



French Presidency of the European Union:
Informal meeting of Health Ministers

Monday 8 September and Tuesday 9 September 2008

Angers

Press Release

**Press Contact – Ministry for Health, Youth, Sports and Associations
01 40 56 40 14**

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	a) Alzheimer's disease and similar conditions;	
	b) Health and safety;	
	c) Health in Europe at the service of patients;	
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	3) Other health topics discussed during the informal meeting:	
	a) The future of the European Regional Office of the WHO and the coordination of the European Union;	
	b) The draft directive on "Patients' rights and cross-border healthcare	
	4) Calendar of health events within the framework of the upcoming EU French Presidency.	

I – General presentation of the health ministers’ informal meeting

1) The health representatives present at the informal meeting.

The ministers, vice ministers, Secretaries of State, Senior Officials or Heads of Delegation present:

- 1) **Belgium:** Laurette Onkelinx
- 2) **Czech Republic:** Thomas Julinek
- 3) **Denmark:** Steffen Hansen Egesborg
- 4) **Germany:** Ulla Schmidt
- 5) **Estonia:** Maret Maripuu
- 6) **Greece:** Georgios Konstantopoulos
- 7) **Spain:** Bernart Soria
- 8) **France:** Roselyne Bachelot-Narquin
- 9) **Ireland:** Mary Harney
- 10) **Italy:** Maurizio Sacconi
- 11) **Cyprus:** Christos Patsalides
- 12) **Latvia:** Ivars Eglitis
- 13) **Lithuania:** Gedeminas Cerniauskas
- 14) **Luxembourg:** Mars Di Bartolomeo
- 15) **Hungary:** Tamas Szekely
- 16) **Malta:** Joseph Cassar
- 17) **Netherlands:** Abraham Klink
- 18) **Austria:** Hubert Hrabcik
- 19) **Poland:** Ewa Kopacz
- 20) **Portugal:** Ana Jorge
- 21) **Slovenia:** Darko Ziberna
- 22) **Slovakia:** Richard Rasi
- 23) **Finland:** Paula Risikko
- 24) **Sweden:** Maria Larsson
- 25) **United Kingdom:** David Harper

- 26) **Bulgaria:** Evgenii Jelev
- 27) **Romania:** Eugène Nicolaescu
- 28) **Turkey:** Recep Akdag
- 29) **Croatia:** Drazen Jukovic
- 30) **Former Yugoslav Republic of Macedonia:** Buyar Osmani
- 31) **Switzerland:** not registered
- 32) **Norway:** Rigmor Aasrud

Other representatives present at the informal health meeting:

Dr. David Heymann, Assistant Director General of the World Health Organization

Marc Danzon, World Health Organization Regional Director for Europe

Jaroslav Pietras, Director General of the EU Council

Zsuzsanna Jakab, Director of the European Centre for Disease Prevention and Control (ECDC)

Androulla Vassiliou, European Commissioner for Health

Guest of honour of the informal health meeting:

Michael Leavitt, Secretary of Health and Human Services of the United States of America

Programme of the health ministers' informal meeting, Monday 8
September and Tuesday 9 September 2008

Monday 8 September

- 10.00** Interview of Roselyne Bachelot-Narquin, French Health Minister, with Ulla Schmidt, German Health Minister
- 11.00** Interview of Roselyne Bachelot-Narquin, French Health Minister, with Evgeni Jelev, Bulgarian Health Minister
- 12.00** Interview of Roselyne Bachelot-Narquin, French Health Minister, with Marc Danzon, World Health Organization Regional Director for Europe
- 12.30** ANGERS – Conference Centre
Working lunch (with interpreters) for the ministers of the European Union and Androula Vassiliou, European Commissioner for Health
Topic: The future of the WHO Europe and coordination of the EU
Talk by Commissioner Vassiliou on an initiative in the health field
- 2.30** Start of informal meeting – Conference Centre (Osnabrück room)
Introductory speech by Roselyne Bachelot-Narquin, French Health Minister

Three talks on the subject of **health and safety**

- “The European health and safety system: past and future”, by Androula Vassiliou, European Commissioner for Health
- “Evaluation of health risks: how does the EU system work?” by Zsuzsanna Jakab, Director of the European Centre for Disease Prevention and Control (ECDC)
- “Critical discrepancies between the plans of the member States in preparation for an influenza pandemic: work programme arising from the Euroflu seminar”, by Didier Houssin, Director General for Health in France

- 4.00** Presentation of two scenarios by Didier Houssin, Director General for Health in France.
Roselyne Bachelot-Narquin, French Health Minister, will chair the meeting and vote on the two scenarios
Case studies: yellow fever and respiratory infection of unknown cause. Vote on the issues of the scenarios
- 5.00** First discussions on the observation and the proposals, in the presence of Roselyne Bachelot-Narquin, French Health Minister, Zsuzsanna Jakab, Director of the European Centre for Disease Prevention and Control (ECDC), Marc Danzon, World Health Organization Regional Director for Europe, and David Heyman, Assistant Director General of the World Health Organization
- 5.35** Press review of the Presidency
- 6.15** End of first day

Tuesday 9 September

- 7.30** Interview of Roselyne Bachelot-Narquin, French Health Minister, with Michael Leavitt, American Secretary of Health and Human Services
- 9.00** Continuation of works of the previous day and results of votes
- 12.00** End of meeting
- 12.15** Group photo
- 12.45** ANGERS – Conference Centre

Working lunch (with interpreters) for the ministers of the European Union and Androula Vassiliou, European Commissioner for Health

Topic: “The draft directive on patients’ rights and cross-border healthcare”

Topic: “Combating Alzheimer’s disease”

2.30 Presidency press conference in the presence of Roselyne Bachelot-Narquin, French Health Minister and Androula Vassiliou, European Commissioner for Health

3.30 End of informal meeting

II – Health and safety as a priority of the French Presidency of the European Union

1) General presentation of the two health alert scenarios.

The need to coordinate health and safety policies has proven essential these recent years, notably after the onset of several outbreaks such as SARS and avian flu. The European Union wishes to be able to quickly offer coordinated responses to such problems.

This is the purpose of this meeting in Angers.

A pragmatic approach has been taken in order that the ministers present, faced with a crisis situation, are able to compare their different political responses.

This is a political exercise and not down to expertise, which is based on two health alert scenarios:

- ★ The emergence of yellow fever in Europe;
- ★ The onset of respiratory infections of unknown cause, such as SARS.

There are of course no right or wrong answers. The differences or convergences that emerge will also reflect the particular features of the different nations.

However, a coordinated political response would not be the sum of all the national approaches, and this is why this exercise has a fundamental dimension.

To answer the questions raised, an electronic vote, using handsets, has been set up. The answers are anonymous and only the distribution of responses between the different choices offered will be presented.

In practical terms, a presenter will lead the exercise. Once he opens the vote, an “open vote” instruction will appear on the screen where the slide show is projected.

The participants choose the key (s) corresponding to their response, which will light up in red. Then they confirm on the OK key, which will light up in green. When the presenter notes that the total number of votes has been achieved, he will close the vote and the results will be displayed.

2) 1st health alert scenario: yellow fever.

For each question (A, B, C), several positive answers are possible

Context

Winter and spring 2009 are particularly mild and rainy in Europe.

Chronology of events

- ★ **End June 2009:** Symptoms of fever diagnosed in about a dozen participants in a forum bringing together 80,000 people.

The World Social Forum convenes over 80,000 participants in Riodésil, a South American country. Although the Forum is over, a few dozen participants are presenting with a fever with nausea and vomiting. Collective food poisoning is suspected, but not confirmed.

- ★ **14 July 2009:** importation of a case of yellow fever in country no. 1 within the EU.

The emergency department of Letitbloude hospital in a country in the south of the European Union notifies the health authorities of **a case of yellow fever** in a traveller returning from the Forum. The epidemiological study shows that it is a case of yellow fever imported following the stay of an unvaccinated patient in Riodésil, where yellow fever is endemic.

- ★ **31 July 2009:** contamination in country no. 2, several undiagnosed cases

The health authorities of Olivie, another country in the south of the European Union, are informed of several dozen **grouped cases of unexplained fever** in a coastal town hosting many European tourists. These cases concern residents of Olivie, but also tourists from two other member States of the European Union.

The diagnosis of Chikungunya virus is very quickly suggested due to the onset of similar episodes in previous years. The onset of new clinical symptoms (jaundice) in some patients and the seriousness of some cases rapidly suggest the clinical diagnosis of yellow fever. The **results of biological analyse are pending**. According to informal sources, **one death has allegedly occurred**. At this stage, the information available suggests a vector-borne disease, transmitted by a mosquito. The vector in question could be the mosquito *Aedes albopictus*, present in this region of Europe.

