NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC

INDEX

EXECUTIVE SUMMARY

Dating back to the end of 2003, when the outbreaks of Asian influenza of the A/H5N1 virus became endemic in birds in the Far East, with the virus causing serious infections also in humans, the risk of an influenza pandemic has become more substantial and persistent.
For this reason the WHO has recommended that all countries prepare a Pandemic Plan to be updated constantly and following established guidelines. The present Plan, drawn up in accordance with the WHO recommendations of 2005, updates and substitutes the previous Italian Multiphase Plan for Pandemic Influenza, published in 2002.
It represents the national reference to form the basis for preparation of Regional operative plans.
The Plan has been developed according to the six pandemic phases declared by the WHO, envisaging objectives and actions for each phase and level.
Many of the actions identified have already been carried out to keep pace with the requirements of the epidemiological situation.
National Guidelines to conduct further actions anticipated will be issued by the National Centre for the Prevention and Control of Disease (CCM) in the form of technical annexes to the Plan, and will be updated and incorporated periodically.

In consistence with the Principles of the Plan, the Ministry of Health is charged with identifying and harmonising:

- - guaranteed health activities with the Regions, both of a preventive as well as of a health care nature throughout Italy
- - extra-sanitary activities and support with the Ministries involved, having an aim both to protect the community and to mitigate the impact on national economy and on social operations which are logically needed for preparedness and response to a pandemic, as well as ethical and legal aspects to support the agreed activities
- - aspects of international cooperation and humanitarian assistance with the Ministry of Foreign Affairs and the relevant international organisations

The aim of the Plan is to strengthen preparations for a pandemic at the national and local level so as to:

1. Identify, confirm and rapidly report on cases of influenza caused by new viral subtypes to enable their timely recognition at the outset of a pandemic
2. Minimise the risk of transmission and limit morbidity and mortality resulting from the pandemic
3. Reduce the impact of the pandemic on health and social services and ensure the maintenance of essential services
4. Ensure adequate training for personnel involved in the pandemic response
5. Guarantee up-to-date and timely information on decisions, health workers, the media and the public
6. Monitor the efficiency of the interventions undertaken

Key actions to achieve the objectives of the Plan are:

1. Improve epidemiological and virological surveillance
2. Implement prevention and control measures for infection (public health measures, prophylaxis with antivirals, vaccination)
3. Guarantee treatment and assistance for cases
4. Prepare emergency plans to maintain health services and other essential services in operation

5. Prepare a training plan
6. Prepare suitable communication strategies
7. Monitor the implementation of actions planned for risk phases, the existing capacity/resources for response, the additional resources necessary, the effectiveness of interventions undertaken; monitoring needs to take place in a continuous and interconnecting manner, integrating and analysing the data coming from the different information systems.

The Plan's functioning will be evaluated through national and regional monitoring exercises, with participation from all the institutions involved should a pandemic occur

The present Plan is open to periodic revisions, in line with changes in the epidemiological situation.

1. INTRODUCTION

Influenza has been commonly known for centuries, but the influenza virus was identified only in the year 1933. The virus infects both humans as well as a large sector of birds and mammals.
Human influenza viruses are grouped into three types: A, B, and C, the last one being of little importance for humans. The influenza virus type A has the greatest dissemination. It is usually the cause of the most serious diseases, compared with the other two. It triggers the greater part of seasonal epidemics and is the only one that has generated pandemics.
At the basis of influenza epidemiology there is a marked tendency of all the influenza viruses to vary, that is, to acquire modifications to their surface proteins that allow them to get around the immune barrier present in the population that has contracted the infection in previous years. These changes can take place according to two distinct mechanisms:

1. A*ntigenic drift.* This describes small mutations in the surface proteins of the virus. This phenomenon applies both to the A and B viruses (but in A it happens in a more marked and frequent way) and is responsible for seasonal epidemics. In fact the new variants are not recognised by the immunity system in the greater part of the population, so that a large number of individuals result as susceptible to the new strain.

2. *Antigenic shift*. This is a phenomenon that affects only the Type A influenza virus and consists in the appearance in humans of a new viral strain, completely different from the ones previously circulating in humans. The antigenic shifts are due or to a combination between human and animal viruses (avian or swine) or the direct transmission of non-human virus to humans. Therefore, the sources of new subtypes are always animal viruses. Because the population has never before encountered these antigens, in certain circumstances these changes of a greater entity can provide a sudden and invasive infection in all age groups and on a global scale, taking the name of “pandemic”. The appearance of a new viral strain is not in itself enough to cause a pandemic. In fact, it would necessitate the new virus having to be able to transmit effectively from human to human in an effective way.

Pandemics have occurred at unpredictable times, and over the last 100 years occurred in 1918 (Spanish, virus A, subtype H1N1); 1957 (Asiatic, virus A, subtype H2N2) and in 1968 (Hong Kong, virus A, subtype H3N2). The most severe, in 1918, caused at least 20 million deaths.

From the end of 2003, from when the outbreaks of avian influenza from the A/H5N1 virus became endemic in birds in the Far East, with the virus also causing grave infections also in humans, the risk of an influenza pandemic has become more substantial and persistent. Furthermore, since 2005, outbreaks of avian influenza have been documented also in Europe, and in 2006 there have been cases of transmission to humans in Turkey.
Up to now, there is no evidence that the H5N1 virus can transmit from human to human. Just the same, in case of an emergency caused by a new influenza virus which has acquired such ability, the greater mobility of the population at a global level and the greater speed of means of transport would make the control of the spread of infection particularly problematic.
The uncertainty and the modality and times of dissemination determine the need to prepare response strategies to a possible pandemic well in advance, bearing in mind that such preparations must take times and ways of response into consideration. In fact, if on the one hand a delay in preparation can cause an insufficient response and consequent

grave damage to health, on the other hand, in the case that the event does not take place, an excessive investment of resources in such preparation can, within the framework of limited resources, cause wastefulness and divert investments from other priority sectors.

2. HISTORICAL BACKGROUND

WHO urged all countries to draw up and implement national influenza preparedness and response plans and to constantly update them in line with agreed guidelines. Following the WHO recommendations of 2005, issued in the light of changes to the world epidemic situation and of the new emergencies, this Plan updates and substitutes the previous Italian Multiphase Plan for Pandemic Influenza, published in 2002.
This document sets out the mandate for Health Authorities for each of the six pandemic phases established by the WHO, including health interventions as well as interventions that involve other than health structures. The Plan represents the national reference on the base of which Regional operative plans will be prepared. The functionality of the Plan will be assessed through national and regional exercises, to be agreed between the CCM and the Regions and other institutions that would play a role in the case of a pandemic.
The present Plan is open to periodic revisions, in accordance with changes in the epidemiological situation.

3. PRINCIPLES

The main inspiration for the Plan is the assumption that global emergencies call for coordinated and global responses, where planning times must be shared by the decision-makers and the timing of interventions must be made known before the event takes place so that all concerned can properly carry out their roles and responsibilities.
Pandemic influenza constitutes a threat to the security of a State: coordination shared between State and Regions and coordinated management constitutes a guarantee for harmonising measures with the WHO recommendations to be implemented by other countries.
Furthermore, considering the repercussions that a health risk determines on different sectors of social life, health measures need to be agreed with those undertaken by other institutional bodies outside the health sector.
Therefore the Plan identifies key actions for the national and regional health authorities and for the other actors involved and establishes the measures to be adopted for each phase. Such actions and measures follow the acceptance of “Essential Health Care Levels” adopted in Italy, establishing the guaranteed minimum essential.
The Ministry of Health has the task of harmonising health activities with the Regions, and, with the Ministries involved, as well as activities outside the health sector necessary for preparedness and response to a pandemic, and ethical, legal and international aspects, including possible bilateral agreements where necessary with other countries to support these activities.

