Belgian Advisory Committee on Bioethics

Opinion no. 48 of 30 March 2009 on the Belgian "influenza pandemic" operating plan

Request for an opinion of 20 March 2008,
from Mrs L. Onkelinx, Minister of Social Affairs and Public Health,
on the "influenza pandemic" operating plan

CONTENT OF THE OPINION

Question put to committee

On 20 March 2008, Mrs Laurette Onkelinx, Belgian Minister of Social Affairs and Public Health, sent the following request for an opinion to the Belgian Advisory Committee on Bioethics:

"Since the end of 2005, the Belgian authorities have invested a lot of time into developing an operating plan for managing an influenza pandemic in our country. This operating plan has been drawn up within the Belgian Interministerial Influenza Coordination Committee (CII), with a team comprised of collaborators from the Federal Public Service for Public Health, the Safety of the Food Chain and the Environment (SPF SPSCAE), the Scientific Institute of Public Health (ISP), the Federal Agency for the Safety of the Food Chain (AFSCA), the Federal Agency for Drugs and Health Products (AFMPS) and departments from the Regions and Communities. To prepare for a potential pandemic, our country has set about updating this preparedness plan constantly, pursuant to the related scientific recommendations, and particularly ensures that a stock of antiviral drugs, masks and vaccines is built up.

Pursuant to Articles 1 and 8 of the Cooperation Agreement of 15 January 1993 creating an Advisory Committee for Bioethics, I hence permit myself to request an opinion on a certain number of pertinent ethical problems for the Interministerial Influenza Coordination Committee.

All these ethical problems are linked to the great uncertainty surrounding what we should expect in case of a pandemic. A pandemic will be due to a virus still unknown at present, such that it is impossible to present an exact evolution. As part of our preparatory works, we have therefore based ourselves on two scenarios: one, more serious, makes reference to the observations made during the 1918 pandemic, the other is not so alarming. It is however certain that, during a pandemic, demand for healthcare is significantly higher than usual. It will, in addition, be more difficult to dispense this healthcare as it should be, since the medical personnel will also be affected by the pandemic. I hence question the priorities which must, where appropriate, be defined - particularly with regards antiviral drugs, vaccines and access to healthcare.

***1.** The Belgian State has bought the antiviral drugs necessary to build up a strategic stock at national level. These antiviral drugs can also be administered both for preventative reasons and to treat patients presenting symptoms. The national stock must enable the State to treat all sick people, within the framework of a scenario where 30% of the population would be sick. However, the difficulty of anticipating a pandemic entails various problems. Neither its magnitude, nor when it will occur can be defined in advance. This is why it is also difficult to determine whether our strategic stock will be sufficient to be able to treat all people presenting influenza symptoms using antiviral drugs. Consequently, we must also start from the principle that we will perhaps have to make choices and define certain priorities in respect of certain groups.*

***2.** With regards the (pre)pandemic vaccines, the Interministerial Influenza Coordination Committee is applying the strategy described below. The amount of prepandemic vaccines bought will be sufficient to administer an initial dose to the entire Belgian population and we will already place as quickly as possible an order to receive a second dose of the pandemic*

vaccine[1] *for the entire population. Given the uncertainty surrounding the timing and the magnitude of the amount delivered of the pandemic vaccine, the problem of priorities could also be posed at the ethical level. What group of people could in fact be entitled first of all to the vaccine if we were faced with delivery problems?*

3*. An identical problem is posed in terms of access to healthcare. Just like the rest of the population, the group of healthcare professionals will also be affected by the pandemic. Absenteeism is likely to be very high, potentially over a long period. This is likely to compromise the continuity of primary and secondary healthcare. Furthermore, the capacity of Belgian hospitals is not unlimited, in terms of number of beds, ventilators and personnel. As for the vaccines and the antiviral drugs, it will undoubtedly be necessary to define certain priorities. ".*

The plenary meeting of the Committee of 26 May 2008 declared the request for an opinion admissible and forwarded it to the 2008-2 select commission.

I. Introduction

The 1918 Spanish flu caused 40 million deaths throughout the world. This was a mutated virus of avian flu which is transmitted to humans. The 1957 Asian flu and the 1968 Hong Kong flu had less dramatic consequences. They resulted from the recombination of the avian flu and human flu virus. According to the Belgian website www.influenza.be, a mortal influenza pandemic occurs every 40 years approximately. The last one, called "the Russian flu", occurred in 1977 and caused a million deaths throughout the world. This was a reappearance of the H1N1 virus of the Spanish flu. The World Health Organisation (WHO) for its part speaks about three pandemics a century, separated by intervals of 10 to 50 years.

Since the end of 2003, several outbreak sites of avian flu have been observed, initially in Asia, then in Africa and Europe. The virus is of the A/H5N1 type. To date, it has mostly been people who have been in contact with infected birds who have been contaminated. The cases of human-to-human contamination have remained exceptional and have only affected individuals who had a very promiscuous lifestyle. On 19 January 2009, at world level, there were 397 people contaminated, of whom 249 have died from it according to WHO sources. Affected countries decided whether or not to destroy all poultry in or around poultry breeding farms where avian flu has been found.