1 August 2009, the newspapers of Olivie and the bordering countries cover the information on the grouped cases of unexplained fever. The media reports the worries of the citizens and tourists present in Olivie and in the bordering countries. The health authorities of Olivie have not commented.

Question A: with no biological confirmation, as health minister, what information do you decide to communicate to citizens?

Response choices:

A1	<i>You immediately communicate the information you have.</i>
A2	<i>You await confirmation of the diagnosis and communicate the confirmed information.</i>

Response choices:

A3	<i>You decide at a national level what will be communicated</i>
A4	<i>You bilaterally contact the countries concerned before drafting your communication.</i>
A5	<i>You ask for a consultation with the European Commission to share the information available with all the member States and define a common language element.</i>

On 3 August, the laboratories confirm the diagnosis of yellow fever. These are the first cases of indigenous yellow fever in Europe since the middle of the 19th century.

Question B: no case of indigenous yellow fever has been notified in your country, but the vector mosquito is present there. You wish to avoid the establishment of this disease on your territory by applying the measures specified by the International Health Regulations. You must consider the constraints of the summer period, characterised by a significant influx of tourists. What do you decide?

<i>Response choices:</i>	
B1	<i>You inform the public about preventative measures and conduct to follow, on the basis of the fact that the number of cases notified in the member State concerned remains relatively low.</i>
B2	<i>You suggest to your government that quarantine measures (six days) should be implemented for any unvaccinated person arriving from a member State where yellow fever has been confirmed.</i>
B3	<i>You decide to suggest that your government suspends application of the Schengen Agreements concerning the free movement of people. Any unvaccinated person arriving from a member State where yellow fever has been confirmed may not enter your country.</i>

Question B (continued): Furthermore, citizens and travel agencies are contacting the health minister for advice for travellers who want to visit high-risk areas. What do you decide?

<i>Response choices:</i>	
B4	<i>You decide to inform travellers about preventative measures.</i>
B5	<i>You recommend postponing travelling to the high-risk area.</i>
B6	<i>You recommend vaccination 10 days prior to travel.</i>

The experts of the health ministries of several member States suggest management measures in order to limit the spread of cases of yellow fever. Among these measures, vaccination against yellow fever is suggested. The experts from your ministry point out that the stock of vaccines available is limited because almost all the annual worldwide reserve of vaccines against yellow fever has already been used up.

► **Question C:** Although cases of yellow fever are likely to soon be notified on your territory, you have a limited stock of yellow fever vaccines. How do you decide to use them?

<i>Response choices:</i>	
C1	<i>You use the national stock of vaccines to vaccinate travellers going to high-risk areas.</i>
C2	<i>You reserve the national stock of vaccines for possible later use if the disease appears in your country.</i>
C3	<i>You ask for a European coordination meeting to build, by pooling of the resources available in each member State, a stock of vaccines which will be provided to Olvie to contain the sites of yellow fever.</i>

3) 2nd health alert scenario: air traffic and the flow of travellers upon a severe acute respiratory infection alert.

For each question (A, B, C), several positive responses are possible

Context

On 23 December 2008, many European tourists are spending the end of year celebrations in the isles of Seehandsun, in the Asiatic Southeast, a very popular tourist country renowned for its beaches and its turquoise seas.

The health authorities of this country are informed of the onset in Kiamalkri, capital of Seehandsun, of several dozen cases of severe febrile respiratory infection, including five deaths. The treating hospital staff are also affected. The disease seems to be transmitted very easily from a contaminated person to another person upon close contact.

No notification has yet been made by the health authorities of Seehandsun within the framework of the International Health Regulations (IHR), but your departments have been alerted to this event via the monitoring of informal channels such as Promed.

Still according to informal dispatches, epidemiological investigations have allegedly identified among the patients several people residing in a village concerned by a seat of infection of avian flu A/H5N1 virus. A test for H5N1 virus and other viruses potentially responsible, including coronavirus (SARS agent), is underway.

In view of the highly contagious nature of the disease and similarities with the first episode of SARS and with episodes of influenza pandemics, experts are mentioning the risk of pandemic and the possible emergence of a new virus.

In this period of uncertainty, the citizens and the media of the countries concerned are putting pressure on the governments to avoid introduction of the disease onto their territory. Countries bordering Asia are setting up a body temperature check by thermal camera upon the arrival of travellers arriving from Seehandsun onto their territory.

Question A: Your country has an international airport with direct flights to and from Seehandsun. The virus responsible for the cases of respiratory infection has not yet been identified. The WHO has not issued any recommendations. What provisions do you foresee implementing with regard to the flow of travellers upon entry onto your territory?

<i>Response choices:</i>	
A1	<i>Informing of passengers as to the clinical signs that must be checked out and the conduct to follow. Implementation of tracking of passengers from Kiamalkeri.</i>
A2	<i>Establishment of a thermal camera check upon arrival of passengers, with organisation of treatment of feverish people.</i>
A3	<i>7-day quarantine period for people arriving from Kiamalkeri.</i>
A4	<i>Suspension of direct flights from Kiamalkeri.</i>

N.B.: the particular difficulties linked to flights in transit will be tackled as part of the comments.

On 28 December, although 30,000 nationals of the European Union are still in Seehandsun, the cases of severe febrile respiratory infection are multiplying, notably among tourists. All member States are affected. Both prevention and treatment resources of Seehandsun are limited.

Question B: what measures do you envisage offering to your citizens?

Response choices:

B1	<i>Advise citizens in Seebandsun to take responsibility for their own health.</i>
B2	<i>Recommend that citizens stay in Seebandsun.</i>
B3	<i>Provide individual protection measures in diplomatic posts: medicines, masks.</i>
B4	<i>Organise repatriation of nationals.</i>
B5	<i>Request a consultation at EU level to support Seebandsun in the management of this alert, and particularly in the treatment of patients.</i>

On 4 January 2009, a leading laboratory in one of the countries of the EU identifies a new virus. On the same day, the laboratory specifies the efficacy of an antiviral drug recently marketed by a drug firm.

Question C: due to the high cost of treatment (1,800 euros per patient), the costs likely to be incurred will be particularly high. What decisions do you make?

Response choices:

C1	<i>You suggest building a strategic national stock.</i>
C2	<i>You suggest that the European Commission builds a strategic European stock in order to treat the patients for whom the indication is a priority.</i>

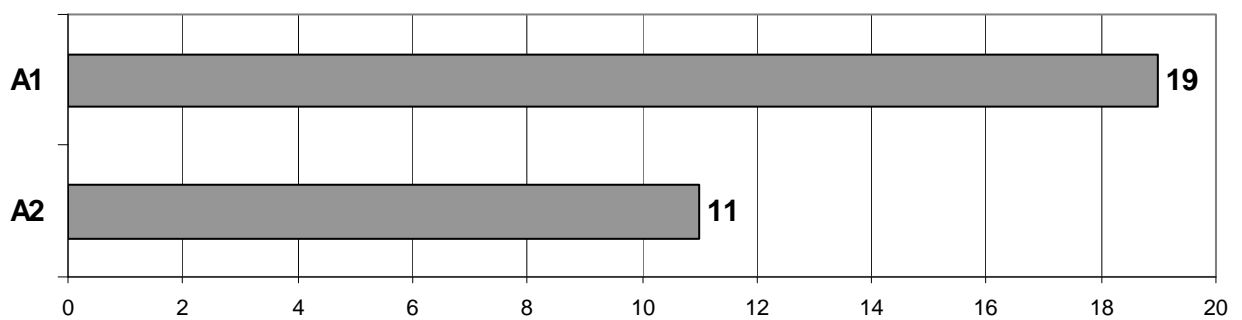
Exercice results : yellow fever

A - Communication and expertise

Without biological confirmation, what information do you decide to communicate to citizens?

