?*		No	No answer	TOTAL
	Yes	*No*			
9	*6*	*3*	***14***	**2****	**25**

* Data for Belgium, Cyprus and Luxembourg are not available.
** Italy and Spain

Comments

As previously stated, 80% (20/25) of the countries included in this survey investigate AEFIs in order to establish a causal relationship. 15 of them carry out systematically AEFI investigation and 5 when needed. Generally, in Europe all the countries record AEFIs; 80% of them has mandatory rules or laws to report and investigate AEFIs; 60% investigates and has a system/network for identifying and analysing them; 36% (9/25 – Table 28) has a large – linked databases available and suitable for vaccine safety studies and, finally, only 6 countries use these databases (Austria, Denmark, France, Poland, Sweden and United Kingdom). As above stated, few countries perform case studies on AEFIs (32%, 8/25 – Table 19) and 3 of them (Denmark, Poland and United Kingdom) are among those ones that use these databases.

Table 29 - Countries in Europe with N° of serious AEFIs with permanent sequelae attributed to vaccines and N° of vaccine doses sold not known or not reported* according to the years 2003, 2004 and 2005 - 2007 **

N° of countries with serious AEFIs attributed to vaccines not known or not reported			N° of countries with serious AEFIs with permanent sequelae attributed to vaccines not known or not reported			N° of countries with vaccine doses administered/sold not known or not reported		
2003	***2004***	***2005***	***2003***	***2004***	***2005***	***2003***	***2004***	***2005***
6	**2**	**2**	**15**	**13**	**12**	**11**	**11**	**11**

* Greece didn't report any data for all the years and Italy and Spain for the year 2003 about serious AEFIs and serious AEFIs with permanent sequelae
**Data for Belgium, Cyprus and Luxembourg are not available

Comments

The interpretation and utilization of data about the number of serious AEFIs with or without permanent sequelae and the number of vaccine dose administered/sold is very difficult because of the following reasons:

- According with the Table 29 some countries do not know or report the number of serious AEFIs or AEFIs with permanent sequelae and a significant number (11 countries) does not report the quantity of vaccine doses administered or sold
- When reported, the number of vaccine doses is always about the doses sold and not administered. Usually the AEFI rate is a proportion of administered and not sold doses. So the rate reported in some questionnaire is a proxy of the indicator internationally recommended: if you use these data, you have to take

care when you compare them with data based on international standard indicator as above described.

Finally only 5 countries reported the rate of serious AEFIs/year: for 2 of them rates were exact (Iceland and Finland), for 1 it was not so clear which denominator was considered (the number of vaccine doses administered/sold not was not reported) and for 2 of them the calculated rates were not properly reported.

Prevention and Treatment

Countries were asked if a nation/local protocol to reduce the frequency of AEFIs and for their management was developed. The issue about the implementation of a counselling service for pre- and pos-vaccination AEFI prevention is mentioned in the chapter about identification of AEFI, but, of course, is strictly related to this topic.

Table 30 - Countries with a national/local protocol to reduce the frequency of AEFIs in Europe – 2007*				
Yes	**No**	**Not known**	*Upload or fax*	**TOTAL**
2**	**22**	**1*****	*1*	**25**
Countries with a national/local protocol for AEFI management in Europe – 2007*				
Yes	**No**	**Not known**	*Upload or fax*	**TOTAL**
4****	**18**	**2**	*4******	**24**
* Data for Belgium, Cyprus and Luxembourg are not available. ** Italy and United Kingdom *** Sweden **** Austria, Latvia, The Netherlands and United Kingdom				

Comments

- 36% (9/25 – Table 16) of the countries has a counselling service for pre- and post-vaccination AEFI prevention. In this context 8% of the countries in Europe has developed a protocol to reduce the frequency of AEFIs and 16% for their management, but only 2 of them Latvia and The Netherlands have a counselling service for pre and post-vaccination AEFI prevention (Table 30). United Kingdom, Austria and United Kingdom have a protocol but without a counselling service for AEFIs and in Italy there is not a service delivering system in place at national level, but only at Veneto Region level (Green Channel),