The WHO fears a mutation of the avian flu virus or a recombination of this latter with a human flu virus, which would also enable the inter-human transmission of the virus. It has announced that we are currently in phase 3, which corresponds to a pandemic alert phase: all countries are hence encouraged to prepare for a potential pandemic. The WHO distinguishes six different phases. During phase 4, human-to-human contaminations occur, but the spread of the virus remains very localised, which would indicate that the virus has not yet adapted well to humans. During phase 5, the disease remains localised, but the number of persons affected is higher. During these two phases, measures will be taken in Belgium so that contaminated persons are directly treated and cannot spread the virus. Agreements in this

[1] Here, we probably target the *pre*pandemic vaccine.

respect have been entered into with all airports. Phase 6 is the pandemic phase. At this stage, the spread of the virus has intensified and affects the global population.

II. The Belgian emergency plan

At the end of 2005 and start of 2006, Belgium drafted an emergency plan (an operational plan) for an influenza pandemic. The plan was drafted by the Belgian Interministerial Influenza Coordination Committee (C.I.I.) with the help of collaborators from the Federal Public Service for Public Health, the Safety of the Food Chain and the Environment[2], the Scientific Institute for Public Health and the Federal Agency for the Safety of the Food Chain (AFSCA). The Interior Federal Public Service, the Federal Public Service for Foreign Affairs, Foreign Trade and Cooperation in Development, the Ministry of the Flemish Community, the Ministry of the French-speaking Community, the Ministry of the German-speaking Community, the Ministry of the Walloon Region and the Ministry of the Brussels-Capital Region were also involved.

The operating plan clearly specifies the nature and the role of the responsibilities of each entity involved in the plan, both in respect of the communication designed for citizens and healthcare providers and the monitoring of contaminated patients and persons who have been in contact with the latter. An Interministerial Influenza Coordination Committee has been set up: comprised of representatives from the Communities and Regions, it is supported by civil servants from the FPS Public Health and can call upon the departmental crisis units stipulated in Article 5 of the appendix to the Royal Decree of 31 January 2003 on emergency plans, which require coordination at national level. An Influenza Steering Committee is also planned, as well as a Scientific Influenza Committee, which collaborates with the Superior Health Council and the Scientific Committee of the FPS Public Health.

If there is a pandemic outbreak and there is a need to go into crisis configuration, a central coordination unit will be put in place with a management unit presided over by the Minister of the Interior, an evaluation unit presided over by the Director General of the FPS Public Health, an information unit presided over by the Head of Communications of the Minister of Public Health and an EcoSoc unit, which evaluates the socio-economic consequences of the pandemic. The decisions of the management unit which require local actions are sent by the evaluation unit to the provincial crisis centres (see Royal Decree of 31 January 2003). International and, particularly, European collaboration is planned.

The professional groups of the primary healthcare services can find a manual available on the internet on what is expected of them during the different WHO phases and how they can protect themselves. A call centre is also created and the management unit and the provincial units communicate their instructions via these channels.

During the pandemic, local "healthcare" contact points are created in all towns and communes, under the responsibility of the Burgomaster. Patients likely to be affected by influenza may go there; other than this consultation function, the centres keep a database up to date and respond to requests for information. They also coordinate the domestic healthcare dispensed to patients, in collaboration with the healthcare platforms and volunteers. The

[2] In the text referred to as FPS Public Health.

coordination of the local "healthcare" contact points is incumbent upon the province governors who, in turn, send the data they have to the national crisis unit of the Governmental Crisis Coordination Centre. The population is informed of the status of the situation by all possible channels (radio, television, newspapers, etc.) and it is expected to follow the required instructions in order to prevent the spread of the virus as much as possible. If necessary, some public meeting places will be closed. Some mass demonstrations, concerts, sports meetings, *inter alia*, may be cancelled.

In the scenario of the pandemic plan in Belgian hospitals, the Saint-Pierre Hospital in Brussels is appointed as the number one reference hospital, i.e. the establishment where the first suspect cases must be treated. Every other hospital should appoint a pandemic coordinator responsible for regulating the treatment of patients affected by influenza, with the collaboration of a chief doctor and the senior management. The province governors receive a report of the amount of beds available in the different hospitals in their province and send this information to the local "healthcare" contact points. The hospitals set up separate reception areas (waiting rooms, emergency services and hospital beds) to treat patients who are worried they have contracted influenza. Non-emergency treatment will be refused so that the medical and paramedical personnel remain available for patients affected by influenza.

Patients can only go to the hospitals if they are sent there by their regular doctor. Treatment is administered, where possible, at home. The regular doctor or the doctor from the local "healthcare" contact point provides the patients with the antiviral drugs and surgical masks (see, on this subject, chapter IV, point 3.c.1.), asking them to avoid travel, to wear a surgical mask when they are contact with the people living under the same roof as them and to do so for the 7 days following the appearance of the symptoms. The virus would be communicable for 7 days, but is already active the day before the symptoms appear. Every time a case of avian flu is ascertained, the persons who have been in contact with the patient are looked for.