4. STRUTTURE

The Plan is divided into the six pandemic phases established by the WHO, envisaging objectives, actions and actors for each phase. Chapter 7 describes key actions and constitutes the basis for the development of national Guidelines to be issued, on behalf of the CCM, as technical annexes to the Plan, to be periodically updated and integrated.
Many of the identified actions have already been carried out in line with the needs of the epidemiological situation, as illustrated in Chapter 9.

Chapter 10 represents an easy key to reading the Plan and describes, for each phase and risk level, general aims, specific aims, and actions aimed at the pursuance of such objectives. Moreover, the chapter also includes, in broad terms, the roles and responsibilities involved in implementing these actions.
Within the first three months of the ratification of the Plan, a Monitoring Group, with its structure outlined in paragraph 7.7, will update and define such chapter in detail, also on the basis of agreements set up by the Ministry of Health with the Regions for health activities and with the ministries and institutions involved for activities and support activities outside the health sector, in accordance with the principles of the Plan.
In the same way, contained in the Plan, which will be made available also through the Ministry of Health's website, the column relating to "Current status" will continuously report – within the time limits anticipated by the monitoring system – on the state of the art of the Plan's implementation.

Finally, the Guidelines for drawing up Regional Plans will be included as an Annex to the Plan.

5. PHASES AND RISK LEVELS

With the present Plan, Italy is adopting the new phases issued by WHO in April 2005, and shares the aims for the public health authorities recommended by WHO for each phase.
The phases and risk levels are therefore classified as follows:

Interpandemic period

Phase 1. No new influenza virus subtypes have been detected in humans. An influenza virus subtype which has caused human infection may be present in animals. If present in animals, the risk of human infection or disease is considered to be low.

Phase 2. No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease.

Level 0: absence of risk inside Italy

Level 1: presence of risk in Italy or presence of extensive travel/trade links with affected countries

Period of Pandemic Alert

Phase 3. Human infection(s) with a new subtype, but no human-to-human spread, or at most rare instances of spread to a close contact.

Level 0: no infection in Italy

Level 1: presence of infection in Italy, or presence of extensive travel/trade links with countries where clusters of the disease have been identified**.**

Phase 4. Small cluster(s) with limited human-to-human spread but spread is highly localised, suggesting that the virus is not well adapted to humans.

Level 0: no small clusters in Italy

Level 1: presence of small cluster in the country or presence of extensive travel/trade links with countries where clusters of the disease have been identified.

Phase 5. Larger cluster(s) but human-to-human spread still localised, suggesting that the virus is becoming increasingly more adaptive to humans, but may not be fully transmissible (substantial pandemic risk).

Level 0: no large cluster(s) in Italy

Level 1: presence of large clusters in Italy or presence of extensive travel/trade links with countries where large clusters of the disease have been identified.

Pandemic period

Phase 6. Increased and sustained transmission in the general population.

Level 0: no cases in Italy's population

Level 1: presence of cases in Italy or presence of extensive travel/trade links with countries where a pandemic is in act

Level 2: decreasing phase

Level 3: new wave

Postpandemic period

Return to interpandemic period

Table 1 shows the phases, levels and objectives to be followed for each phase.
The respective public health objectives for each phase are described.

Table 1. New pandemic phases, WHO 2005

PANDEMIC PHASES	LEVELS	PUBLIC HEALTH OBJECTIVES
Interpandemic period		
Phase 1. No new influenza virus subtypes have been detected in humans. An influenza virus subtype which has caused human infection may be present in animals. If present in animals, the risk[a] of human infection or disease is considered to be low**.**		Strengthen pandemic preparedness at global, country and local level
Phase 2. No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk[a] of human disease.	**Level 0**: no risk in Italy	Minimise the risk of transmission to humans; identify and rapidly report such transmission if it occurs
	Level 1: risk in Italy or presence of extensive travel/trade links with countries at risk	
Period of Pandemic alert		
Phase 3. Human infection(s) with a new subtype, but no human-to-human spread, or at most rare instances of spread to a close contact.	**Level 0**: no infection in Italy	Ensure the rapid characterisation and rapid identification of the new viral subtype, reporting and response to further cases
	Level 1: presence of infections in Italy or presence of extensive travel/trade links with affected countries	
Phase 4. Small cluster(s) with limited human-to-human spread but spread is highly localised, suggesting that the virus is not well adapted to humans[b]	**Level 0**: no small clusters in Italy	Contain the spread of the new virus inside the circumscribed outbreaks or delay the spread to gain time, with an aim to implement preparedness measures, including the development of a vaccine
	Level 1: presence of small clusters in Italy or presence of extensive travel/trade links with countries where clusters of disease have been identified	
Phase 5. Larger cluster(s) but human-to-human spread still localised, suggesting that the virus is becoming increasingly better adaptive to humans, but may not be fully transmissible (substantial pandemic risk [b)].	**Level 0**: no large clusters in Italy country	Maximise efforts to contain or delay the spread of the virus, to avoid the pandemic as far as possible and to gain time with an aim to implement response measures
	Level 1: presence of large clusters in Italy or presence of extensive travel/trade links with countries where large clusters of disease have been identified	
Pandemic Period		
Phase 6. Increased and sustained transmission in general population [b].	**Level 0**: no cases in Italy's population	Minimise the impact of the pandemic
	Level 1: presence of cases in Italy or presence of extensive travel/trade links with countries with a pandemic in act	
	Level 2: decreasing phase	
	Level 3: new wave	
Post-pandemic period Return to interpandemic period	Return to interpandemic period	Work towards ensuring the country's recovery

[a] The distinction between *phase 1* and *phase* 2 is based on the risk of infection in humans or disease resulting from strains circulating in animals. The distinction must be based on different factors and on their relative importance in accord with current scientific knowledge. These factors can include: pathogenity in animals and humans; the presence in domestic animals and farm-reared animals or solely wild animals. If the virus is enzootic or epizootic, geographically limited or widespread; other information from the viral genome; and/or scientific knowledge.

[b] The distinction between *phase 3, phase 4* and *phase 5* is based on the assessment of a pandemic risk. A number of factors and their relative importance can be considered, in accord with current scientific knowledge. These factors can include: transmission rate; geographic localisation and spread; severity of the disease; the presence of genes coming from human strains (if derived from an animal strain); other information from the viral genome; and/or other scientific information.

5.1. Sequence of declaration of phases and levels

Phases and risk levels have been established by WHO, also in non-sequential progression.

In the event of simultaneous situations posing different pandemic risk levels, e.g. new and different influenza virus subtypes, or different extension and diffusion in different areas, the phase will be determined by the highest risk level.