- A1 You communicate straightaway the information you have
- A2 You wait for the confirmation of the diagnosis and you communicate on the basis of confirmed elements

Data analysis : 30 voters – only one answer possible

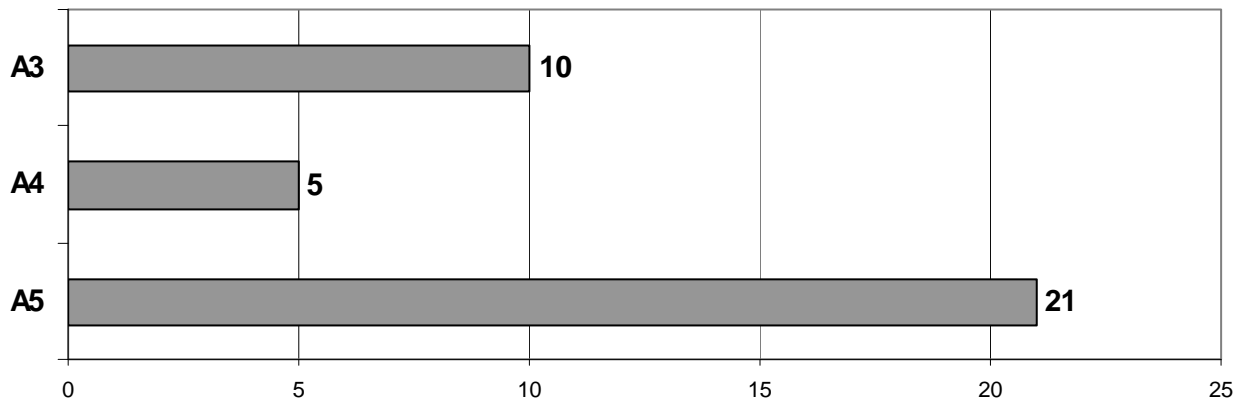


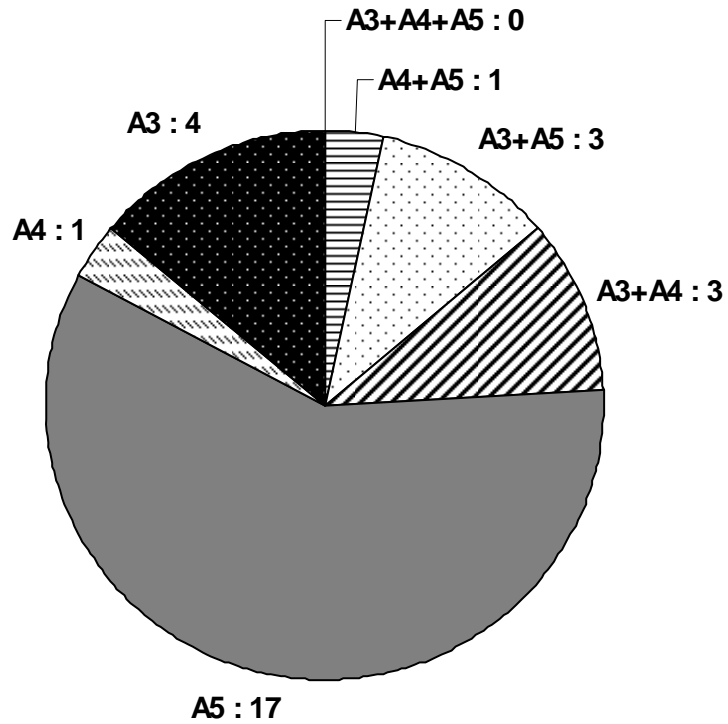
More than 60% of voters prefer to communicate straightaway, despite of uncertainties. One third favours securing information before communication: this may induce the need to communicate in reaction (lost of control and credibility).

Without biological confirmation, what information do you decide to communicate to citizens?

- A3 You decide at national level what will be communicated
- A4 You bilaterally contact the countries concerned before working out your communication
- A5 You ask the European Commission to initiate coordination in order to share available information with all Member States and to define a common language element

Data analysis : 29 voters – one or more answers





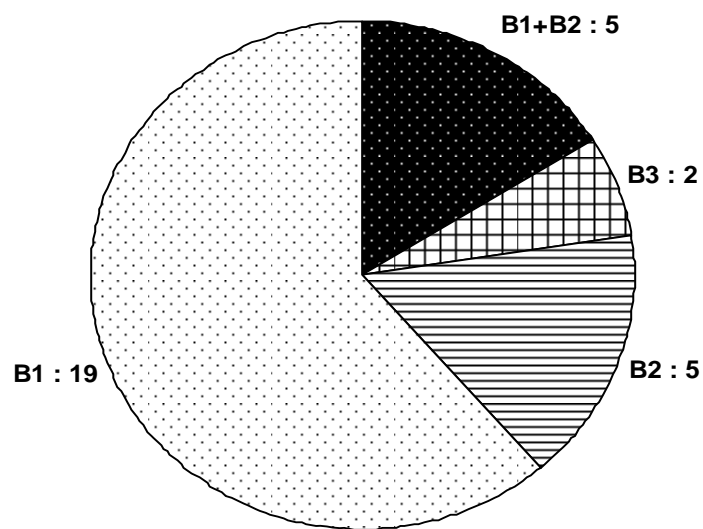
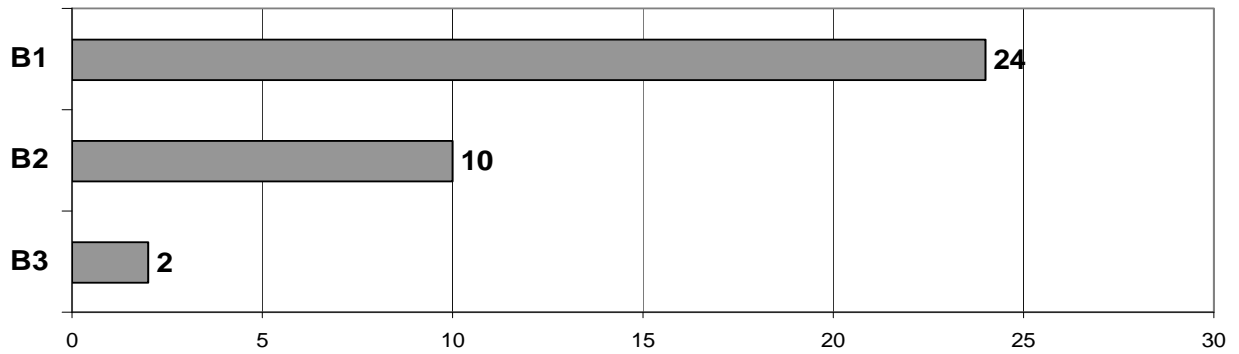
This question highlights a clear willingness for the coordination of the sharing of information and the elaboration of common language elements, as 72% of voters consider this dimension in their responses. More than 60% of this 72% of voters keep only the solution of an EU coordinated communication.

B – Travellers coming from yellow fever endemic areas

During a ministerial meeting at national level, you have to explain your position. What do you decide regarding people coming from Olivie?

- B1 You provide information on the preventives measures on the basis that the number of cases reported in Olivie is relatively limited
- B2 You suggest that quarantine measures (six days) should be implemented for any unvaccinated person coming from Olivie
- B3 You suggest restrictive cross border measures for some persons (in particular the suspension of Schengen agreements for Members States concerned); unvaccinated people coming from Olivie will not be allowed to come in your country.

Data analysis : 31 voters – one or more answers



More than 60% of the voters choose the softest measure (information for travellers). The others envisage stronger measures (quarantine or restrictive cross border measures). This split in the strategies of rules governing movement of people may induce two types of difficulties:

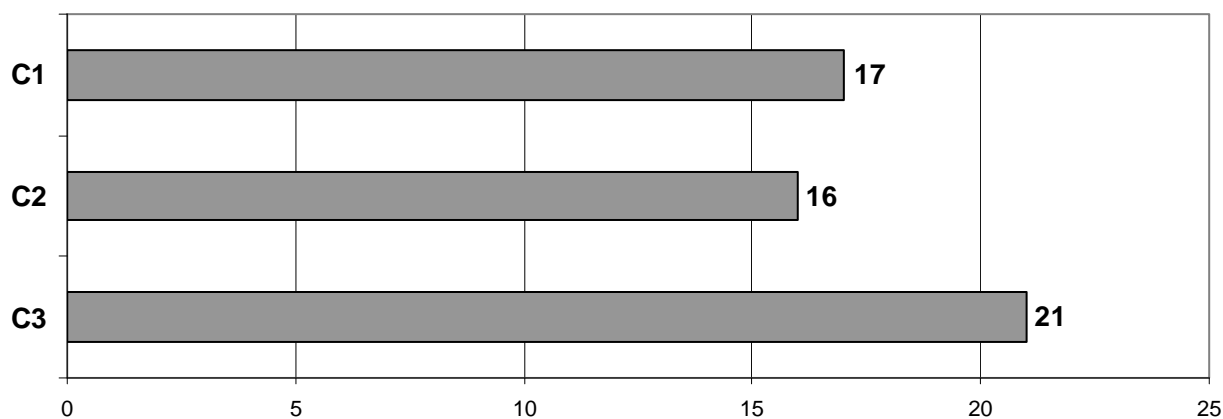
- in terms of communication and awareness about the measures taken;
- in terms of efficacy of restrictive measures, there is a possibility of circumvention via Member States which put in place neither quarantine neither restriction of movement.

