

## Appendix C

### Q.6. Country responses where national reporting systems are partial

#### Question 6 – NATIONAL REPORTING SYSTEM: Austria

6a) Is there a **national** incident reporting system?

Yes

In Austria, we have an extensive system of pharmacovigilance, clinical studies, a recall system for pharmaceuticals, regulations for medicinal products etc.

For detailed information please contact:  
Federal Ministry of Health and Women  
department III/6  
Radetzkystrasse 2  
1030 Vienna  
Austria  
Tel. +43-1/711 00-0  
Fax +43-1/711 00-14300  
<http://www.bmgf.gv.at>

No

But at present, there is no systematic national recording of “errors“ that occur in the health care system, although awareness of the existence of errors within the Austrian health care system is constantly on the rise.

For future plans please see Question 2

If yes, please answer points b) to i)

b) Please provide contact details:

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website:

c) Does the system collect information on near misses? Yes/No

d) Is the data protected from legal inquiry? Yes/No

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|--|
| e) Is the system connected in any way to litigation? Yes/No  |
| f) How is the data collected used? (Please briefly describe)   |
| g) Is there a system for analysing reported events? Yes/No   |
| h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list<br><br>-<br><br>-<br><br>-<br><br>- |
| i) Can patients report incidents directly to the national reporting system Yes/No  |
|  |

**Question 6 – NATIONAL REPORTING SYSTEM: Belgium**

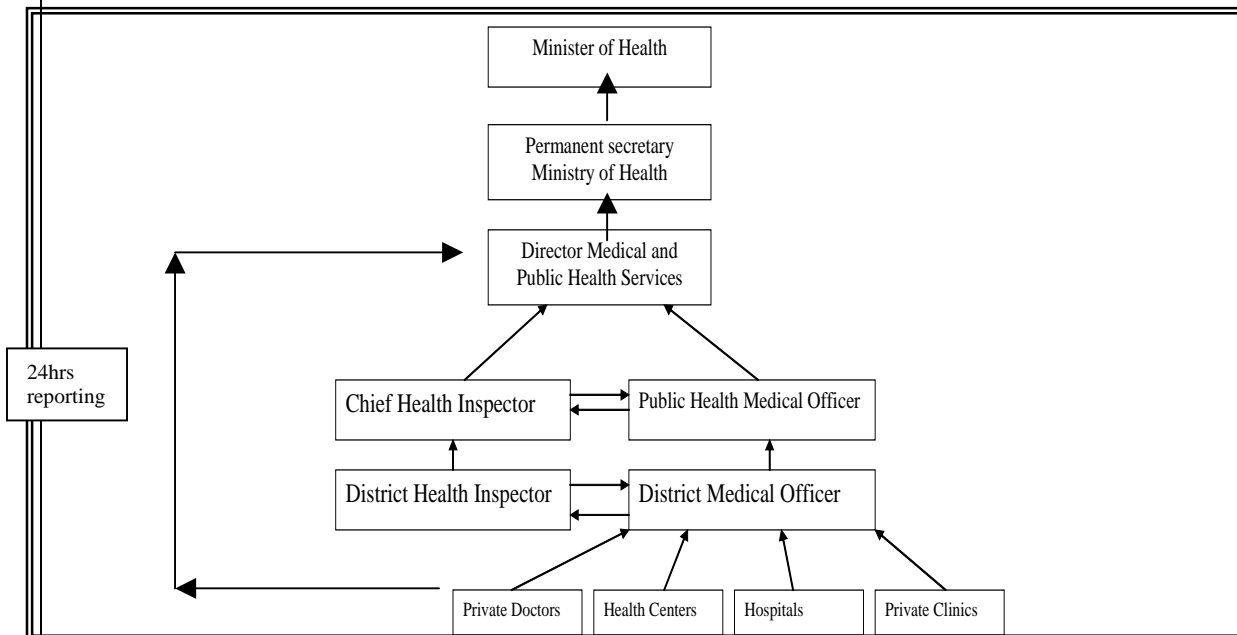
|   |
|---|
| 6a) Is there a <b>national</b> incident reporting system? Yes/No PARTLY<br>If yes, please answer points b) to i)<br>Administrative Data available<br>Voluntary Claim Reporting    |
| b) Please provide contact details:<br><br>Address: see above Federal Service of Health<br><br>Postcode:<br><br>Country:<br><br>Telephone number(s):<br><br>Email:<br><br>Website: |
| d) Is the data protected from legal inquiry? NA   |

|  |
|--|
| e) Is the system connected in any way to litigation? NA  |
| f) How is the data collected used? (Please briefly describe)<br>To inform hospitals on AE detected   |
| g) Is there a system for analysing reported events? Yes/   |
| h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list<br><br>-Depend on the hospitals methodology<br><br>-No systematic Methodology<br><br>-<br><br>- |
| i) Can patients report incidents directly to the national reporting system /No   |