Communication and Information

In such sensitive area countries were asked

- To whom the communication, if any, on AEFIs is given
- Who is in charge of giving information to communication media and
- If an AEFI annual report is released

Tables and comments are the following:

Table 31 - Categories of people to which the communication on AEFIs, if any, is given to - 2007*						
Respondent					**Not respondent**	**TOTAL**
27**					**1*****	**28**
p/p	***vp***	***po***	***mav***	***o***		
10	**23**	**12**	**3**	**7******		

* Data for Cyprus and Luxembourg have been extracted from the first general questionnaire
** p/p = parent/patient, vp = vaccine personnel , po = public opinion, mav = movement against vaccines, o = other
*** Portugal (validation by the answer of the first general questionnaire)
**** AEFI reporters, health professionals, web-site communication, report available on home page, SAM - State Agency of Medicine, health care professional, marketing authorisation holder, physicians, pharmacists

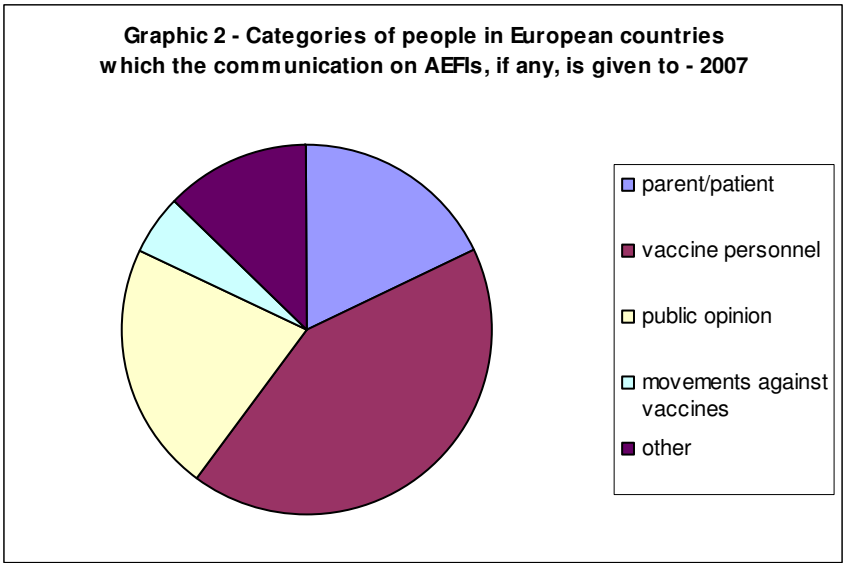

Table 32 - Categories of people in charge of giving information on AEFIs to communication media in European countries – 2007*			
Lhp**	**Na****	**o****	**TOTAL respondents*****
7	**23**	**4******	**25**

* Data for Belgium, Cyprus and Luxembourg are not available.
** lhp = local health personnel, na = national authority, o = other
*** Greece didn't give any answer and it has been defined as "not respondent", in the meanwhile the answer of Portugal is a contradiction of the absence of any answer to the previous question
**** Agency for Health and Food Safety, Ministry of Health, vaccine manufacturers, regional health authority (epidemiologists, medical officers)

Table 33 - Countries releasing an AEFI annual report in Europe - 2007*			
Yes	**No**	*Upload or fax*	**TOTAL**
10	**15**	*2*	**25**

* Data for Belgium, Cyprus and Luxembourg are not available.

Comments

Based on the answers of the first general questionnaire of 2006, the absence of answer in the questionnaire of Portugal is interpreted as absence of any systematic activity about communication. Anyway, it is important to validate the answer. Greece doesn't implement any kind of shared communication. Of the other 26 countries, 10 (38%) give communication on AEFIs to patient or parents, 22 (88%) to vaccine personnel, 12 (46%) to public opinion, only 3 (12%) to Movements Against Vaccines (MAVs) and 7 (27%) to others not included in the categories above mentioned (Table 31 and Graphic 2). In the category other AEFI reporters, health professionals, web-site communication, State Agency of Medicine, health care professional, marketing authorisation holder, physicians and pharmacists are included. In 6 countries (Estonia, Italy, Norway, Romania, Slovakia and Spain) communication on AEFI is given to vaccine personnel only. Public opinion is informed about AEFIs in 12 countries (Belgium, Bulgaria, Cyprus, Denmark, Finland, France, Germany, Hungary, Iceland, Ireland, Lithuania and United Kingdom): in 3 of them (Denmark, Germany and United Kingdom) communication is given also to MAVs. Finally in Slovenia

communication on AEFIs is made available to vaccine personnel and on home page and in The Netherlands only through a report on home page.