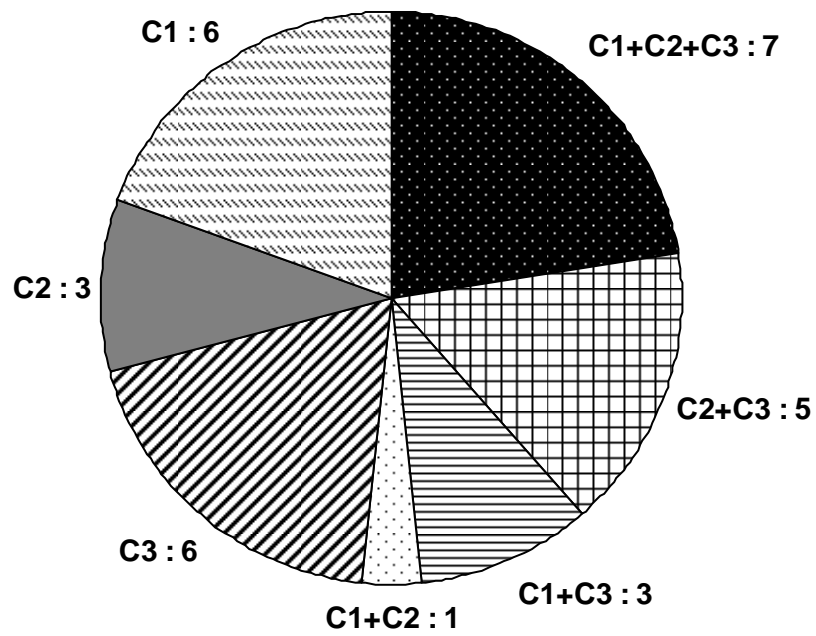
C – Travellers going to yellow fever endemic areas

What do you decide regarding advice for citizens who wish to travel abroad to Olivie ?

- C1 You inform travellers about preventive measures to be taken
- C2 You advise travellers to postpone their trip to risk areas
- C3 You recommend prior vaccination 10 days before travelling

Data analysis : 31 voters – one or more answers





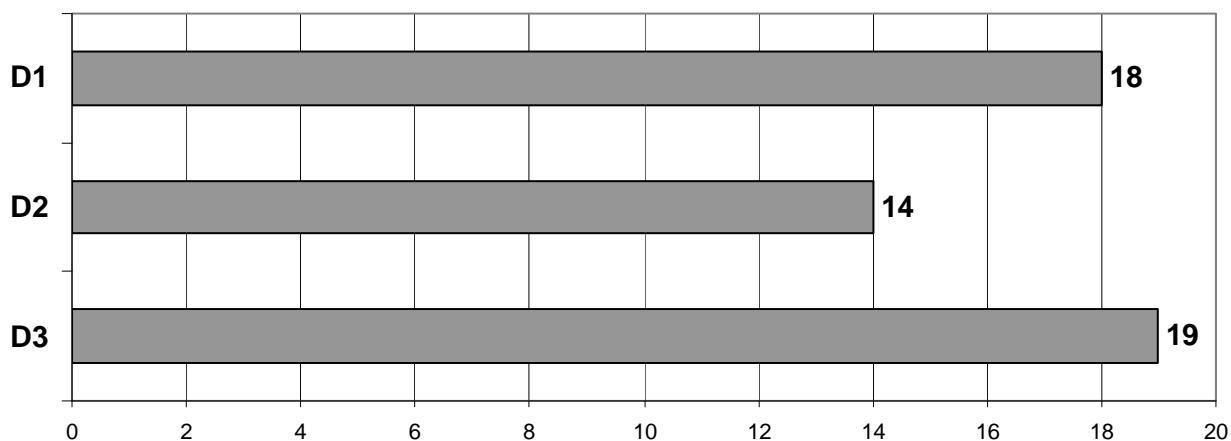
The analysis highlights the greatest diversity of answers (7 possible combinations are represented). The main split concerns the implementation of prior vaccination, chosen by two thirds of voters, but rejected by the others. Please note that 20% of voters consider that the sole information of travellers is sufficient.

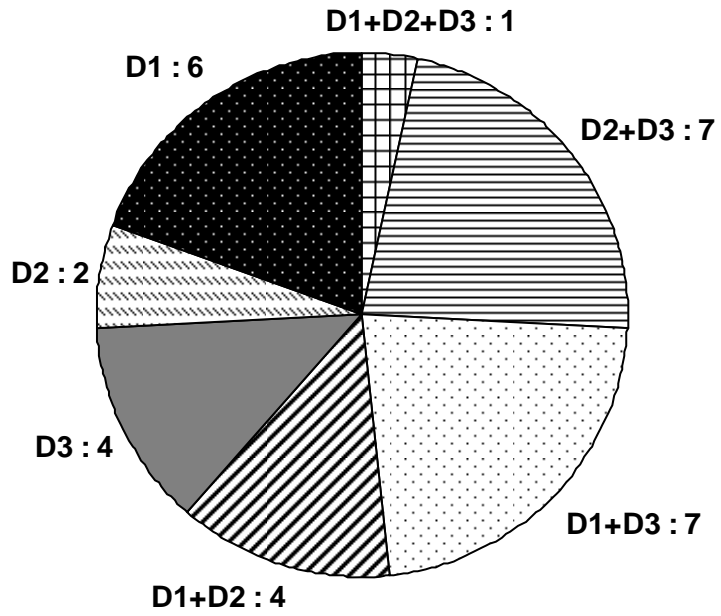
D - Vaccination

How do you decide to use the limited vaccines' stockpile?

- D1 You use the national stockpile of vaccines to vaccinate travellers going to risk areas
- D2 You keep the national stockpile of vaccines for possible use if the disease appears in your territory.
- D3 You ask for a European coordination meeting to share the available resources of each Member State to build a stockpile of vaccines which will be provided to Olivie to control the yellow fever at its source

Data analysis : 31 voters – one or more answers





The answers to this question reflect various health strategies which include, for more than 60% of these strategies, a containment of cases in Olivie.

CONCLUSION :

Amongst the important lessons of this scenario, the wish to communicate quickly seems common to several Member States and it is in lines with another wish, which is also widely shared, of a dialogue at the EU level.

What can we do to match speed and dialogue?

Concerning the management measures, the dominant feeling is a very wide diversity of the chosen options. The feasibility of certain measures can be questioned, as well as the capacity **to communicate in a sufficiently convergent manner.**

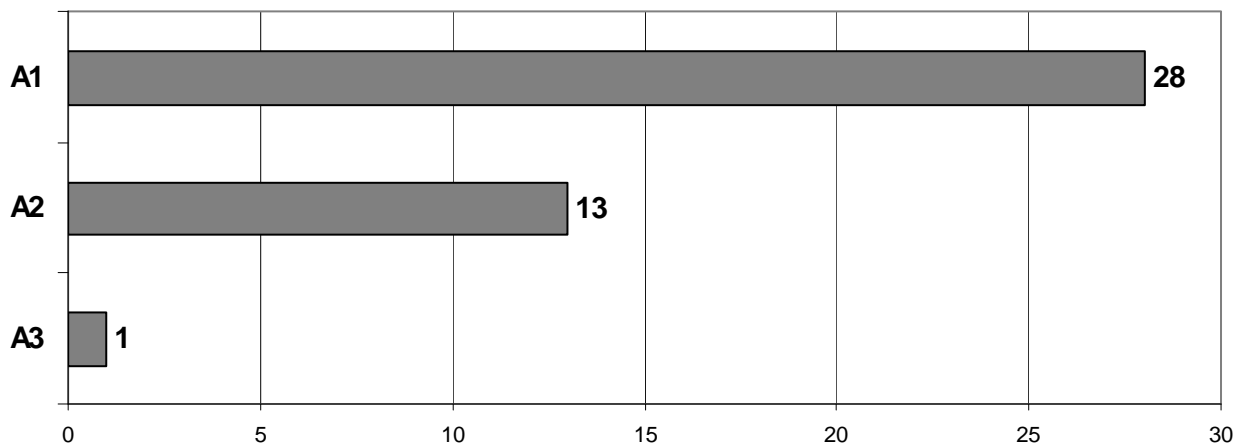
Exercice results : ASRS

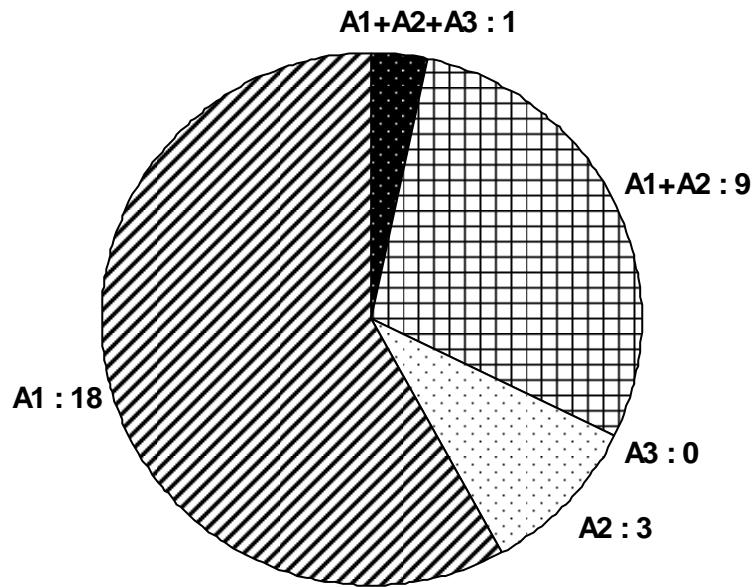
A - Journeys and movements towards or from Seehandsun