**Question 6 – NATIONAL REPORTING SYSTEM: Cyprus**

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|---|
| 6a) Is there a <b>national</b> incident reporting system? ✓ Yes /No   |
| <p><b><u>NETWORK FOR THE SURVEILLANCE AND CONTROL OF COMMUNICABLE DISEASES</u></b><br/> <b><u>MEDICAL AND PUBLIC HEALTH SERVICES</u></b><br/> <b><u>MINISTRY OF HEALTH</u></b><br/> <b><u>CYPRUS</u></b></p>  |
| <p>A Network for the Surveillance and Control of Communicable Diseases has been developed under the Medical and Public Health Services of the Ministry of Health of Cyprus. Following a relevant amendment of the legislation, four systems for Surveillance of Communicable Diseases have been introduced:</p> <p>1. <i>Mandatory Notified Communicable Diseases Network</i>, a System for reporting the</p> |

Mandatory Notified Communicable Diseases, currently 57 in number. The notification procedure is described in the following diagram:



Apart from the timely notification of all these cases, for a number of them of special Public Health importance for Cyprus, there is a direct within 24hrs notification to the central level:

Through detailed Notification Forms, information of epidemiological importance is collected for all reported cases. Special notification forms were developed for a number of these diseases (i.e. viral meningitis, meningococcal disease/ bacterial meningitis, poliomyelitis, foodborne diseases, HIV e.t.c.) . The recommended by EU *Case Definitions* (categorizing as probable, possible or confirmed) are used for all 57 diseases.

2. *Sentinel Network*, it is a system for reporting 11 diseases/syndromes based on clinical diagnosis. Reporting is voluntary, mainly by primary health care physicians (GPs and Pediatricians) of Private and Public Sector, from all over Cyprus.
3. *Laboratory Network*, a voluntary System for reporting isolation of microorganisms/ positive serology results. Reporting is voluntary by Microbiology Laboratories of Private and Public Sector, from all over Cyprus.
4. *Sexually Transmitted Diseases Network*, a voluntary System for reporting a number of STDs. Reporting is voluntary by Gynecologists and Dermatologists of Private and Public Sector, from all over Cyprus.

All data are entered on EPI Info 2000 database which apart from statistical analysis provides geographic distribution information.

The system is going to provide feedback to the periphery through a 6monthly newsletter and will facilitate flow of information, related to Communicable Diseases, to EU.

If yes, please answer points b) to i)

b) Please provide contact details:

Address: Dr. Chrystala Hadjianastassiou, Chief Medical Officer, 10, Marcou Drakou Street, Pallouriotissa, Nicosia

Postcode: 1449

Country: Cyprus

Telephone number(s): +357 22 400146

Email: cycomnet@cytanet.com.cy

Website:

c) Does the system collect information on near misses? Yes/ No- **Non Applicable**

d) Is the data protected from legal inquiry?  Yes/No

e) Is the system connected in any way to litigation? Yes/ No

f) How is the data collected used? (Please briefly describe). **For the surveillance of communicable diseases and for early detection of outbreaks**

g) Is there a system for analysing reported events?  Yes/No

h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list

- **Routine analysis on a weekly, monthly, six monthly and yearly basis which aim to assess the incidents of the communicable diseases.**

i) Can patients report incidents directly to the national reporting system Yes/  No

**Question 6 – NATIONAL REPORTING SYSTEM: France**

6a) Is there a **national** incident reporting system? Yes/No  
If yes, please answer points b) to i)

b) Please provide contact details:

in France there are several national reporting systems. Some are mandatory :

- mandatory reporting systems to AFSSAPS on failures with health products ( "vigilances"),
- mandatory reporting system on associated health care infections that are to be declared to INVS (since 2001) on unusual and gravity criteria
- a mandatory reporting system for all health care professionals will soon concern severe adverse events. The first step is an experimentation and is in progress

Others are voluntary : like the one on the "near miss" events, linked to the doctors and health care teams accreditation process. Adverse events related to high risk interventional activities are going to be declared to HAS . A "decree" has just been published in July 2006

Corrective measures are taken by the different agencies. For nosocomial infections the reports are gathered at the national level which draws conclusion about best practices, gives recommendations and develops national guidelines

In conclusion the reporting system in the fields of drug, blood, medical devices and other healthcare products, along with nosocomial infections is highly structured, at national, regional, and local levels.