All the measures foreseen for Phases 1-6 are to be understood as additional and, therefore, where the pandemic event begins in Italy at a time consequent to the first phases, all the measures foreseen for the previous phases but not implemented will have to be implemented at the same time, in addition to the measures expressly anticipated for the declared phase (if a phase is left out in the passage from a lower to a higher phase, it should be understood that the actions contained in the omitted phase necessitate implementation, without their being surpassed by actions in the new phase).
As a result, arriving at a phase and a certain level, they must constitute preparatory times for the implementation of counter measures anticipated for successive phases and levels, taking into account the progress of the epidemic.

5.2. Procedure for declaration of phases

Communication/declaration of phases, including the increase or decrease in impact, will fall to the Director General of WHO, in agreement with the existing regulation governing the notification and control of infective diseases (e.g. International Health Regulation), and, if necessary, in consultation with other organisations and institutions.
At the national level, information on the declaration of phases by the WHO and on the corresponding levels of alert in the country will be given by the Health Minister.
The communication to the nation of the declaration of a pandemic on the part of the WHO will be given by the Prime Minister following advice from the Health Minister.

5.3. Criteria to reduce impact of phases

All the phases, with the exception of phase 1, are temporary. On each announcement of a new phase, the WHO will determine a period of time after which the declaration of a new phase will be reviewed. With regard to a possible reduction in impact, the criteria “epidemic connotation not corresponding to the requisites of the current phase” will be used, on the basis of:

- evaluation, on the part of the WHO and, with regard to infection in animals, in cooperation with other organisations such as the Food and Agriculture Organization (FAO) and the World Organization for Animal health (OIE) of data coming from adequate national surveillance and international reporting
- risk assessment, taking into consideration the factors leading to the designation of phases with other potential factors; for example, if the season for respiratory diseases is in course in the area, a reduction of impact of the phases can be delayed because of the increased risk that a reassortment event might take place with the seasonal strain and from the fact that surveillance for the identification of a new strain co-circulating with the seasonal strain could be more difficult.

6. OBJECTIVES

The objective of the Plan is to strengthen pandemic preparedness at national and local levels, in order to:

1. Identify, confirm and rapidly describe cases of influenza caused by new viral subtypes for the timely recognition of the outbreak of a pandemic.
2. Minimise the risk of transmission and limit the morbidity and the mortality resulting from the pandemic.
3. Reduce the impact of the pandemic on health and social services and guarantee the maintenance of essential services
4. Ensure adequate training for personnel involved in pandemic response
5. Guarantee up-to-date and timely information for decision-makers, health workers, the media and the public.
6. Monitor the efficiency of interventions already begun

7. KEY ACTIONS

Key actions to achieve the objectives of the Plan are:

1. Improve epidemiological and virological surveillance
2. Bring out measures for the prevention and control of infection (public health measures, anti-viral prophylaxis, vaccinations)
3. Guarantee treatment and assistance for the sick
4. Prepare emergency plans to maintain health services and other essential services
5. Prepare a training programme
6. Prepare suitable communication strategies
7. Monitor the implementation of the actions planned for risk phases, existing resources for the response, extra resources necessary, effectiveness of interventions already begun. This monitoring must take place in a continuous and interconnecting manner, integrating and analysing the data coming from different information systems.

Each of the key actions anticipates the implementation of a group of specific interventions for each phase, described later and illustrated in detail in the appendix, where the actors and their responsibilities are identified for each intervention
In coherence with the constitutional mandate, all the actions aimed at the protection of the individual and the community are guaranteed to all persons present on national territory and, in agreement with the Ministry of Foreign Affairs, personnel present in the Italian Embassies in affected countries.

7.1. Improve surveillance

Epidemiological and virological surveillance for influenza has already been active throughout Italy for some time. The surveillance system “INFLUNET” is an institutional system, ratified by the Agreement signed at the State/Regional Conference in 2000.
The system is regulated so that it can be implemented, through additional actions, during the increased risk phase.
Therefore, the actions identifying during the planning of the system are set out below. Many of these have already taken place, and the remaining will be carried out during the risk phases expected.

<u>Interpandemic Period interpandemico (Phases 1-2)</u>

Epidemiological and virological surveillance of the influenza syndrome is maintained, together with veterinary surveillance on avian influenza, according to already identified national protocols.

Phases of alert (Phases 3-5)

During these phases, action is aimed at improving the influenza syndrome surveillance system, and the preparation of further activities for the timely recognition of cases of influenza in humans associated to new influenza viruses and to the description of a possible pandemic, according to the following list:

a. maintenance and strengthening of the influenza syndrome by the national medical sentinel system

- maintain epidemiological surveillance, with an annual evaluation. at regional level, of the characteristics relating to a percentage of the population under surveillance; breadth and timeliness of the reports and flexibility of the system in gathering data not requested until now
- maintain and strengthen virological surveillance, carrying out a quality control of laboratories at 1° and 2° levels and preparing new methods for rapid and differential diagnoses by laboratories at the 2° level.
- extend virological surveillance activities, now carried out only during the months of epidemical circulation of influenza viruses, to the rest of the year.

b. maintenance and strengthening of veterinary surveillance

- surveillance of wild birds, particularly aquatic birds living in wet zones, which represent the main reservoir of influenza viruses in nature and the main source of introduction for domestic animals.
- guarantee an active surveillance system that allows for early identification of viral circulation in domestic poultry, with special attention to poultry farmers in rural areas where migratory birds are present.
- define information flows relating to control activities in existence at the quarantine centres for ornamental species coming from Third Countries and in recognised stations for the conservation of species (Decision 666/2000/CE, Directive 90 425/CE).

c. Integrate human and veterinarian epidemiologic information

- define and implement the information flow to integrate epidemiologic and virological surveillance on humans with that in the veterinary environment
- identify the different animal-rearing farms (according to species) where workers could be submitted to special surveillance, and provide a census of the workers themselves
- define ad hoc epidemiological and virological surveillance protocols among those exposed to animal influenza

d. Prepare additional tools to monitor cases of influenza attributable to new viral strains, and a possible pandemic.

- prepare, update periodically and distribute to health workers a definition of a possible case, probable and confirmed
- prepare and issue surveillance protocols for:
  - travellers arriving from affected areas

    - o health workers assisting patients with suspected or confirmed influenza from a potentially pandemic strain
    - o laboratory workers handling clinical samples at risk
    - o contacts with suspected cases
- initiate, where there are suspected cases, immediate and in-depth epidemiological investigations by the ASL (Local Health Units), according to pre-defined protocols
- provide the ASL and the Regions with support from CCM staff and from the National Institute of Health (ISS)
- define and issue surveillance protocols for:
    - o clusters of influenza syndrome potentially attributable to a pandemic virus, both through family doctors and paediatricians as well as institutional care facilities)
    - o clusters of unexpected mortality due to ILI/IRA (Influenza-like Illness, Acute Respiratory Infection) in hospital or other health care institutes
- provide weekly data on total mortality in a sample of communities
- define protocols for medical sentinel surveillance on rates of absence from school and work in a number of selected sites (e. large factories, poultry farmers and schools situated in different parts of the country)

In Risk Phase 5, the actions carried out are finalised, likewise, to redirect strategic choices when found necessary, including redefinition of those categories where vaccination has to be given priority distribution.