Experts of the health ministry suggest various measures for control of passenger traffic from Seehandsun, some including restriction of freedom. What do you decide ?

- A1 Tracking of passengers coming from Seehandsun using the nominative data of airline companies
- A2 Implementation of a 7-day quarantine for passengers arriving from Seehandsun
- A3 Suspension of direct flights from Seehandsun

Data analysis : 31 voters – one or more answers possible





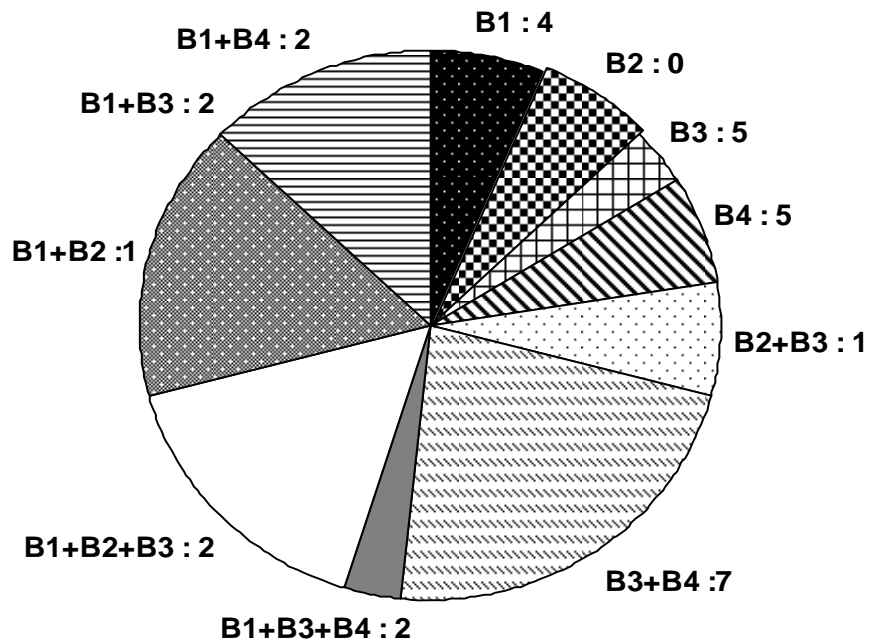
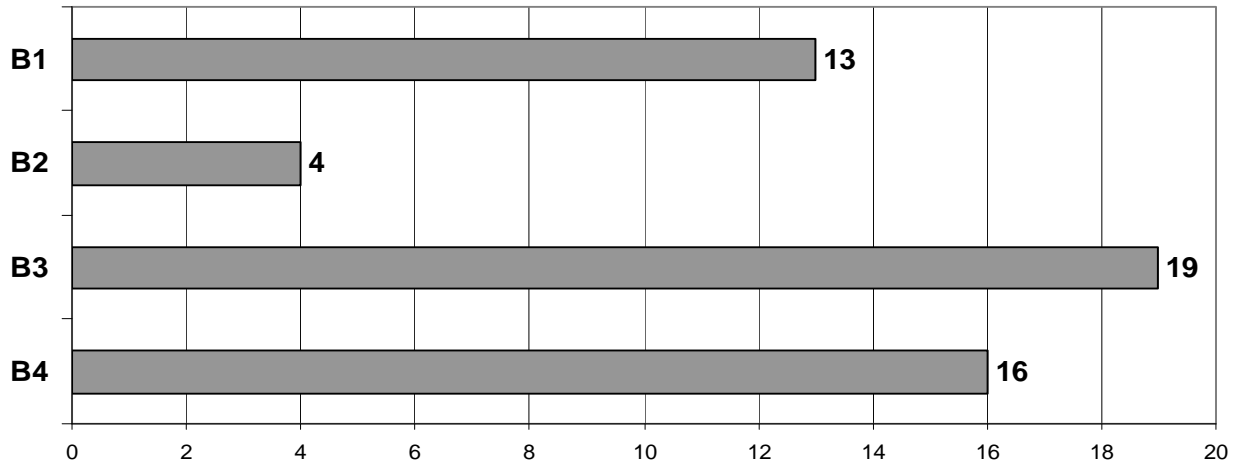
28 voters out of 31 (i.e. 90%) choose to put in place a measure of contact tracing of passengers. 10 of these 28 decide to associate a measure of quarantine. The efficacy of this measure can only be relative, taking into account the possibilities of circumvention constituted by points of entry of Member States which do not put this measure in place.

B – Coverage of nationals

What measures would you offer your nationals in Seehandsun ?

- B1 You advise citizens to take personal responsibility for their own health
- B2 You recommend them to stay in Seehandsun
- B3 You provide them individual protection measures in diplomatic missions : medicinal products, masks
- B4 You arrange repatriation of nationals

Data analysis : 31 voters – one or more answers possible



Half of the voters envisage arranging a repatriation of their nationals; the other Member States choose to recommend them to stay in Seehandsun. This divergence may be difficult to explain and may raise questions within the EU population.

The most frequent answer (more than 60% of voters) is the availability of individual protection means in diplomatic missions. This supposes that these missions be equipped sufficiently with the necessary materials.

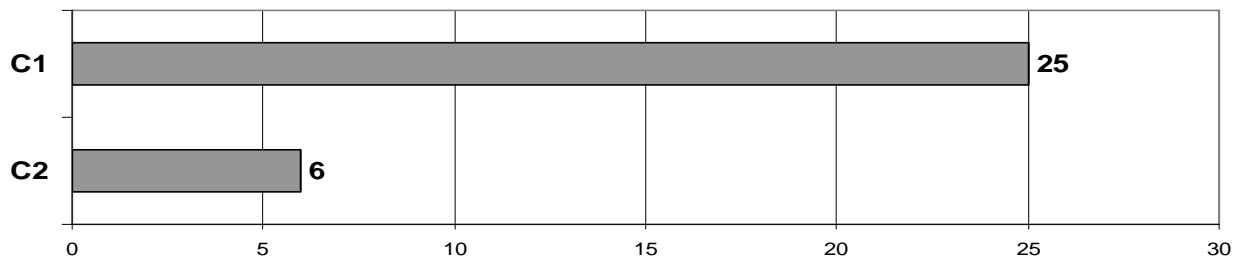
C – Medicinal products stockpile

Is it useful to build up a medicinal products stockpile?

C1 Yes

C2 No

Data analysis : 31 voters – only one answer possible



D - Medicinal products stockpile (continued)

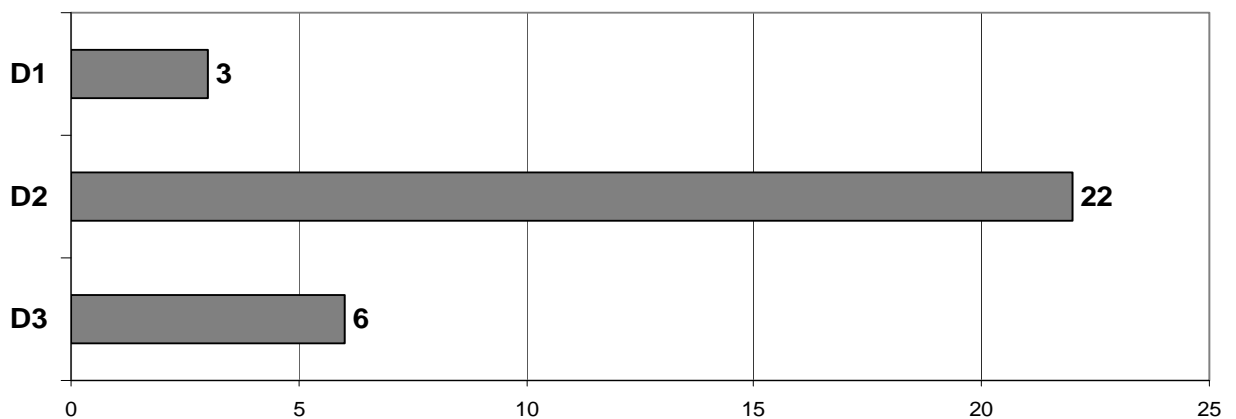
At what level, do you wish to build up the stockpile?