Concerning nosocomial infections, the Ministry of Health is directly in charge of the definition of a risk reduction program and of its different action areas. As an example, the 2005-2008 program focuses on training, research, improvement of health care organisation and clinical practice .A national audit programme for nosocomial infections is carried out with a focus on hand hygiene is being carried out

Concerning other adverse events, reporting systems are in progress

Postcode:

Country:

Telephone number(s):

Email:

Website:

Does the system collect information on near misses? **Yes X/No**  
Near misses related to high risk interventional activities will be reported by physicians to the HAS on a voluntary basis and in exchange the physicians will receive an accreditation and a reduction in the cost of their insurance premium

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|---|
| <p>Is the data protected from legal inquiry? Yes/No <b>X</b><br/> The HAS and the Ministry of Health are conducting work to consider if solutions to protect data from legal inquiries can be adopted in regard to French law</p> |
| <p>e) Is the system connected in any way to litigation? Yes/No <b>X</b></p>   |
| <p>f) How is the data collected used? (Please briefly describe)</p>   |
| <p>g) Is there a system for analysing reported events? Yes/<b>X</b> /No<br/> the national strategy is being defined and one of the aims will be to adopt more systematic rigorous approaches</p>                                  |
| <p>h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list</p> <p>-</p>  |
| <p>i) Can patients report incidents directly to the national reporting system<br/> j) Yes/<b>No</b></p>   |

**Question 6 – NATIONAL REPORTING SYSTEM: Italy**

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|---|
| <p>6a) Is there a <b>national</b> incident reporting system? Yes/No <b>NO At the present time trust are requested by Ministry to report sentinel events (a list is provided)</b><br/> If yes, please answer points b) to i)</p> |
| <p>b) Please provide contact details:</p> <p>Address:</p> <p>Postcode:</p> <p>Country:</p> <p>Telephone number(s):</p> <p>Email:</p> <p>Website:</p>  |
| <p>c) Does the system collect information on near misses? Yes/No</p>  |
| <p>d) Is the data protected from legal inquiry? Yes/No</p>  |
| <p>e) Is the system connected in any way to litigation? Yes/No</p>  |

f) How is the data collected used? (Please briefly describe)

g) Is there a system for analysing reported events? Yes/No

h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list

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i) Can patients report incidents directly to the national reporting system Yes/No

## Question 6 – NATIONAL REPORTING SYSTEM: Netherlands

6a) Is there a **national** incident reporting system? Yes/No

The reporting of incidents is only obligatory for a very limited amount of incidents, only for the serious adverse events ('calamiteiten'). Calamiteiten or serious adverse events need to be reported to the management of a hospital, who is obliged by law to report to the Healthcare Inspectorate. This obligation is led down in the Law on Quality of Healthcare Organisations (Kwaliteitswet Zorginstellingen 2005)

If yes, please answer points b) to i)

b) Please provide contact details:

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website: [www.igz.nl](http://www.igz.nl)

c) Does the system collect information on near misses? Yes/No

d) Is the data protected from legal inquiry? Yes/No, only to a certain extent. Based on the Law on Public Openness (Wet Openbaarheid van Bestuur WOB) incident reports can be made public (after anonimisation) under specific circumstances.

e) Is the system connected in any way to litigation? Yes/No

f) How is the data collected used? (Please briefly describe)

Hospital management can start an internal investigation in case of a serious adverse event. They always have to report this incident and the actions taken to the Inspectorate. The Inspectorate can be satisfied with this reaction of the hospital itself, but always has the right to start to conduct their own research.

g) Is there a system for analysing reported events? Yes/No

h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list

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i) Can patients report incidents directly to the national reporting system Yes/No

Other relevant information in this respect:

- **PREZIES network:** <http://www.prezies.nl/>

PREZIES stands for Prevention of Hospital infections by surveillance (= *PREventie van ZIEkenhuisinfecties door Surveillance*) The PREZIES network is a collaboration of participating hospitals, the Dutch Institute for Healthcare Improvement CBO and the National Institute for Public Health and Environment (RIVM). Results of PREZIES show that the risk on nosocomial (or hospital) infections indeed decrease by surveillance. PREZIES collaborates with national surveillance systems for nosocomial infections in other EU countries in the HELICS-project (<http://helics.univ-lyon1.fr/>).