Pandemic phase (Phase 6)

During this phase the aim of the surveillance is to assess the impact of the pandemic and describe its characteristics so as to direct control measures and evaluate efficiency. Therefore it is important that epidemiological as well as virological surveillance are both maintained. In particular, virological surveillance, carried out on a limited number of samples, is needed to monitor the characteristics of the virus, given its lesser importance, in this phase, for laboratory confirmation of single cases. To estimate the impact of the pandemic, the following indicators are also necessary:

- weekly number of hospital admissions according to diagnosis
- weekly number of admissions for influenza syndrome resulting in death
- weekly number of total deaths taken from a sample of communities
- sentinel monitoring on absenteeism in schools and at work

7.2. Implement prevention methods and infection control

To contain the initial outbreaks in the country attributable to a pandemic virus and reduce the risk of transmission, the following measures are required:

- o public health measures such as limitation of movement, isolation and quarantine for cases and contacts
- o strategies for the utilisation of antivirals, both for prophylaxis as well as treatment
- o vaccination strategies

7.2.1 Public health measures

Public health interventions which may result as being effective to limit and/or delay the spread of infection, are based on the reduction of contacts between infected persons and persons not infected, and/or on the minimisation of the probability of transmission of infection in the case of contact through common rules of hygiene and barrier measures (e.g. individual protection mechanisms, DPI).

Interpandemic phases (phases 1-2)

- Health information on the population to promote the adoption of common rules of hygiene rules, including::
  - frequent washing of hands
  - cleaning household surfaces with normal detergents
  - covering mouth and nose when coughing or sneezing
- Adopting measures to limit transmission of infection in communities (schools, care homes, public gatherings, such as avoiding crowds and providing environments with adequate ventilation
- Preparation of appropriate control measures on the transmission of pandemic influenza in a hospital environment
  - Provision of individual protection mechanisms (DPI) for health workers
  - Control of sanitising and disinfecting systems
  - Identifying suitable treatment for the sick or suspected sick
  - Survey of availability of beds in isolation wards and rooms with negative pressure
  - Survey of the availability of protective equipment to aid patients

Pandemic alert phase (phases 3-5)

All the measures listed above, plus:

- Health education and information for the population on risks and on behaviour
- Preparation of protocols on the use of individual protection mechanisms for professional categories at risk, and their adequate supply
- In the presence of human-to-human transmission:
- assess the opportunity of restricting movement from and to other countries where epidemic clusters have been ascertained
- assess the possibilities and ways of returning home for Italian citizens resident in affected areas
- establishing health controls on borders
- implement the protocols established by the International Health Regulation in case of the presence of passengers with suspect symptoms on board aircraft or ships
- isolation of patients with suspect symptoms, preferably at home, to reduce the quantity of resources entailed (one person only to assist the patient, taking necessary precautions for individual protection) or in suitable equipped areas of public structures
- adoption of common rules of hygiene on the part of patients with suspect symptoms, including the use of surgical masks to limit the spread of nasal pharyngeal secretions; the use of surgical masks is also to be considered for those needing medical assistance, while it is not recommended for persons without symptoms who are in public places
- information campaigns to promote early diagnosis, also on the part of the patients themselves, aimed at reducing the interval between the onset of the symptoms and isolation
- quarantine and active surveillance of contacts, even when the antiviral prophylaxis is under way

- assess the advisability of closing schools or other communities and/or the suspension of public events involving crowds to slow down the spread of infection
-

Pandemic phase (Phase 6)

During the pandemic phase, the impact of measures to restrict the mobility of the population is limited. Measures to be adopted include:

- Limitations on travel to areas not affected
- Adoption of common rules of hygiene
- Isolation of patients with suspect symptoms, preferably at home, to reduce the quantity of resources entailed (one person only to assist the patient, taking the necessary precautions for individual protection) or in suitably equipped areas of public structures
- Adoption of common rules of hygiene by patients with suspect symptoms, including the use of surgical masks to limit the spread of nasal and pharyngeal secretions. The use of surgical masks is also to be considered for those needing medical assistance, while it is not recommended for persons without symptoms present in public gatherings
- information campaigns to promote early diagnosis, also on the part of the patients themselves, aimed at reducing the interval between the onset of the symptoms and isolation

7.2.2 Use of antiviral drugs

The Ministry of Health, following assessments made by the Scientific Committee of the National Centre for the Prevention and Control of Diseases and the Italian Drugs Agency, has acquired around 4 million cycles of antiviral drugs belonging to the category of neuraminidase inhibitors.
At the time of issue of the present Plan, an initial stockpile of drugs amounting to 170,000 cycles is currently available at the Ministry of Health. This reserve will be completed before the end of 2006.
Rapid mobilisation and the correct use of antiviral drugs are crucial aspects for an effective public health response to a pandemic. The main aim is to ensure that the antiviral drugs are available rapidly, both for prophylaxis use as well as for treatment. It is therefore essential to have a peripheral supply available of this national stock, further justified by the need to:

1. Ensure the immediate availability of these drugs in the event of a pandemic.
2. Guarantee the exclusive and appropriate management of these drugs by the public health service.
3. Use the drugs according to a common national strategy.

The national reserve of antiviral drugs will, therefore, be gradually dislocated at the peripheral level and on a regional basis, according to a Distribution Plan to be agreed with the Regions.
Considering that the national geographic location for the outbreak of a possible pandemic cannot be predicted, a part of the national antiviral drug reserve will be stocked at the Ministry of Health (*compensatory quota*). This compensatory quota will be used whenever

the epidemiological situation calls for the need, and has to be ready for mobilisation in a rapid and safe way throughout the entire country.

Through the functioning powers of the Regions and Local Health Units, the Ministry guarantees control over the distribution of anti-influenza drugs along the chain to the final user so as to guarantee a fair distribution and appropriate use of these drugs which will be available only in limited quantities. In this manner, the risk is reduced both of any resistance appearing, as well as wastefulness linked to an improper use.

Prophylaxis

Oseltamivir, belonging to the class of neuraminidase inhibitors, can be used for the post-exposure of subjects aged 12 years or more. Dosage for the purpose of a post-exposure prophylaxis is 75 mg per day for 7–10 days.

Prophylaxis strategies are described as follows:

Phase 3

- definition, on the basis of national and Community regulations on procedure to authorise the use of antiviral drugs
- constitution of national reserves, on the basis of scientific evidence and needs, both on Italian territory as well as for Italian personnel present in Embassies abroad
- identifying regional sites for stockpiles, to be established within the system of hospital pharmacies present in every Region throughout the country
- definition and maintenance of suitable storage conditions (temperature control, relative humidity, hygienic conditions of storage facilities, security)
- identification of a person to take charge of the drugs reserve, and of required procedures
- definition of ways of intra-regional transport, guaranteeing their arrival within 4 hours to any point whatsoever in the Regions.
- stockpiling of a reserve of antiviral drugs at the Ministry of Health (*compensatory quota)* which can be mobilised in a rapid and safe manner throughout Italian and international territories.
- in the case of outbreaks of avian influenza with a high pathogenicity, *pre-exposure* prophylaxis for persons who, for professional reasons, are in close contact with infected animals, especially for those handling their slaughter. In this case, in addition to the adoption of respiratory therapy apparatus, prophilaxis with oseltamivir is envisaged for the whole of the period when the worker is in close contact with infected animals or with contaminated surfaces. Continuous use for more than 6 continuous weeks is not recommended. During this phase, *post-exposure* prophilaxis for subjects having had had close contacts with infected animals can be taken into consideration.