D1 Local level (region ; district ; land ; canton ; province...)

D2 National level

D3 European Union level

Data analysis : 31 voters – only one answer possible



80% of voters consider it useful to constitute a stockpile of antiviral medicinal products and 70% prefer to have this stockpile at national level.

However, these answers raise another question : would all the Member States, if they wanted to, have the capacity to constitute a stockpile ?

CONCLUSION :

This scenario leads to the following question : in a context where strategies of response are frequently presented as purely national, can the management measures be fully efficient without a dialogue between the Member States ?

This dialogue seems desirable, and especially for the rules governing movements of people, help provided to EU nationals in the endemic areas and access to available treatments.

III- The health field within the framework of the French Presidency of the European Union: priorities and prospects

1) The priorities and general prospects in the health field, within the framework of the French Presidency of the European Union

Health is a constant concern of European citizens, for themselves and for their families, at all ages of life. Everyone hopes to benefit from the best advice and treatment.

The member States are working to fulfil this expectation, notably by devoting a significant proportion of their human and financial resources. This is one of the most remarkable characteristics of the European social model. In this field, and with respect for the principle of subsidiarity, Europe can however offer us a framework that could improve our performances.

The coinciding of the new proposals of the Commission with the French Presidency of the European Union gives us the opportunity to together seek how to develop European health in consultation. The many meetings and conferences organised by France furthermore echo this. The interest of building strengthened cooperation in order to mobilise resources and skills available in each of the member States and respond to the major challenges with which we are all confronted is also highlighted.

To best respond to the expectations of our citizens, we must encourage debate, giving all parties concerned the opportunity to express themselves: the patients and their families, health professionals, the managers of the administration and management of the health systems, the researchers and the institutions.

In fact, constructing a real European health System is not only down to the political managers. It assumes a collective commitment and discussion.

During this half-year, the discussions and decisions must enable us to progress in this field so essential to the security and wellbeing of all.

The Trio programme: France, the Czech Republic and Sweden

Contributing to a high level of health for all European citizens: this is the general objective of the 18-month programme from which France, the Czech Republic and then Sweden will conduct their works, while respecting continuity, up to the end of 2009.

It is thus that on 9 December 2008, with the Commission and the Trio, France will organise the first meeting of the high level group on public health, which should examine the major challenges of tomorrow's health and the responses which can be envisaged collectively.

Europe's action must concentrate on the areas where it offers real added value.

For example, if it intends to favour mobility, it must guarantee patient safety and quality of treatment, "regardless of whether the patient, the doctor or the service has crossed the border", as specified in the Trio health programme.

The three presidencies – each according to its own specific perspective – are granted in order to show common priorities: improve health and safety, age in good health, make tangible Health in Europe at the service of patients and their families, act on health drivers, and progress applications relative to drugs.

The French Presidency of the EU wishes also to continue the work of its predecessors, Portugal and Slovenia, and work within the framework of the European strategy described in the white paper "Working together for health: a strategic approach for the European Union 2008-2013", adopted by the Commission on 23 October 2007.

2) The five priority measures of the French Presidency in the health field

While considering the first three as priorities, the French Presidency will base its programme around the following five topics: Alzheimer's disease, health and safety, Health in Europe at the service of patients, medicines, and everything based around health drivers.

a) Alzheimer's disease and similar diseases

The dual challenge of the ageing population and the treatment of dependent patients is arising more and more strongly for all member States, with already significant repercussions in the social field. Faced with this situation, and in order to respond to the expectations of patients and their families, a common approach based on discussion and sharing of experience seems to offer solutions.

This is what France intends to encourage, by listing the fight against Alzheimer's disease and degenerative diseases – which are already a priority at a national level – among the European priorities.

The objectives pursued:

The European dimension could give a significant impetus to the different aspects of the fight against these diseases. Hence the joint announcement made on 1 July by José Manuel Barroso, president of the Commission, and by France to set the objective of the preparation of a European plan to combat Alzheimer's disease. It could be based around three themes: research, treatment and quality of life, ethics and legal aspects.

The key point is to improve cooperation on a European level in order to together conduct a discussion on the threefold scientific, medical and social challenge. Within the framework of a comprehensive and pragmatic approach, we suggest studying further the following themes:

- sharing of experiences and drawing up of common principles relative to the quality of treatment of patients and their carers;
- development of specific skills and adaptation of jobs;
- facilitation of the coordination of research programmes.

Indeed, the development of a common platform of best standards in the field of care and treatment will help to delay the development of the disease and make it more tolerable to patients and their families. A new dynamic of collaboration in research, biology, health and social sciences

should enable us to progress more quickly in the path to delay the onset of the first symptoms. A discussion would also be led on common objectives with regard to training of medical and socio-medical staff to take account of the new skills necessary to the specificity of treatment of these diseases, and a discussion on the adaptation and promotion of personal carer professions. The ethical dimension of these various subjects will be explored, along with any legal implications. In fact, the delicate questions of (legal) representation of patients and their consent to participation in clinical trials arise. These works fall clearly within the principles laid down in the EU Charter of Fundamental Rights. While the choices and decisions are personal, family-based, and within the framework of national legal frameworks, the complexity of the issues makes sharing of experience necessary.

It also seems important to convince European citizens that while the absence of a definitive treatment is a fact, there are solutions to the day-to-day problems. This message of hope must be passed on (“you can also live with Alzheimer’s disease”) within the EU and society’s perception of Alzheimer’s disease and similar diseases must be changed.

A high level conference will be organised in Paris on 30-31 October in order to mobilise more the institutions of the European Union, the member States and civil society in their fight against these diseases.

During this conference the essential aspects of combating diseases of this type will be tackled: that of treatment of patients, requiring merging of care and social support; that of development of specific skills and adaptation of jobs according to the needs of patients and the evolution of knowledge; and lastly that of research, through coordination of the research programmes already in progress in the various European countries.

France will also submit a proposal of conclusions of the Council on this subject in order, among other things, to launch a process aiming for each country of the EU to be equipped with a plan, a strategy or national measures which lead to effective terms of application founded on an inter-sector and concerted approach towards these diseases in Europe.

b) Health and safety

During recent years, several alerts have shown the fragility of the responses that the European Union was able to offer to major health crises. The lack of coherence in the measures adopted by each of the member States in such circumstances reduced the effectiveness of their action. This situation has proved unsuitable for a world where the movement of people and goods is accelerating, as is communication.

The entry into force of the new International Health Regulations (IHR 2005), and the evaluation underway of the European Centre for Disease prevention and Control (ECDC), are opportune factors to bring the matter to a European level.

The issue is to be organised among the European countries – preferably by liaising internationally – faced with sudden and potentially serious public health situations which call for rapid and effective decisions.

France will propose a pragmatic approach to health and safety at the informal meeting of European ministers responsible for health organised on this subject on 8 and 9 September in Angers. Through tangible examples (yellow fever epidemic, SARS) this meeting should be the opportunity to assess the need for coordination, to discuss practices in the analysis of risks and the ways of responding to them, and to envisage the means to establish coordination at a European level.

The discussion of the ministers will also be fed by the conclusions of the seminar on avian flu which, from 3 to 5 September in Angers, will follow on from the meetings organised on the same subject in 2007 in London (in July) then in Luxembourg (in September).

France wants the conclusions of the December EPSSCO Council meeting to be able to translate a shared concern for improvement in risk management, so as to be able to put appropriate methods in place.

c) Health in Europe at the service of patients

This topic responds to the tangible expectations of European citizens. It should render visible the advances of European health in several fields. This will notably be the object of the “Health in Europe at the service of patients” conference organised in Paris on 13 and 14 October. This event will give a large place to the point of view of the patients and health professionals. It will tackle as much the strategies that could improve the quality of care as the issue of patients’ rights or the response that the EU can offer to rare diseases with the creation of reference centres.