- **Performance Indicators of Dutch Healthcare Inspectorate (IGZ)**

The Dutch Healthcare Inspectorate (IGZ) in 2004 for the first time started to ask hospitals to provide them with information on certain quality performance indicators. These results are made public and are a method for hospitals to be transparent on their quality and safety performance. This enables the IGZ to prioritise in governing the healthcare sector by focusing on high risk areas and to work more efficient and effective. This method is meant to fasten the application of best practices by hospitals. Of course the overall aim is to improve quality and safety for patients. The report of the Inspectorate on performance indicators 2005 is available on [http://www.igz.nl/15451/17873/Rapport\\_2005-05\\_Het\\_resulta1.pdf](http://www.igz.nl/15451/17873/Rapport_2005-05_Het_resulta1.pdf)

- **Complaint procedure within hospitals**

On 1 August 1995 the Law on Rights to Complain for Patients in Healthcare Organisations (Wet Klachtrecht Cliënten Zorginstellingen) came into force. Furthermore in December 2004 a standard on complaints was issued (Klachtenrichtlijn:

<http://www.cbo.nl/product/richtlijnen/folder20021023121843/klacht-rl-2004.pdf>)

The Law from 1995 aims to create complaint procedures that are easy accessible and that facilitate quality improvement. Healthcare organisation are obliged by law to have rules on complaint procedures, to have a complaint commission with an independent chairman, to annually report to the Inspectorate and to report serious adverse events to the Inspectorate. The complaint procedure system should by law be easy accessible, have expertise, objective, react quickly and inform the complainer on the actions that are taken.

- **Central Medication Registration (Centrale Medicatie Registratie, CMR)**

The Dutch Association of Hospital Pharmacists has developed a national database for uniform classification and registration of medical errors, Central Medication Registration (Centrale Medicatie Registratie, CMR). This database was piloted in the period starting 1 July 2004. At this moment all hospitals can subscribe to the CMR. The CMR:

- i. national uniform classification and registration of medication related incident reports
- ii. Feedback on reported data to participating hospitals
- iii. Spreading alerts on alarming medication errors

More information can be found on: [http://www.nvza.nl/kr\\_nvza/default.asp](http://www.nvza.nl/kr_nvza/default.asp)

**Question 6 – NATIONAL REPORTING SYSTEM: Portugal**

6a) Is there a **national** incident reporting system? **Yes**

If yes, please answer points b) to i) **only for medicines and medical devices**

b) Please provide contact details: **INFARMED see Question 2**

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website:

c) Does the system collect information on near misses? **Yes**

d) Is the data protected from legal inquiry? **NO**

e) Is the system connected in any way to litigation? **NO**

f) How is the data collected used? (Please briefly describe)

**For statistical purposes and notice to public and professionals; to suspend or redraw products from the market.**

g) Is there a system for analysing reported events? **Yes**

h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list

- **none of the above**

- **analyse of concurrent medication and/or use of medical devices**

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i) Can patients report incidents directly to the national reporting system **Yes**

### Question 6 – NATIONAL REPORTING SYSTEM : Slovenia

6a) Is there a **national** incident reporting system? Yes

If yes, please answer points b) to i)

b) Please provide contact details

Address: Ministry of Health, Štefanova 5, LJUBLJANA

Postcode:1000

Country:Slovenia

Telephone number(s):

T:+3861 478 6061

F:+3861 478 6058

Email: e-mail:andrej.robida@gov.si

Website: www.mz.gov.si

c) Does the system collect information on near misses? No

d) Is the data protected from legal inquiry? Yes

e) Is the system connected in any way to litigation? No

f) How is the data collected used? (Please briefly describe)

For feedback information and alerts

g) Is there a system for analysing reported events? Yes, by providers with the help of MoH

h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list

Only sentinel events as defined by JCAHO are anonymously and confidentially collected on voluntary basis.

-RCA

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