Phases 4 e 5

Prophilaxis use of antivirals can be seen as especially useful in the presence of early clusters of influenza caused by a pandemic virus, when the vaccine is not yet available. This is a strategy for brief periods, useful above all in the presence of isolated cases or small clusters, particularly if these take place in closed communities.
Therefore, the following are envisaged:

- prophilaxis with antiviral drugs for close contacts of cases, including health workers
- monitoring of the efficacy and adverse effects of the drugs

In the case of clusters of large dimensions (Phase 5, level 1), the prophylactic use of antivirals has to be considered for contacts belonging to priority categories 1–4, identified as candidates for the pandemic virus, listed under paragraph *Vaccinations"*

Phase 6

During the phase of a declared epidemic, prophylaxis with antivirals is of little use. In fact, massive use of these drugs increases the risk of the insurgence of resistant viral strains and the risk of collateral effects. In addition, simulations of pandemic influenza have shown that the use in mass of these drugs does not reduce the number of influenza cases in any significant way.

7.2.3 Vaccinations

Interpandemic period (Phases 1-2)

The vaccine strategy to be adopted during the interpandemic period is well described in the pamphlet on the control and prevention of influenza, reviewed annually and issued by the Ministry of Health. It includes objectives, target populations and monitoring of vaccine coverage. The seasonal vaccination campaigns are occasions for the preparation of the necessary tools and for collecting essential data also for the pandemic period, especially:
- collecting data on vaccination coverage for risk categories
- monitoring adverse effects of the vaccine

Phases of pandemic alert (Phases 3-5)

In phase 3, characterised by the presence of a new viral subtype, but an absence of human-to-human transmission, it is essential to identify the priority categories to be given the pandemic vaccinations

The present Plan identifies 6 categories, listed according to priority:

1. Health care personnel and other workers in:
- hospitals
- family doctor and own-choice paediatricians
- long-term health care facilities
- health authorities and public health services in contact with the public ambulance services
- clinical laboratories
- pharmacies

2. Personnel connected with services essential for security and emergency needs
- police force in contact with the public
- fire brigades
- key decision-makers in case of urgency and emergency

3. Personnel in public utility services
- armed forces
- municipal police and other police forces not included in priority Group 2

- essential public transport workers and those carrying out deliveries of raw materials
- workers in the public utility sector (schools, postal services, etc.)

4. Persons with a high risk of severe or fatal complications due to influenza

- Included in this category are the population groups already identified in the recommendations for annual vaccination against influenza.

5. Healthy children and adolescents aged between 2–18 years

6. Healthy adults

The priority scale, for points 4–6 can be subject to revision during pandemic alert phase 5, on the basis of the epidemiological characteristics of the virus in circulation.

During the pandemic alert phases 3-4, provision is also made to:

- Estimate the number of pandemic vaccine doses need at national level, so as to guarantee their pre-emption.
- Define, on the basis of decisions taken in national and Community circles, procedures authorising the emission of drugs onto the market
- Identify methods of supply of vaccines for the entire country (number of doses per period), their distribution and stockpiles in local areas
- Guarantee the national productive capacity and concur with the pharmaceutical companies on times for development, trials, registration and availability of the vaccine
- Identify the supply chain for the vaccines (number of doses per period), their distribution and stockpiling in local areas
- Draw up, at the level of Local Health Units, the nominative lists of persons falling under priority categories 1–4, and establish methods for a periodic updating of such lists; estimate the percentage quotas of vaccine for each category necessary to maintain essential services
- Estimate at the national level, with the contribution of the interested Ministries, the personnel quotas in priority categories and define the percentage quota that will be required to maintain essential services coming from each category,
- Identify the relevant personnel from the public structures of the National Health Services or other administrations directly interested, to be selected for administration of the vaccine
- Identify, in cooperation with the interested Ministries, possible support personnel for vaccination activities, as well as sites where the vaccination can be carried out in the shortest possible timeframe
- Prepare methodology to register the vaccinations carried out, through computerised systems able to programme and maintain records of timeframes for the administration of second doses
- Strengthen the system of electronic pharmaceutical vigilance already used at the national level to report on adverse effects of the vaccine

<u>Pandemic phase (Phase 6)</u>

- Monitoring of vaccine coverage for groups at risk
- Monitoring of adverse effects of the vaccine
- Organisation of a timely interpretation of WatchDog data on pharmaceuticals
-

7.3. Guarantee treatment and assistance

During an interpandemic phase and in an alert phase it is crucial to prepare procedures to guarantee a reasonable access to treatment so as to obtain optimal use of resources:

- Survey the ordinary and extraordinary availability of health care facilities, socio-health structures and socio-health care, workers involved with basic care, general practitioners, own-choice paediatricians, doctors working in the welfare field and specialised outpatient clinics.
- Survey the health care structures equipped with respiratory therapy apparatus
- Define the levels of the structure where patients could best be treated during a pandemic (first, second and third, including emergency units and intensive care wards)
- Determine the triage and the flow of patients between health care structures at various levels
- Identify potential alternative locations for medical treatment (e.g. socio-sanitary structures, residential care homes, schools, outpatient clinics, etc.)
- Define the criteria for the suspension of planned hospitalisations and the consequent availability of extra hospital beds.
- Guarantee sufficient supplies, stocks and adequate distribution of antivirals precisely as described under the section on their use as a prophylaxis
- Provide guidelines for the use of antivirals for treatment aims. With regard to treatment, the antivirals currently in use are effective if administered in the first 48 hours from the start of symptoms. In addition, the susceptibility of a pandemic virus to antiviral will be seen only when the probable strain is isolated. The use of antivirals must, however, take place only upon medical advice and vigilance at the level both of family doctors and hospitals.
- Define guidelines for treating patients at home
- Identify other support measures, not of a health type, such as an increase in welfare vouchers, ex-L.104/92, domestic assistance services (meals delivery/shopping), recognition of work and voluntary work vouchers

7.4 Prepare emergency plans to maintain health services and other essential services

Providing essential services guarantees the well-functioning of society. In addition to health services, crucial to reduce morbidity and mortality in a pandemic, examples of essential services are: electricity networks, water supplies, transport and telecommunications. Taking on board the effects of a pandemic on essential services forms an essential part of planning, in line with following actions:

- Identify personnel who can be mobilised to provide health assistance during a pandemic
- Develop a list of essential services
- For each of the identified essential services, identify the person in charge and prepare emergency plans to include measures for covering absences during a pandemic
- For each essential service, compile a list of persons whose absence will seriously endanger national security or interferes significantly with response measures against the pandemic. Personnel from these services will be given priority for vaccinations.

The Ministry of Health will have the task of coordinating the actions listed above with the Ministries involved.

7.5. Prepare a training plan

Similar to what has been done on other occasions (National Plan for the Elimination of Measles and Congenital Rubella, AIDS, SARS) it is important for the Plan to be accompanied by a training programme. Therefore, guidelines relating to a National Training Plan will be issued.
The training of workers involved in the different phases of the Pandemic Plan represents an essential activity to be organised and carried out before the onset of a possible pandemic.
The training is aimed not only at acquiring cognitive elements and skills pertinent to the activities and to the tasks to be carried out, but also for their practical, continuous and verified use, above all to allow for rapid and correct responses to simple everyday requests, but also to cope with more complicated interventions in unusual or complex operative events on the professional front.
In the implementation of the Pandemic Plan, therefore, training activities are aimed at developing the motivation and involvement of workers with respect to their roles and responsibilities, to increase technical-scientific and communications-interrelationship skills in order to encourage participation in the Plan and its operational capacity.
Harmonised training activities can contribute to establishing integrated cooperation between health workers and between these latter and other members of society involved in the Pandemic Management Plan.
The didactic must envisage a specific training programme for all the professional figures involved, divided in relation to fields of action, roles and responsibilities: workers in health care services, but also personnel from essential services, and journalists.
The entire training programme has to be jointly participated and agreed at national, regional and local levels.