A complete regulation has been drafted concerning the treatment of Belgians staying abroad during the pandemic and it is expressly provided that all foreign persons on Belgian territory, regardless of their status (legal or illegal) enjoy the same treatment as Belgians. In the emergency plan, it is mentioned that meetings are under way with the neighbouring countries (the Netherlands, Germany, France and the Grand Duchy of Luxembourg) to avoid medical shopping, as well as the requisition of healthcare providers who are residents in one country but who work in another.

A specific pandemic vaccine will only be available 4 to 6 months after the appearance of the new virus. Currently, nothing enables us to state with certainty that it will be possible to manufacture the vaccine for the planet's 6 billion people - to the contrary. At this level also, there is a big risk that some groups of the population, - even continents - stay on the sidelines.

In the meantime, a prepandemic vaccine has already been the subject of research in view of assuring a protective - albeit partial - effect and thus reducing the number of sick people. The protective value of this vaccine is still difficult to evaluate. In May 2008, the European Medicines Agency gave the go ahead for the introduction of the "prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals". This vaccine is identical to Prepandrix® already approved by the European Union and also developed by GlaxoSmithKline, with inactivated human strains of the influenza virus (A and B) and a H5N1 inactivated Vietnamese strain. Two injections are required, three weeks apart, to obtain sufficient immunity.

One of the experts interviewed by the Commission confirmed that a general vaccination of the Belgian population with the prepandemic vaccine is planned, as specified in the letter sent by the Minister to the Advisory Committee. As this vaccine only offers short term protection, it shall only be administered from the moment the pandemic spread of the virus seems likely, i.e. as of phase 5.

In the emergency plan, a generalised vaccination against pneumococcus is advised and particularly recommended in children up to the age of 5 in order to reduce carrying. An infection by pneumococcus is in fact the traditional bacterial complication of an infection by influenza which may be frequently responsible for a fatal outcome.

The State is also making 32 million surgical masks available. These masks considerably reduce the risk of contamination which an infected person has for those around him or her and are therefore planned for all patients, both outpatients (i.e. people who go to the local "healthcare" contact points), and those who are treated at home or are hospitalised.

Six million more effective FFP2 type respiratory masks are also planned for the healthcare personnel. These masks must be changed every 2 to 4 hours. The Belgian emergency plan does however specify that these masks are worn only in case of exposure to a microbial aerosol.

The State provides all clinical biology laboratories with 3 test kits each including a respiratory mask so that the attending doctor can take a nasopharyngeal specimen if he is concerned about a case of avian flu and send it for analysis to the laboratory of the Scientific Institute of Public Health.

Pursuant to the recommendation of the Superior Health Council, antiviral drugs are planned to treat 30% of the population. Part is presented in the form of Tamiflu® (Roche) ready to use in capsules or in powder form for drinkable suspension (as the molecule is oseltamivir), of Relenza® (GSK) ready to use, a powder to be inhaled (as the molecule is zanamivir), whereas another part is presented in the form of a raw material in bulk (oseltamivir phosphate) which is stored with the packaging and medical component excipients of the Belgian army, which has the necessary competencies to transform the raw material into tablets. These antiviral drugs are expressly planned to treat sick people and are not designed for prophylactic use, not even for healthcare workers[3].

[3] In other countries, the stock of antiviral drugs is planned for 5, 10, 20, 30 and up to 50% of the population.

III. Legal framework[4]

The central legal question, which is closely related to ethical considerations, is the following: how to reconcile individual rights and freedoms with a certain number of measures considered necessary by the public authorities in order to contain the disease, such as for example the requisition of persons or the isolation of contaminated persons?

1. Rules of international law

- Article 5 of the European Convention on Human Rights and Fundamental Freedoms (ECHR) provides:
"Everyone has the right to liberty and security of person. No one shall be deprived of his liberty save in the following cases and in accordance with a procedure prescribed by law:
[…]
e) the lawful detention *of persons for the prevention of the spreading of infectious diseases*, of persons of unsound mind, alcoholics or drug addicts or vagrants;"

- Article 8 of the ECHR provides:
"1. Everyone has the right to respect for his private and family life, his home and his correspondence.
2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, *for the protection of health* or morals, or for the protection of the rights and freedoms of others. (our italics)".

- The International Health Regulations (IHR)[5] (2005) of the World Health Organisation (WHO) provides that States Parties to the Regulations have as of 15 June 2007 a period of two years to assess their capacities and draft national action plans, then three years to fulfil the requirements of the Regulations concerning national surveillance and response systems as well as the requirements in the airports, ports and some designated border lines. These regulations make it a requirement for the Member States to declare cholera, plague and yellow fever and give the WHO the right to carry out an investigation[6].

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[4] We will not deal with the institutional and organisational aspects of managing crises at the communal, provincial and national level which are, *inter alia*, governed by:
- the Royal Decree of 18 April 1988 creating the Governmental Coordination and Crisis Centre (Belgian Official Gazette of 4/5/88);
- the Royal Decree of 31 January 2003, laying down the emergency plan for crisis situations and events requiring coordination or management at the national level (Belgian Official Gazette of 21/2/03);
- the Royal Decree of 16 February 2006 on emergency and response plans (Belgian Official Gazette of 15/3/06, ed. 2).
These are general plans and do not specifically target the appearance of a contagious disease such as an influenza pandemic. The specific structures planned in the event an influenza pandemic occurs are, furthermore, the subject of Chapter II "The Belgian Emergency Plan".