Several of the subjects tackled in this conference will later be looked into in more depth in another framework. This is particularly the case for various aspects of combating rare diseases, which will be subject to several meetings (10 October, 16 and 17 October, and 18 November) during which France will be able to share the experience it has already acquired in the matter.

France must also refer to several legislative texts. In this respect, it has fixed the objective of progressing as much as possible the negotiations on the directive relative to the application of patients’ rights in cross-border care. The proposal was presented by the Commission on 2 July 2008 as part of the “social agenda package”. This long awaited text pursues a threefold objective: to reiterate the common values and principles underlying the care systems; to standardise the rulings of the European Court of Justice and thus clarify patients’ rights to be treated abroad; and to support and promote cooperation between member States in the health field. It will notably relate to finding the balance between two points: firstly the strengthening of patients’ rights, and secondly the protection of national jurisdiction in the organisation and financing of the care package.

Other texts of the Commission are expected during the French Presidency of the EU to reinforce the quality or safety of care: a directive and an action plan on organ donations and transplants, and also recommendations or communications on patient safety and nosocomial infections, on rare diseases, on telemedicine and technological innovations in the treatment of chronic diseases, and a communication on the smoke-free environment.

d) Medicines

The proposed directive on changes to marketing authorisations (AMM) is currently being examined by European Parliament. Work on this text began under the Slovenian Presidency, with the objective sought being adoption upon first reading.

Furthermore during November the Commission should present several initiatives which will take the form of a “drugs package”. It should make it possible to progress pharmacovigilance and patient information on a European level, and also the future of pharmaceutical products and combating counterfeiting.

These texts will arrive too late for the EPSSCO Council meeting of 16 December to be able to rule on them, but the debate will be opened on 2 October at the “Pharmaceutical Forum” in Brussels, to which the 27 European health ministers are invited. Other events concerning drugs will be organised by the Presidency, notably the colloquium on “The Challenges of Health in Europe” on 10 September, and the conference devoted to resistance to antibiotics on 6 and 7 November in Paris.

e) Health drivers

Prevention will be present in the programme of the French Presidency, notably with regard to the health of children and young people. The threefold issue of nutrition, overweight and obesity are currently the object of a report by European Parliament, awaited with interest. It will also be covered at a conference organised by the network of EPODE cities on 2 and 3 October in Béziers.

With regard to combating smoking, France, like a growing number of member States, has recently imposed a ban on smoking in all public places. It is thus working ahead of the Commission’s recommendation for a smoke-free environment planned for the end of the year. It will also come down to the French Presidency to coordinate the positions of the countries of the EU as part of the works linked to the WHO “International convention on combating smoking” from 17 to 22 November in Durban, South Africa.

Similarly, different aspects of addictive behaviours will be tackled during several conferences organised under the aegis of the MILDT (inter-ministerial mission for combating drugs and addictions).

3) Other health topics discussed at the informal meeting:

a) The future of the European Regional Office of the WHO and the coordination of the European Union

The European region of the WHO is composed of 53 member States, extends from the Atlantic to the Pacific, and is inhabited by over 880 million people. It covers an unbelievable diversity of populations and health situations, and the countries of the region are faced with varied health problems that require different strategies.

The European Regional Office of the WHO includes a permanent secretariat with its head office in Copenhagen. It also includes five decentralised offices, and country offices distributed in 29 member States of the region. The presence of the European Union within the region (over half of the States of the WHO EURO are members of the EU) represents a major strategic issue for the regional director of EURO, who must try to well position himself with regard to all the States of the region.

Since 2000 the WHO EURO office has been directed by a Frenchman, Marc Danzon (elected in September 1999). His second term of office will end in February 2010. A new regional director will be elected for 5 years at the 59th Regional Committee meeting (13/14 September 2009) by the 53 member States of the Region.

The principal **priorities for actions** of the office are concentrated around the following fields:

- transmissible diseases and health and safety,
- health and the environment,
- non-transmissible diseases,
- the strengthening of the health systems.

To do this, the WHO EURO Office has developed many **partnerships** (European Commission, ECDC, Council of Europe, OCDE, etc.) and encourages an inter-sector approach to health issues (e.g. implementation of the “2nd European action plan of the WHO for a food and nutritional policy” with the signing of the European Ministerial Charter to combat obesity, adopted in November 2006 in Istanbul, and Tallinn Ministerial Charter: health, health system, prosperity signed in June 2008).

More than half of the member States of the WHO Europe are members of the European Union, so the future regional director must consider that the Community is a major issue within his organisation. Similarly, the member States of the European Union must consider their responsibility to assure cohesion within the future office. The election of the new director will take place during the second half of 2009, under Swedish Presidency, so still within the framework of the trio with the Czech Republic and France. This is why Roselyne Bachelot-Narquin wanted the first steps of this discussion to be launched under the French Presidency.

b) The draft directive on “Patients’ Rights and cross-border healthcare”

Context

Healthcare has been excluded from the field of application of the 2006/123/EC directive relative to services within the domestic market. The Council and Parliament invited the Commission to deal with issues relative to cross-border healthcare in a separate instrument.

The Commission has led a public consultation in order to accurately list the problems. The authors of the majority of the 280 contributions received declared themselves in favour of a Community healthcare initiative – in a form to be determined – combining legislative elements and practical support to the cooperation between the European health systems.

On this basis, and within the framework of the renewed social agenda, on 2 July the commission presented its proposed directive aiming to facilitate the exercising of the rights of European patients with regard to healthcare, and a communication relative to improvement in cooperation between the member States in this field. While, in clear and constant case law, the Court of Justice has confirmed that the treaty confers on patients the right to be treated in other member States and obtain, in theirs, reimbursement of the costs incurred, the more general terms of application of the principles established by this case law are not yet well defined. Through this

proposal, the Commission aims to assure legal safety on this issue. In this it responds to European Parliament and the Council of Ministers, which had invited the Commission to propose an initiative specially devoted to cross-border healthcare, explicitly adapted to the unique nature of the healthcare sector and respecting this particular feature. Furthermore, the proposed directive lays down a solid base making it possible to release the huge potential that the European cooperation possesses in order to contribute to improving the efficiency of all the health systems of the European Union (EU).

The objectives of the directive

Generally this directive, once adopted by the Council and European Parliament, will provide a clear framework governing cross-border healthcare. The principal provisions are as follows:

- patients have the right to be treated abroad and be reimbursed to the limit of what they have paid in their country. The directive will clarify the method of exercising these rights – including the restrictions that member States can impose with regard to the provision of care abroad – and the level of financial cover for cross-border care;
- healthcare dispensed on the territory of a member State comes under the jurisdiction of this State. Patients must have assurance that the quality and safety standards applicable to the treatments given to them in another member State are properly controlled and that they are based on good medical practice;
- the directive will facilitate European cooperation in the healthcare sector. It will flatten the bases enabling support of the establishment of reference European networks, which will voluntarily bring together specialised centres in different member States. For the patients this collaboration, which will facilitate access to highly specialised treatment, could be extremely beneficial. It could also prove useful for health systems because it should encourage the optimisation of resources, for example by grouping them together in centres based on the treatment of rare diseases;
- the evaluation of health technologies is another field where, clearly, Europe can offer added value. This initiative will contribute to reducing overlapping and duplications in this field, in this way promoting an optimum exploitation of resources;

- the activities in the field of on-line health will also be strengthened. Information and communication technologies have a huge potential for improving the quality, safety and efficacy of healthcare. The Commission is already supporting on-line health projects in fields such as the provision of specialised remote support services through major hospital infrastructures to the benefit of smaller local entities. Common standards and models that can be used from one system and one country to another will however be the default. The directive will contribute to their establishment.

4) Calendar of health events within the framework of the upcoming EU French Presidency

MEETING of the EPSSCO COUNCIL – health division

- 16 December in Brussels

INFORMAL MEETINGS of MINISTERS

- 8-9 September in Angers (Centre des congrès)

Health ministers' informal meeting.

Chaired by Roselyne Bachelot-Narquin, Minister for health, youth, sports and associations, this meeting will have the topic of health and safety, one of the three priorities of the French Presidency in the health field.

OUTSIDE of France

- 2-3 October in **Brussels**

“Pharmaceutical Forum”, organised by the European Commission in liaison with the French Presidency

- 16-17 November in **Cairo (Egypt)**

Euro-Mediterranean ministerial conference on health

Jointly chaired by Roselyne Bachelot-Narquin and Hatem Mostafa Al Gabali, minister for health and citizens of the Republic of Egypt, this conference will bring together the health ministers of the 27 countries of the EU and 16 countries surrounding the Mediterranean. It will deal with strengthening the health systems, and combating non-transmissible and transmissible diseases. It will be preceded by a meeting of experts and senior representatives.