Assuming that Ministry of Health (Czech Republic) and Agency for Health and Food Safety (Austria) are national authorities, out of 25 countries considered, 23 have a national authority in charge of giving information on AEFIs to communication media: 7 of them include also local health personnel (Denmark, Germany, Ireland, Latvia, Lithuania, Norway and Romania) and 2 other categories (vaccine manufacturers in Denmark and epidemiologists/medical officers at regional level in Hungary – Table 32).

Finally, 40% of the countries (10/25 – Table 33) release an AEFI annual report making it available to the public.

Vaccination campaigns and Training

The issues are

- if during vaccination campaigns a different surveillance system is planned and, in that case, to describe it and
- if the country has never developed a training program/manual for helath staff on prevention, identification and treatment of AEFIs

Table 34 - European countries included in VENICE survey planning a different AEFI surveillance system during mass vaccination campaigns - 2007*				
Yes	**No**	*Describing*	*Upload or fax*	**TOTAL**
6**	**19**	*6***	*1*	**25**
* Data for Belgium, Cyprus and Luxembourg are not available. ** The 6 countries planning a different surveillance system during vaccination campaigns are: AT, FI, FR, IE, NL and UK. 4 countries, generally speaking, state to develop and implement a different system and 2 describe some aspects: clinicians alerted to campaign and reminded to report any adverse events, Registration of acute events, reactogenicity, and passive surveillance				

Table 35 - European countries included in VENICE survey that have developed a training program/manual for health staff on prevention, identification and treatment of AEFIs - 2007*				
Yes	**No**	**Not known**	*Upload or fax*	**TOTAL**
9	**16**	**1**	*2*	**26**
* Data for Cyprus and Luxembourg are not available.				

Comments

6 of 25 countries (24% - Table 34) stated to plan a specific surveillance system during mass vaccination campaign. Of these only 2 gave some details about the system, such as: clinicians alerted to campaign and reminded to report any adverse events, registration of acute events, a not better defined "reactogenicity" and passive surveillance.

Also few countries (a bit less than 35%, 9/26) have developed a training program/manual for health staff on prevention, identification and treatment of AEFIs (Table 35).

CONCLUSIONS

These data should be validated by each country, mainly by those one that filled in partially or in an unclear way the questionnaire. Nevertheless it is already possible to attempt some general conclusions and pinpoint some relevant strengths and weaknesses.

Relevant strengths

- General picture enough homogenous without great differences between the countries
- Strong political commitment
- Relevant and articulated systems for reporting and assessing AEFIs
- Great potential capacity of surveillance systems to collect and analyse data
- Strong connection with EU surveillance networks
- Identification of interesting practices (such as UK AEFI reporting system, the Veneto Region Green Channel AEFI counselling service in Italy)

Relevant weaknesses

- A gap between a strong political commitment at national level and delivery services in AEFI counselling, prevention and management area
- Weak implementation of the potential capacity of surveillance systems to collect and analyse data
- Poor use of available data and monitoring and evaluation (M&E) activity
- Poor analysis and study of interesting practices
- Weak involvement of public opinion and, generally speaking, not-qualified people
- Neglect of health staff training program on prevention, identification and treatment of AEFIs

Preliminary suggestions

- To implement a coordination mechanisms for harmonization of the AEFI related delivery services with the political commitment
- To study and analyze the identified interesting practices

- To identify other interesting or best practices useful for a more effective AEFI surveillance system
- To focus the institutional attention on the relevance of the health staff training program and on the availability of suitable training tools for preventing, identifying and treating AEFIs