[5] can be consulted on www.who.int/csr/ihr/fr

[6] D. Bloem, M. Nazarian & G.V. Grigorieff, "La quarantaine médicale humaine, réflexions juridiques, éthiques et sanitaires sur une pandémie ", footnote on page 9, *in* Médecine et droit, Questions d'actualité en droit médical et en bioéthique, 2007, Anthemis, Louvain-la-Neuve.

- Decision no. 2119/98/EC of the European Parliament and of the Council of 24 September 1998 provides that each Member State must inform the other Member States and the Commission, via the community network EWRS (Early Warning Rapid System), of the nature and scope of the control measures it intends to take or has taken faced with the emergency.

2. Belgian federal legislation

2.a. Patient rights

Article 8.2 of the Belgian law on patient rights of 22 August 2000 provides that "patients are entitled to consent freely to any treatment from professional practitioners provided prior information is given. ". They are therefore entitled to refuse or withdraw their consent for a treatment (Art. 8.4). When, in a case of emergency, there is uncertainty as to the existence or not of a desire expressed in advance by the patient or his or her representative, any necessary treatment is given immediately by the professional practitioner in the interest of the patient (Art. 8.5).

Article 10.2 of the same Law provides that no interference is authorised in the exercising of the right to the protection of private life or the right to respect for privacy of the patient "except such as in accordance with the law *and is necessary for the protection of public health* or for the protection of the rights and freedoms of others. (our italics)".

2.b. Requisition

Requisition is a public law procedure by which, in specific circumstances, the public authorities ensure the collaboration of citizens or seize certain affairs[7]. Belgian legislation recognises civil requisition and military requisition.

This overview solely deals with the civil requisition of persons. Requisition is limited to exceptional circumstances, when ordinary measures such as the recruitment of personnel by appointment or by employment contract are deemed insufficient.

The main provisions likely to be of interest in case of pandemic are the following:

- pursuant to Article 4 of the Belgian Law of 8 July 1964 on emergency medical assistance, doctors must respond to a requisition from the public authorities;

- Article 9.3 of the Royal Decree no. 78 of 10 November 1967 on performing healing, nursing, paramedical professions and medical commissions confers to the health inspector and to the pharmacy inspector the competence to take measures to assure the normal carrying out of on-call services should these be jeopardised;

- for requisitions within the framework of the Royal Decree of 1 March 1971 on the prophylaxis of communicable diseases, see point 2.c. below;

[7] J. Dujardin, M. Van Damme & J. Vande Lanotte, Overzicht van het Belgisch administratief recht, 2002, Kluwer, Malines, no. 293.

- for requisitions within the framework of the regulations of the Communities on the prophylaxis of communicable diseases, see point 3 below;

- Article 17 of the Belgian Law of 5 August 1992 on the police provides that in case of calamity, catastrophe or incident, the police services of the zone affected are competent, until the intervention of the competent authorities, to take all measures necessary for saving people in danger, *inter alia* requiring the assistance of the population which must comply;

- Article 11.3 of the Royal Decree of 16 February 2006 on emergency and response plans (Belgian Official Gazette of 15 March 2006) provides that, in an emergency situation, the medical resources are placed under the administrative authority of the federal health inspector and that the operational management is incumbent upon the director of medical assistance;

- Article 181 of the Belgian Law of 15 May 2007 on civil security (Belgian Official Gazette of 31 July 2007, err. Belgian Official Gazette of 1 October 2007), provides that the Minister or his or her representative may, during the operations carried out within the framework of civil security and for the purposes thereof, proceed with the requisition of the persons and objects deemed necessary. The same power is recognised in the Burgomaster who may delegate this to the zone commander or to officers in the field. The King sets down the terms and conditions for reimbursing the requisition-related costs;

- in respect of *the private sector*, the Belgian Law of 19 August 1948 on services of public interest in times of peace provides that the joint commissions must define the measures and the services which must be assured in case of collective and voluntary cease of work or in case of collective redundancy of personnel, in view of dealing with certain vital needs or vital tasks commanded by an unforeseen necessity. These vital needs must be determined by the joint commissions. The appointment of persons who must be employed in certain companies because they are essential for dealing with vital needs must be done by mutual agreement between the employers and the employees. It is only in the absence of agreement between the social partners that these people may be requisitioned by the Minister of Labour and Employment or by the Minister of Economic Affairs and Energy or their representatives, for example the province governor[8].

2.c. Quarantine measures

- The Health Decree of 18 July 1831 provides in its Article 1.3 that the Head of State determines by decrees the extraordinary measures which the invasion or the fear of a pestilential disease would render necessary on borders or inside the country. The decree provides that persons coming from infected countries may be subject to longer or shorter quarantines. They may even be forced out of the territory if the quarantine cannot take place without exposing public health. Infringements are severely punished[9].