CONFERENCES organised by the Ministry for Health

September

- 3-5 September in Angers (Centre des congrès)
“EUROGRIPPE/EUROFLU” Seminar organised by the DILGA (Inter-Ministerial Delegation to Combat Avian Flu)

The conclusions of this seminar on avian flu will be presented at the opening of the informal meeting of ministers on the subject of health and safety

October

- 13-14 October in Paris (Institut Pasteur)
Conference on “Health in Europe at the service of patients”
- 30-31 October in Paris (Bibliothèque nationale de France)
Conference on “Combating Alzheimer’s disease and similar diseases”

November

- 4-5 November in Paris (Ministère de la santé – Laroque room)
Ministerial conference on “Human bio-surveillance in Europe”, organised by the General Health Directorate (DGS) and the Institute for Health Monitoring (InVS)
- 6-7 November in Paris (Ministère de la santé)
Workshop on “Progress in the rational use of antibiotics”, organised by the DGS (General Health Directorate)
- 18 November Paris (Ministère de la santé)
European seminar on “National plans and policies on rare diseases”, with presentation of the EUROPLAN (European Project for Rare Diseases National Plans Development) programme, organised by the DHOS (Directorate for hospitals and treatment organisation) with EURORDIS.

September

- 10 September in Paris (Sorbonne)
Colloquium on “The Challenges of Health in Europe”, organised by the LEEM (the drug companies)
- 19 September in Paris
European colloquium on “Abortion in Europe”, organised by the MFPPF (French Movement for Family Planning)
- 22-23 September in Paris
Meeting on “Patient safety in the European Union – EUNetPas”, organised by the Higher Health Authority (HAS)
- 29-30 September in Paris (Strasbourg)
Consensus conference on “Academic clinical trials in Europe – the innovative medicine initiative”, organised by EMRC-ESF-INSERM¹

October

- 2-3 October in Béziers
Congress of the EPODE cities (“Working together to prevent obesity among children”), event gathering together all representatives of the participating cities
- 2-3 October in Saint Maurice
Seminar on “Non-specific syndrome monitoring in Europe”, organised by InVS (Institute for Health Monitoring)
- 3 October in Paris
Colloquium on “Health risks and imports”, organised by AFSSA
- 12 October in Paris
“Health is about keeping moving”, sport/health prevention operation in Europe, organised by the French mutual society with the UNSS (National Educational Sport Union)
- 16-17 October in Paris (Assemblée nationale)

¹ EMRC-ESF-INSERM: European Medical Research Councils – European Science Foundation – Institut National de la Santé et de la Recherche médicale [National Institute for Health and Medical Research]

9th EPPOSI workshop (European Platform for Patients' Organisations, Science and Industry) on the development of treatments for rare diseases: this will relate to *partnerships in favour of orphan drugs*.

- 20-21 October in Paris

European conference on "Electronic patient files: an exchange of views with the United States", organised by the GIP DMP²

- 30-31 October in Paris (Cité des sciences La Villette)

Colloquium on "Public health in Europe", organised by EHSP-Rennes with the European association of public health schools and the London School of Economics

November

- 20 November in Paris (Institut Pasteur)

EUnetHTA (European Network for Health Technology Assessment) conference, organised by the HAS (Higher Health Authority)

- 20-21 November in Paris (Auditorium of the HEGP)

European workshop devoted to "Ethical approaches to the influenza pandemic", organised by AP-HP (Public Assistance – Paris Hospitals) Ethical Area

- 21 November in Paris (UNESCO)

European HIV Diagnosis summit on "Early diagnosis of HIV", organised by GILEAD France

- 21 November in Paris (CCI Kléber)

Colloquium on "Money from drug trafficking, the underground economy and seizure of criminal gains in Europe", organised by the MILDT

- 27-28 November in Paris (Fédération hospitalière de France)

Meeting of the member States of the European Alliance ESTHER and other EU member States on the topic of HIV/AIDS "Working together for a therapeutic hospital solidarity network", organised by the secretariat of the European Alliance

- 28 November in Paris (Salon Hoche)

Conference on "The European health professional card", organised by the National Council of the Order of Pharmacists.

December

- 5 December in Paris

Conference on “European medical interoperability: demographics and circulation of doctors in Europe”, organised by the National Council of the Order of Doctors

- 9-10 December in Paris

Colloquium on “How can we improve treatment of drug addictions? New scientific and clinical challenges for Europe”, organised by the MILDT

- 12 December in Paris

Conference on “The development of the regulator’s job in Europe”, organised by AFSSAPS

MEETINGS OF AN INSTITUTIONAL NATURE

July

- 3-4 July in Paris (Pullmann 15)

Informal meeting of the national authorities on in vitro diagnostic devices and medical devices, organised by AFSSAPS³

- 10-11 July (Villers le Mahieu, Yvelines)

1st informal meeting of drug agency managers, organised by AFSSAPS (AFSSA⁴-ANMV⁵)

September

- 18-19 September in Paris

Meeting of the Consultative Forum of the European Food Safety Authority, organised by AFSSA

- 19 September in Paris

Meeting of the national food safety agency heads, organised by AFSSA

- 29-30 September in Paris (Pullmann 15)

² GIP DMP: public interest group “Personal medical record”

³ AFSSAPS: French agency for the health and safety of medicinal products

⁴ AFSSA: French agency for the health and safety of foods

⁵ ANMV: national veterinary drugs agency (integrated into AFSSA)

Informal meeting of managers responsible for combating illegal activities,
organised by AFSSAPS

October

- 1^o October in Paris, in parallel
 - *Informal meeting of the coordination group for mutual recognition and decentralised veterinarian procedures (CMDV),* organised by AFSSA
 - *Informal meeting of the veterinary drugs committee,* organised by AFSSA
- 2 October in Paris
 - Informal meeting of the coordination group for mutual recognition and decentralised veterinarian procedures (CMDV) and the veterinary drugs committee,* organised by AFSSA
- 2 October in Paris
 - Meeting of the Board of Directors of the European Food Safety Authority,* organised by AFSSA (precedes the colloquium of 3 October on “Health risks and imports”)
- 2-3 October in Paris (CCI Kléber)
 - Meeting of the director generals for health*
- 6-7 October in Paris (Pullmann 15^o)
 - Joint meeting of the regulatory committees sitting at the European Medicines Agency (EMA),* organised by AFSSAPS
- 9-10 October in Paris (Pullmann15^o)
 - Meeting of the working group of managers responsible for the implementation and control of liaison (EMACOLEX),* organised by AFSSAPS
- 13-14 October in Paris (Novotel Tour Eiffel)
 - Informal meeting of the pharmacovigilance group PhVWP,* organised by AFSSAPS (AFSSA-ANMV)
- 22 October in Paris (CCI Kléber)
 - Seminar of drug coordinators of the European Union*

November

- 6-7 November in Paris (Hilton Arc de Triomphe)

2nd meeting of the drug agency heads, organised by AFSSAPS (AFSSE⁶-ANMV)

- 12-14 November in Paris (CCI Kléber)

Meeting of the Board of Directors of the ECDC (European Centre for Disease prevention and Control), organised by InVS (Institute for Health Monitoring)

December

- 10-11 December in Paris (Maison de l'Amérique latine)

Meeting of the High Level Committee on Public Health (HLCPH), Committee of the Commission

- 16-17 December in Paris (Pullmann 15°)

Informal meeting of the plant-based medicines committee sitting at the EMEA (European Medicines Agency), organised by AFSSAPS

- 18-19 December in Paris (Pullmann 15°)

Informal meeting of the homeopathic medicines group, organised by AFSSAPS

EVENTS TAKING PLACE OUTSIDE OF FRANCE

September

- 11-13 September in **Wroclaw (Poland)**

European summit: "Colloquium on geriatric disorders"

October

- 2-3 October in **Brussels (Sofitel)**

Conference on "Nanotechnologies and health", organised by the European Commission

November

- 4 November in **Brussels**

Conference "Free movement of HIV positive people", organised by the HIV/AIDS "Think Tank"

⁶AFSSE: French agency for environmental health and safety

- 17-22 November in *Durban (South Africa)*
Conference of the parties to the framework agreement on combating smoking, organised within the framework of the WHO

December

- 5 December in **Brussels**
Meeting of the GHSI (Global Health Security Initiative) organised by the European Commission
- 9 December in **Brussels**
1st meeting of the High Level Group on Public Health (HLGPH), “senior” group of the Council