The overall objectives of the training programme are:

- Develop knowledge on the pandemic and on its management to be able to carry out prompt and appropriate interventions
- Supply the skills to conduct the activities envisaged by the Plan aimed at guaranteeing a suitable level of protection for the population as a whole
- Optimise capacities with regard to risk communication
- Develop communicative-interrelationship skills for use in emergency management

The specific objectives must be defined on the basis of tasks and training needs for each specific target for which an ad hoc training programme will be planned.
It is considered timely to set out these training activities in short training models, based on interactive didactic experiences, conducted with methods and active learning techniques so as to encourage participation and feedback by the participants: group discussions on “themes” and on “cases”; work carried out in small groups, simulations, role-playing, up-front teaching combined with discussions.
So as to guarantee that all the workers involved are adequately trained, it would be useful to envisage three levels for the implementation of training activities to begin A CASCATA’’:

- national/interregional
- regional

- local

At the national level, therefore, training of trainers will be carried out at the regional level, planning accredited training modules**.**
It is required that at the regional level, individuals with specific didactic skills can be identified to guarantee the realisation of a global training course in a process of Cascade training**.**
The aim is to create a network of trainers to ensure training at a peripheral level throughout Italy. The regional trainers have the task of organising and conducting training activities at regional and local levels.

To facilitate the whole initiative it is appropriate to prepare in advance standard written and/or electronic didactic material to support the training process. This will be a comprehensive training package with information content, bibliographic and telematic references, organisation and methodological indications.
It could also be effective to adopt distance training to be combined with classroom training, and, to be feasible, this must include internet access for all interested workers.
The material provided at central level must be adaptable to specific regional situations.
To guarantee the continuity of the training process, after the first training meeting it will be possible to make use of specific means to facilitate communication exchanges between the parties involved, such as E-mail, specific internet sites, meetings in small groups in local settings, and to plan periodic meetings where training experiences can be reviewed in depth.

7.6. Prepare adequate communication strategies

Communication represents a capacity and a resource for the Health Care Organisation that is essential for the management of public health events.

A communications plan must therefore envisage:

- the preparation of national, regional and local organisational structures to establish cooperation between the institutions and to guarantee circulation of information between workers in the field (internal communications) and among all the social parties involved, having different roles, skills, interests and ideas.
- the choice of a spokesperson at national and local levels
- the construction of a continuous communicative process on risk, bidirectional, interactive, for the exchange and sharing of information and opinions to guarantee clarity, transparency, timeliness, homogeneity and reliability of information, and to strengthen the credibility of institutions (external communications)
- the creation of partnerships with other authorities and institutions present on national territory and at the international level, and with civil society
- planning of a communications strategy to anticipate the integrated use of communication methods selected from time to time on the basis of targets, objectives, resources, keeping pace with the aim to encourage not only a unidirectional flow of information (media, websites, information pamphlets, documentation, articles) but also a bidirectional exchange (face-to-face interviews, telephone interviews, free numbers)
- development of collaboration with the media through the constant and clear communication of information available, even if uncertain (communicating uncertainties)

Specifically, with regard to communications with the general population, the following measures are foreseen:

- define clear and consistent messages, shared at national and local levels, developed on the basis of a collective perception of risk
- strengthen relationships with mass communication means at all levels
- prepare ad hoc information material destined for use by different parties, communicators, organisational spokespersons, preparation of communications for the use of the media
- set up communication channels with the public by way of unidirectional means of communication (website, E-mail) and bi-directional means (subject-specific telephone lines, and communications such as between citizens and workers in different spaces and at different times)
- prepare audio and/or video conferences with key structures at central and local levels.

7.7. Monitor effectiveness and efficiency of measures undertaken

It is essential to establish a monitoring system for the Plan, the functions of which need to be developed for each phase.
The monitoring system is based on a network structures involving CCM-Regions-Ministries, within which a continuous flow of useful data is generated for the Plan's activities, depending from the CCM scientific subcommittee "Influenza and Influenza Pandemics".

<u>During the interpandemic phase</u>

Identification of network references)
Identification of input and output methods and
Standardisation of procedures for data collection

<u>Phase 3</u>
Monitoring on the issuance of regional plans and on the coherence of the Guidelines in drawing up Regional Plans
Calculation of the capacities/resources envisaged by the Plan
Monitoring the implementation of the capacities/resources identified by the Plan and by Regional Plans

<u>Subsequent phases</u>
An assessment on the efficiency, and also the efficacy, of the measures undertaken, to include

- During the pandemic, monitor by means of surveillance data the efficacy on the ground of the public health measures undertaken, of the antiviral drugs and the pandemic vaccine
- Monitor by means of surveillance data the security of antiviral drugs and the pandemic
- Ensure the evaluation of the response to the pandemic once the first wave is over. The evaluation should concentrate on the response at all levels and should lead to recommendations for improvements

- Ensure that the results of the research, both local and international, are made public to support improvements to the response strategies
- Consider whether to conduct studies to determine the risk facts for human infections and the probability of human-to-human transmission. Define the data necessary and develop a strategy for data collection (and if possible for the analyses)

8. MANAGEMENT AND COORDINATION

Surveillance and control of infective diseases involve the State and the Regions in shared and coordinated actions.
In addition, the constitution of the CCM, to which Law 138/04 entrusts the tasks of analysis and risk management, offers an extra operating arm shared between the Regions and the Ministry of Health. In fact, the CCM works in coordination with the Regional Structure, with the National Technical Institutes, Experimental Zooprophylatics Institutions, Universities, Institutes for Health Care Admissions of a Scientific Character and other structures of assistance and research both public and private, as well as Military Health Units.
In addition, inside the guiding Strategic Committee, the political organ of the CCM presided by the Health Minister, are also present the Regions, the Department for Civil Protection and the Ministry of Defence.

In the case of epidemics and epizootics having a national or international charter, Legislative Decree 112/98 (Title IV, heading 1, art. 112, clause 3, letter g) entrusts the Ministry of Health with further tasks, including the harmonisation of measures of a non-health care type with bodies and institutions involved and links with supra-national institutions.

The health care actions at a territorial level are guaranteed by the Regions: harmonisation and coordination among actions undertaken can guarantee the efficacy of the interventions and the containment of epidemics also extending to regions, or at national level.
Therefore, the adoption on the part of the Ministry and the Regions of actions foreseen by the present Plan, aimed at the achievement of public health objectives, in unity with the World Health Organisation, can minimise the risk of the spread of a new virus and/or minimise the impact of the pandemic, above all considering that the pandemic could be preceded by outbreaks of infection localised in a number of geographic areas (Phases 4 and 5).

Instead, if it happens that the impact of the pandemic cannot be contained with these prevention and control tools and a calamity looms, which for its intensity and extension requires to be faced with extraordinary means and powers, the Council of Ministers, on the basis of requests and/or assessments presented by the Health Minister and following advice from the Prime Minister, can declare a state of emergency.