- The Health Law of 1 September 1945 indicates in its Article 1 that the King is authorised to prescribe by general regulations and after obtaining the opinion of the Superior Public Health Council, the prophylaxis and sanitation measures as well as all the necessary organisation and

[8] J. Dujardin, M. Van Damme & J. Vande Lanotte., Overzicht van het Belgisch administratief recht, op cit. no. 295; W. Van Eeckhoutte, Arbeidsrecht 1999-2000, Gandaius, Kluwer Rechtswetenschappen België, 1999, Antwerp, no. 208-211.
[9] D. Bloem, M. Nazarian & G.V. Grigorieff., op cit. p. 205.

control measures to prevent or fight communicable diseases presenting a general danger, a list of which will have been drawn up on the opinion of the Superior Public Health Council.

- Article 1 of the Royal Decree of 1 March 1971 on the prophylaxis of communicable diseases, amended by the Royal Decree of 18 November 1976, imposes the declaration of any case, established or suspect, of the following diseases:

"1. Quarantinable diseases:

1. Quarantinable diseases provided for by the World Health Organisation International Health Regulations:
cholera, yellow fever, plague and smallpox (also Alastrim);
2. Diseases similar, at national level, to quarantinable diseases;
haemorrhagic or non-haemorrhagic diseases, caused by the viruses of the following families:

a) abro- and Togavirus (such as dengue and Congo fever);
b) arenovirus (such as Lassa fever, American haemorrhagic fevers);
c) rhabdovirus (such as Marburg and Johannesburg fevers);

II. Non-quarantinable diseases subject to international declaration:

exanthematic typhus, relapsing fever, poliomyelitis, *flu of an epidemic appearance*, malaria (our italics);

III. Communicable diseases subject to national declaration:

1. Bacterial origin diseases:
[…]
2. Viral origin diseases:
viral encephalitis, infectious hepatitis, rabies;
[…]
3. Rickettsial and pararickettsial origin diseases:
[…]
4. Parasitic origin diseases:
[…].

Any pathological case of uncertain diagnosis but presenting an indisputable epidemic nature or presenting the symptomatology of a *severe epidemic* infection must also be declared.
Further, persons bound by the declaration must inform the health inspector [...] of any situation having the features of another severe infectious or *epidemic* disease, even when the diagnosis is not definitively established. (our italics)".

The Royal Decree of 1 March 1971 further comprises the following provisions:

Art. 6*a*. "When an established or suspect case of a quarantinable disease is brought to the awareness of one of the authorities [...], each of them may, if case of necessity, proceed with the requisition of any hospital service, situated within its district, *in view of assuring the prophylactic isolation* and the appropriate medical treatment. (our italics)".

Art. 6*b*. 1. "This requisition covers both:
1. the use of buildings, land and equipment and the personnel of the requisitioned service;
[…]

2. The requisitioning authority may order, further, the prior and immediate, total or partial, evacuation of the requisitioned service, by the patients who are hospitalised there and whose presence in the said service could compromise the effectiveness of the prophylaxis. […]".

Art. 6*c*. "When the arrival or the presence in Belgium of an established or suspect case of a quarantinable disease provided in Article 1.1 of the Decree herein is brought to the knowledge of a civil service doctor of the Ministry of Public Health and Family Affairs having in its functions the health inspection of land-based, maritime, river and air borders, and particularly those of ports and airports, this doctor may also proceed with the requisition of any hospital service situated on the national territory, *in view of assuring the prophylactic isolation and the appropriate medical treatment* of any person affected by the quarantinable disease in question or suspected of having it [...]. "(our italics).

Art. 6*d*. "[...] The senior management of the establishment concerned facilitates, assures and supervises the performance of the requisition, by all means in its power, particularly by *the immediate admission in the requisitioned service of any established or suspect case of the quarantinable disease in question.*
Each member of the requisitioned personnel is informed individually of the requisition upon the initiative of the senior management, initially verbally and then in writing.
[…]
The requisition remains in force as long as it has not been lifted by the requisitioning authority on the opinion of the prophylactic commission provided in Article 6*e*.
[…]. (our italics)".

Infringements of this Royal Decree shall, depending on the Article concerned, be punished by penalties established by the Health Decree of 18 July 1831 or by the Health Law of 1 September 1945 (Art. 10).

NB: this Royal Decree
- has been repealed and replaced for the Flemish Community;
- has been partially repealed and replaced for the Brussels-Capital Region;
- has been completed for the French-speaking Community.

See, on this subject, point 3 below.

Note: no provision has been found which also provides for putting medical personnel in quarantine, as happened in Canada at the time of the SARS epidemic[10].

2.d. Evacuation and travel ban

Article 182 of the Belgian Law of 15 May 2007 on civil security (Belgian Official Gazette of 31 July 2007, err. Belgian Official Gazette of 1 October 2007) provides that "the Minister or his or her representative may, in case of dangerous circumstances, in view of assuring the protection of the population, force this to move away from places or regions particularly exposed, threatened or affected, and assign a provisional place to stay for the persons targeted by this measure; he or she may, for the same reason, prohibit any travel or movement of the population. ".

[10] D. Bloem, M. Nazarian & G.V. Grigorieff, "La quarantaine médicale humaine, réflexions juridiques, éthiques et sanitaires sur une pandémie", op cit., pages 218-219.

3. Regulations of the Communities

Article 5.1.I.2 of the Special Institutional Reforms Law of 8 August 1980, taken in execution of Article 128 of the Belgian Constitution, provides that the Communities are competent for the health education as well as the preventative medicine services and activities, with the exception of national prophylactic measures.

3.a. Regulations of the Flemish Community

- the Flemish decree of 21 November 2003 on the preventative health policy (Belgian Official Gazette of 3 February 2004), which replaces the Royal Decree of 1 March 1971, provides in its Article 47 more specific quarantine measures;

- awaiting the entry in force of the implementing order of this Decree, which is being prepared, the previous regulations in this matter, which are in force at the time of the entry in force of the said Decree, *inter alia* in respect of the prophylaxis of contagious diseases, remain in force.

This particularly relates to:

- the Decree of 5 April 1995 on the prophylaxis of contagious diseases (Belgian Official Gazette of 19 July 1995);

- the Decree of the Flemish Government of 19 April 1995 implementing the Decree of 5 April 1995 on the prophylaxis of contagious diseases (Belgian Official Gazette of 14 July 1995).

Article 5.1 of the Decree of 5 April 1995 on the prophylaxis of contagious diseases provides that, to prevent and fight the diseases referred to in the Decree herein, the competent civil service doctors may:
"1. *force* the persons affected by such a disease and who hence constitute a risk of contagion for the community, *to undergo the appropriate medical treatment* in order to fight against this contagion and where need be *order their temporary isolation* in a hospital department designated by the civil service doctors;
2. in case such a disease is ascertained, *submit* the persons who may transmit this disease due to their professional activities, *to a medical examination* aiming to detect the source of contamination;
3. *prohibit* the persons referred to in point 2 who are infected and may transmit the disease, *from performing their professional activities* as long as they constitute a risk for public health;
[…]
6. requisition the hospital areas necessary for the admission and isolation of persons contaminated or suspected of being affected by a severe contamination. (our italics)".

The diseases referred to in the Decree and for which the immediate declaration is mandatory, are listed in Appendix I of the aforementioned Decree of the Flemish Government of 19 April 1995, which provides under 11 "Any other severe contagious disease not indicated on the list *and which is likely to present an epidemic nature.* (our italics)".

3.b. Regulations of the French-speaking Community

The Royal Decree of 1 March 1971 has been completed by:

- the Decree of 17 July 2002 of the Government of the French-speaking Community on the prophylaxis of communicable diseases in the school and student environment (Belgian Official Gazette of 26 October 2002);

- the Decree of 17 July 2002 of the Government of the French-speaking Community laying down the list of communicable diseases implying the implementation of prophylaxis and screening measures (Belgian Official Gazette of 26 October 2002).

3.c. Regulations of the Brussels-Capital Region

The Decree of 19 February 2004 of the College of the Community Commission for the commune of the Brussels-Capital Region of 19 February 2004 amending the Royal Decree of 1 March 1971 on the prophylaxis of communicable diseases (Belgian Official Gazette of 16 March 2004) provides in its article 1 *inter alia* that Members of the College, competent for the health policy, may complete the list of diseases for which declaration is mandatory. Any pathological case of uncertain diagnosis *but presenting an indisputable epidemic nature or presenting the symptomatology of a severe epidemic* infection must also be declared (our italics).

3.d. Regulations of the German-speaking Community

No regulations have been found.

4. Ethical rules

The *Code of Medical Ethics of the Belgian Medical Association* provides *inter alia*:

Art. 3.
"The performance of the medical profession is an eminently humanitarian mission; in all circumstances, doctors look after the health of persons and of the community. […]".

Art. 5.
"Doctors must treat all their patients with the same conscience, regardless of their social situation, their nationality, their convictions, their reputation and how they feel about them. ".

Art. 6.
"All doctors must, regardless of their function or speciality, give first aid to a patient in immediate danger. ".

Art. 7.
"In case of public danger, doctors may not abandon their patients, unless they are forced to do so by the qualified authorities. ".

Art. 8.
"Doctors must be aware of their social duties to the community. ".

Art. 99.
"Doctors must both respect the imprescriptible rights of human beings and fulfil their duties to the community. ".

Art. 101.
"Doctors make their personal contribution to the mission incumbent collectively on the medical corps of promoting the health of the population.

The medical corps provides its assistance, whilst respecting the ethical rules and rights of the individual, the forms of social security, whose aim is to assure that all citizens have the best healthcare. ".

During the SARS epidemic in Canada, contact between doctors and infected patients was limited to the minimum in certain hospitals; consequently, doctors were to a certain extent dispensed of their duty to treat[11].

One may ask oneself to what extent doctors have to continue to be involved despite the risks for their own health and safety.