8.1. Key organisational aspects

Activities foresee preparedness and response to pandemics are both of a health type, including the veterinary field, as well as non-health sector activities.
Therefore, the Regions and the Ministry of Health on the basis of information data available and the risk/impact assessments applying to the existing situation, will identify the operating measures deemed necessary, to be adopted in harmony with the other Administrations concerned.

The following describes the structure concerning management and coordination relating to the response to the various phases of pandemic risk in the absence of a national declaration of a state of emergency.

Consulting body

The Health Minister is assisted by the CCM, the body co-shared with the Regions, and its Influenza and Pandemics Sub-Committee.
The CCM and its Sub-Committee perform the functions attributed to them by current regulations in force on the basis of information data collected.
The Health Minister, where the national or international situations give clear indications, can request prolonged functionality of the Consultancy Body, up to a 24/24–7/7 coverage

Operating structure

With the aim of having an up-to-date picture of the situation to hand, both national and international, representing a vital support for timely and coherent decisional actions, the organisation for management and coordination will take advantage of a number of functions hinged to a monitoring, communications and integrated response network.
The operating structure is implemented at a central level (State) and territorial (Regions/Autono0mous Provinces), in accord with what has been foreseen by Legislative Decree 112/98 and Legislative Decree 267/00, as well as what that established under law 138/04.

The operative structure groups existing capacities and functions in the health fabric of the individual Regions and the Ministry of Health, which is divided into three levels: central, regional and territorial. In detail, each Region defines its own structural operative organisation coherent with the functions called for under this Plan and defined by an appropriate document for the implementation of the Plan at the Regional level.

Functions of the operative structure

The operative structure has the task of monitoring and coordinating all the actions foreseen by the Plan and set out in Charter 7 (surveillance, prevention and control measures for infection, monitoring and supply of resources for the treatment of cases, maintenance of health care and essential services, training and communications).
In addition to what has already been reported, the operative structure:

- Manages relations with national and international organisations: the WHO Influenza Collaborative Centre, OIE/FAO, EISS; ISS-CIRI for the INFLUNET PROTOCOL; Central Crisis Unit of the Health, Veterinarian and Food Headquarters, ex-art 1, L.D. 202/05, ISS-IZSP for veterinary events
- Interfaces systems of rapid alert in the human and veterinary fields (international references – WHO CSR, OIE/FAO and EWRS - , national and territorial references), according to criteria defined for the interpandemic and pandemic phases
- Follows medical intelligence activities (media rumours and classified information)
- Monitors the availability of the following capacities/resources:
  - experts in public health emergencies
  - health care teams, national and territorial, for rapid response to infective emergencies

Security and operability of data transmission systems

The network system for monitoring situation and response and the communication system make reference to data transmission systems directed at that function only, equipped with a support capacity to guarantee operability 24/24–7/7, the identification of qualified users

and security procedures when facing accidental or intentional manipulations on the part of un-qualified users.
Data transmission must envisage the possibility of having to rely on alternative systems and procedures in the case of a prolonged incapacity of the main transmission/communication systems

Responsibility

The Ministry of Health, also through the CCM, takes on responsibility to plan, make available and efficiently maintain the health system capacities/resources for a response to influenza epidemic events under national auspices, in harmony with the present planning. With reference to the integrated and interdepartmental capacities/resources, such responsibility is shared by the Ministry of Health with other institutionally competent ministries and organisations.
The Regions/Autonomous Provinces, each one individually as regards aspects of territorial responsibility but in coherence with the present planning and in concert with the Ministry of Health, assume responsibilities for preparedness and maintaining efficiently and in harmony with the present planning, all the capacities/resources indispensable to start up countermeasures for the phases of prevention, containment, response, and recovery in relation to pandemic influenza events.
With regard to the responsibilities being prepared now, the Ministry of Health, through the CCM, deals with the following:

- in agreement with the Regions/Autonomous Provinces, the activities planned for implementing the capacities/resources necessary, with a quantification of the costs involved to submit for assessment by the governing authority for the requisite and obligatory financing;
- In agreement with the Regions/Autonomous Provinces, activities of specific training of health care personnel conducted also in collaboration with scientific societies and trade associations representing workers in the health system;
- Having heard the opinion of national decisional bodies, and in agreement with interested institutional bodies and with the Regions/Autonomous Provinces, the implementation of exercises aimed at optimising both the planning and the model for response to public health emergencies

8.2. Management and Coordination activities when an emergency is declared

Legal background

Legislation applicable to ensure the coordination of interventions needed to confront and overcome the emergency phase is covered by Law 225/92, D.L. 343/2001, converted into Law 401/2001, D.L. 245/2002, converted into Law 286/2002; D.L. 90/2005 converted into Law 152/2005.
On the basis of this cited legislation, coordination functions will be the responsibility of the Prime Minister, under advice from the Department for Civil Protection, which in its turn will initiate action by the National Civil Protection Service.

Management and Coordination

In a case where the spread of a pandemic presents a picture of calamity which for intensity and extension has to be confronted with extraordinary means and power, the Council of

Ministers, on the basis of requests and/or assessments formulated by the Health Minister, on the advice of the Prime Minister, takes a decision on the State of Emergency pursuant to Art.5, paragraph 1 of Law 225/92.

Taking account of the activities already established by the structures identified for activities in the non-emergency phase, it will be the Prime Minister who will define with the Health Minister – through the identification and the realisation of necessary emergency interventions – the actions it is intended to adopt, inserting them into the appropriate Civil Protection regulations, ex Art 5 of Law 225/92.

In order to ensure a unitary direction and the coordination of activities aimed at facing the emergency, the Prime Minister, in accord with the Health Minister, will delegate the head of the Department of Civil Protection for the urgent convening of the Civil Protection Operative Committee.
This Committee will benefit from participation from the operative national structures of the Italian Civil Protection Service, Regional Administrations, as well as all other interested bodies. As it consists in an emergency of a health nature, the Health Minister will arrange for the presence of representatives from his own Ministry on the Operative Committee, broader than that foreseen in the Prime Minister's decree dated 2 March 2002.
In the same way, the Regional Authorities for Health will be represented on the Committee in a way appropriate to the needs and will be combined with the participation of the Councillors and the Coordinators of the Civil Protection Committees of the individual Regions.

In consideration of the uniqueness of such a calamitous event and of the quality of the measures to be undertaken, the Operative Committee can be added to, upon instructions from the Health Minister or the Coordinator for the Health Councillors, by the presence of persons particularly specialised in health matters (e.g. National Institute of Health (ISS), IIZZSS, etc.)

With the aim of ensuring all necessary harmonisation among the actions undertaken in the non-emergency phase and those to adopt in an actual emergency phase, a permanent consultancy mechanism will be set up, providing a guarantee that the Operative Committee receives all appropriate information needed for them to then put in place timely and efficiently all the operations directed towards management and overcoming the emergency.

9. CURRENT PHASE OF PREPARATION: ACTIONS UNDERWAY

During the phase of preparation and ratification of the Plan, epidemiological signs of risk, originating from outbreaks of avian influenza in the Far East area, and the spread of the A/H5N1 virus in areas where it had never been isolated, led to the adoption of measures aimed at the containment of a possible pandemic risk, in addition to a continuous revision of the Plan itself.