In its *opinion of 24 January 2009* on this subject[12], the *National Council of the Belgian Medical Association* considers that "each doctor has an ethical duty to provide treatment and healthcare. This applies so as not to be exposed, like any citizen, to the consequences which the law attaches to guilty abstention, breach of contract or of a commitment, but above all also due to the hope-loaded social role doctors assume. Hence, the conscious decision to become and to be a doctor is inseparable from the acceptance of a duty to provide treatment and healthcare. This duty is not a related optional condition. It is at the very centre of what enables the medical profession to be defined (see Article 7 of the Code of Medical Ethics). [...] The acceptance by doctors of the duty to provide treatment does not mean that they have to ignore their own safety or other conflicting duties, mostly family-related, altogether. Hence, during the recent SARS threat, those dispensing medical care were afraid of contaminating the members of their family. They had to put their work ahead of the practical problems in the education and the everyday care of their children and even the essential questions concerning the protection of their nearest and dearest. […]
The practice may not in this case be restricted to judging the duty whose calling predominates and must go hand in hand with an approach offering an area where antagonistic values can co-exist. *Inter alia*, a doctor's duty to provide treatment also entails restricting duties for the healthcare institutions and for society. In addition to the social support in the form of adequate medical, invalidity, death and child healthcare insurance, etc. they have to maximise the safety of the different medical workers at the front line. ".

[11] D. Bloem, M. Nazarian & G.V. Grigorieff, "La quarantaine médicale humaine, réflexions juridiques, éthiques et sanitaires sur une pandémie", op cit., pages 218-219.
[12] Opinion of 24 January 2009 on the duty to provide treatment, to be consulted on www.ordomedic.be.

5. De lege ferenda: the Influenza framework law

During the interview of an expert, it was established that an Influenza framework law is being worked on, which would be promulgated at the start of a pandemic and which would modify a certain number of legal provisions in order to deal with the crisis situation.

As an illustration, we will give two examples. An exception would be considered of the provision according to which bank notes must always go through the National Bank of Belgium, where used and damaged bank notes are withdrawn from circulation. Banks also see a problem of supplying the automatic cash machines if it becomes impossible to organise the transportation of funds sufficiently. The Flemish regulation prohibiting undertakers from transporting more than one dead person is another example; an exception will also be planned.

6. Conclusion

Although within the Communities there are a few differences between the regulations concerning quarantine and isolation, which may cause some inaccuracies and hesitations, the current legislation seems sufficient to deal with the influenza pandemic up to WHO phase 5 inclusive, i.e. for individuals or small groups of people infected by the disease. From the time this pandemic enters phase 6, the aforementioned legislation will, in practice, be less appropriate, since one cannot naturally isolate or put in quarantine the entire population. At this time, the communication of medical measures appropriate to the population by different information channels will be of utmost importance. By way of examples, we will cite the fact of staying at home as often as possible, to get supplies in therefore, or even avoiding visits and unnecessary travel, as well as all the health recommendations which will be updated.

IV. Ethical considerations

1. Public health ethics

A State is expected to protect its population by creating and maintaining a certain number of essential infrastructures and devices, in order to satisfy fundamental rights and needs; it must for example ensure that all children can continue their education, that everyone has drinking water, a home, it must guarantee the mobility of citizens, the upkeep of streets and roads, it must guarantee that there are enough healthcare workers to treat those sick, reduce air pollution, etc. The State is also expected to diffuse the necessary information to enable its citizens to make free and appropriate choices, according to their private and personal convictions.

Whilst it is true that, in the past, the State has sometimes adopted too much of a paternal attitude, decreed laws and taken actions guided by the moral conviction of a majority, thus harming the autonomy of some citizens, the situation has changed over the last decade - at least in the western world. The right of the citizen to make independent decisions is expressed more and more. In Belgium, the abolition of the law on vagrancy and the promulgation of the law on patient rights are obvious examples of this.

From the European Convention on the Protection of Human Rights and Fundamental Freedoms (ECHR), adopted on 4 November 1950, it can be deduced that a public authority may restrict private rights when this is deemed necessary for the protection of others against contamination. In this respect, Belgium has an entire series of regulations (see *supra*).

The emergency plan has not been drawn up or drafted with the aim of imposing on citizens one rule of conduct or another applicable to their personal or family environment which would not correspond to their own vision or conviction. This emergency plan has been drafted to reduce the risk of contamination of third party persons and regulate the treatment of patients in the best conditions. The objective is to act "well" for the majority and "harm" the smallest number possible.

From an ethical standpoint, there is no objection to opposing the drafting of an emergency plan by the State or the implementation of a series of units capable of monitoring the evolution of the pandemic and adopting, potentially, measures aiming to restrict the personal freedom of citizens in order to save lives.

The fact that the State has drafted a plan and created a website proves that it has acted in accordance with the principle of precaution and intends to inform citizens as best as possible of the potential danger they incur. It is obviously not a question of imposing "new" coercive measures; on the contrary, the emergency plan starts from the principle that everyone will follow the instructions as required. We find this trend in the operating plans decreed by several European countries and in its opinion no. 106, the French CCNE (National Advisory Committee on Ethics) [13] "draws attention to the danger in extending [these restrictions to fundamental freedoms] beyond what is necessary for fighting the influenza pandemic, or else due to a hard-line (and therefore inappropriate) conception, the principle of precaution, or else for demagogic posting purposes.