The Ministry of Health, therefore, put into being all its abilities, aimed at the preparation of adequate resources to confront the problem of avian influenza and prepare the response to a possible pandemic, and this already during the drawing up of this present Plan.

9.1. Measures of a general and organisational character

- Law Decree 1.10.2005 “Urgent measures to confront avian influenza, animal diseases and zoo-health emergencies and to ensure adequate stocks of antiviral drugs to prevent the risk of an influenza pandemic”)
- The decree is especially targeted at:
  - strengthening and rationalising tools in the fight against avian influenza and the other animal diseases and zoo-sanitary emergencies, through the institution of the National Centre for the fight against Animal Diseases and Emergencies, which will have to carry out activities of technical-operative coordination with the analogous regional and local structures
  - set up the Department for Public Health, Veterinary Sciences, Nutrition and Food Security at the Ministry of Health
  - strengthening ministerial infrastructures through the recruitment of veterinary experts and of fifty technicians for prevention and health control; reinforcing the Carabinieri Anti-Sophistication Nucleus (NAS)

9.2. Preventive measures in the public health sector

Public health measures are reported in Table 2 and are described as follows:

- Strengthening the epidemiological and virological surveillance system for human and animal influenza, by concluding CCM Agreements with the National Institute of Health, the Inter-University Centre for Influenza Research and the IZS of the Venezie Region to strengthen the sentinel surveillance system for influenza, INFLUNET, and to exchange information with the veterinary surveillance system
- Improve vaccination coverage against seasonal influenza
- Recommendations for the free distribution of the seasonal vaccination for those who are for professional reasons exposed to avian viruses, aimed at preventing the co-infection of human and avian viruses in the same individual
- Drawing up appropriate contracts with firms producing the anti-influenza vaccine to guarantee greater availability of the seasonal vaccine
- Agreements on the pre-emption of the pandemic vaccine to be able to implement research and experimentation activities for strategic vaccines and also to ensure, at the time of the pandemic, quotas of vaccine produced through techniques allowing for production times to be cut down by half
- Purchasing and stockpiling of antiviral drugs
- Starting up of procedures to obtain funds to cover the purchase of drugs and protection apparatus to be used in the event of a pandemic
- Strengthening health controls at borders (Decree of 8 November 2005)

9.3. Preventive measures in farming and veterinary sectors

- Ministerial Decree of 26.8.2005
- Ministerial Decree of 10.10.2005

  These instruments particularly include:
  - issuance of the order to make registration obligatory with Local Health Units for firms rearing domestic birds, with the possibility of imposing a marketing ban on animals and aviculture products in case of non-compliance
  - preparation of quarantine and control measures for firms handling domestic birds: a 21-day period of quarantine has been imposed for birds that are to be introduced to these firms

- making labelling on bird meat obligatory: this labelling requirements already in place for fresh meat, preparations and products with a basis of chicken meat, and has twin aims: a) to provide elements of immediate traceability for the veterinary police; b) to inform the consumer on the origin of the meats
- extending these regulations to all species concerned (pheasants, quail, etc.)
- defining a programme for virological control of samples of the most widely represented wild species (migratory birds) in wet zones where there is a greater concentration of domestic bird breeding and a monitoring system for wild birds found dead

9.4. Preventive measures for imports

Through the provisions of 9.8, 26.8, 7.9 and 21.9.2005, it was specifically decided to:

- suspend the importation from affected countries of certain typologies of products and animals at risk for avian influenza (feathers and parts of feathers not transformed" and "birds other than chickens")
- tighten controls on the import of products of animal origin from species susceptible to infection (also when carried in passenger luggage); wild birds that have been shot; goods of any type whatsoever coming from all the geographic areas at risk of illegal imports of products of animal origin; chickens and brooding eggs imported from third countries
- ban the importation from all third countries of birds destined for the repopulation of wild birds (such as pheasants, partridges, grey-cocks) and to the obligatory quarantine of birds introduced by Member States for the purpose of the repopulation of wild birds
- ban the importation of any species of bird whatsoever from the entire Asian continent, including those brought in by travellers

Table 2. Public Health Actions undertaken by the Ministry of Health up to the Plan's approval date

Objectives	***Actions***	***State***
Improve the sentinel clinical-epidemiological and virological state through the network of medical sentinels and reference laboratories and render them suitable for data collection in pandemic periods	1. Change the methods of data collection on the influenza syndrome (INFLUNET) aimed at obtaining, at the end of a surveillance period, an estimate of the proportion of ILI found in categories of subjects of risk, of persons working in essential services, of persons that, for professional reasons, are in contact with animals susceptible to develop and transmit bird flu 2. Set up an agreement to start up epidemiological surveillance with the ISS and Universities 3. Set up an agreement for starting up virological surveillance with the ISS, universities and Regions	1. **Modified: the INFLUNET protocol 2005-2006 influenza season** **2. Signed: biannual agreement with the National Institute of Health and Genoa University** (€ 190.000,00) **3. Signed: biannual agreement signed with the ISS, Genova University, Regions** (€ 410.000,00)
Increase vaccination coverage for at-risk categories (the elderly and persons of all ages suffering from chronic diseases) and of subjects working in essential services by making health workers more aware	Preparation of Guidelines to identify at-risk categories and the actual vaccination offer	**Issued:** annual communications on "Influenza Prevention and Control"
Change and implement the data collection system for vaccination coverage to bring it closer to the need to assess coverage of at-risk categories for those working in essential services	Preparation and distribution of a new data collection model divided into categories and age groups	**Distributed:** Circular letter No. 7 of 7 October 2004, describing new data collection model, divided into categories and age groups
Start up virological surveillance on the circulation of influenza viruses in animals	Set up agreements with the IZS, aimed at starting up virological surveillance for animals at risk	**Signed:** triennial agreement with the IZS of the Venezie Region (€ 400.000,00)
1. Provide the country with adequate reserves of seasonal influenza vaccine 2. Pre-emption of the pandemic vaccine	1. Set up agreements with firms producing vaccines, aimed at increasing their productive capacities so as to have sufficient doses of vaccine available during interpandemic phases 2. Set up pre-emption agreements with vaccine-producing firms, aimed at guaranteeing sufficient doses of vaccine for the Ministry	**1. Identified:** a supply strategy aimed at achieving:: a. an increase in productive capacity such as to guarantee greater vaccine availability, both epidemic and pandemic; b. in the case of an epidemic, pre-emptive rights by the Ministry of Health on anti-influenza vaccines produced;

3. Stimulate research and experimentation activities aimed at the production of strategic vaccines	of Health during a pandemic period. 3. Preliminary purchase of stocks of monovalent pandemic H5, H7, H9 where produced	c. implementation of research and experimentation activities aimed at the production of strategic vaccines, through the preliminary purchase of stocks of monovalent pandemic vaccines H5, H7, H9, where produced **2. Signed** contracts with producing firms
Provide the country with adequate reserves of antiviral drugs	Constitution of a stock of antiviral drugs for prophylaxis and treatment	**1. Identified:** antiviral drugs useful for prophylaxis and/or treatment 2. **Allocated:** resources for the constitution of a first stock of drugs **3. Prepared and sent:** letters and contracts for the purchase of antiviral drugs
Introduce elements useful for prevention awareness to the attention of health workers and the population in general	Training Plan Communications Plan	Training Plan and Communications Plan: **Drafts completed; assignment of the different activities is now taking place**

10. Operational structure for phases and risk levels