The emergency plan also provides for organising a survey with the population (p. 41) in order to check the way in which it perceives a pandemic, how worried it is in this respect and how it can prepare for it. During the crisis phase, all possible means are implemented to ensure communication to the general public. Depending on the evolution of a potential pandemic, the principle of proportionality requires ensuring that the restrictions imposed enable valid results to be achieved.

For public interest reasons, the French Committee, in the aforementioned opinion, considers that in case of pandemic, the individual freedom which consists of refusing vaccination, must not be respected. Whilst it is fitting to devote all the time necessary to convince an individual who would refuse the pandemic vaccination, in order to try to make him or her understand the danger this refusal means for him or her and for others, it would not be fitting to respond to his or her refusal to be treated as the interest of the social corps here relates to the respect for the autonomy of the person.

The Nuffield Council (UK)[14] considers that in the case of a pandemic, it is essential to put in place a surveillance system to monitor the evolution of the disease and its modes of infection. It therefore thinks that it is acceptable to organise the collection of anonymised data which

[13] See www.ccne-ethique.fr/avis
[14] Report "Public health: ethical issues", see paragraphs 4.39 and 4.43,
see www.nuffieldbioethics.org

enable the spread of the infection to be studied without having to obtain the consent of the persons concerned and as long as any invasion of privacy is reduced as far as possible. However, for the Nuffield Council, in certain situations it may be justified to collect non-anonymised data, despite the invasion of privacy and infringement of confidentiality, which such measures mean, for the persons concerned, if there is a public health interest. From an ethical standpoint, it would therefore be justifiable to seek to identify all the contacts which a person, presumed contaminated, recently had with others. In Belgium, this epidemiological approach is of a legal nature in respect of some diseases such as tuberculosis without however arousing debate within the population.

2. Solidarity

The effectiveness of the plan is however largely subordinate to the optimum collaboration of the civil population and groups of healthcare professionals.

2.a. Collaboration of the civil population

Even if the information is transmitted correctly, the average citizen has to be able to understand it and feel that it is credible. In view of the comments published *inter alia* on internet forums in relation to avian flu, a number of people still underestimate the danger of this disease. Shouldn't we therefore think first of all of informing the population about what a virus is, how an influenza virus can, sometimes, be combined with avian flu or other animal-borne virus, or what a mutation of the virus means? Some people have difficulty in understanding why it is useful to eliminate birds found in and near avian flu outbreak sites.

Will everyone realise the importance of keeping their hands clean? To what extent will sick people actually wear a mask at home, avoid visits and protect their nearest and dearest? To what extent will they be aware that, until they are fully recovered, it is preferable not to leave their home so as to avoid contaminating others; that, likewise, it is more prudent to stay at home if the slightest flu symptom appears, at the risk of displeasing, perhaps and if any, their employer?

The emergency plan seems to start from the principle that everyone will respect the instructions, since these are precisely instructions! This assertion is not however a given from the outset in Belgium where a number of citizens see no harm in "finding fault" with each guideline. As emphasised by Marc Guerrier and Emmanuel Hirsch: "Anticipating theoretically or examining the experiences drawn from other significant circumstances is a good way of confronting the eventualities of an influenza pandemic. However, the speculations of experts and the measures planned cannot, alone, create the conditions of mobilisation and reinforcement of social cohesion around shared values"[15].

The members of the Belgian Advisory Committee on Bioethics consider that to instil an optimum and constructive attitude in society, developing information channels is not enough. The Committee feels that, as a priority, the population has to be prepared for a pandemic, even if it is not possible to confirm with certainty that this will occur and, if it does, when. It seems recommended to involve the population in the political plans, at all administrative levels (communal, provincial, regional, community and federal). This theme must above all

[15] Periodical "PandEmiques", no. 2-3, Nov. 2007, p. 2.

be discussed at local level, via the district committees and associative life. Citizens must be prepared for the eventuality of a pandemic and for the fact that they can play a constructive role in containing it. In practical terms one can not only expect the average citizen to show common sense in order to reduce the risk of contamination, but also and above all that this citizen has the impression, thanks to his or her commitment, of being sufficiently involved in order to feel accountable. Each person must be able to appreciate the extent to which they can contribute to containing a potential catastrophe. In doing so, we have to think particularly about preparing groups that live on the fringe of society, such as the homeless and illegal persons, who risk spreading the disease through ignorance.

We also need to consider the necessity of assuring communication on this with the allophone population as well as with the non-negligible part of the population that does not watch televised news, hardly ever listens to the radio or rarely reads a newspaper. Resistance to the avian flu virus is also linked to general living and housing conditions. There is barely question of this aspect in the emergency plan. What about the homeless? And the 14% of Belgians who live under the poverty line and undoubtedly do not have the possibility of stocking up on food or drugs such as antipyretics for a long period?

Preparing the population for the eventuality of a pandemic cannot however entail a wave of panic. At the end of the day, as has been previously said, no one knows with certainty whether there will be an influenza pandemic outbreak or, if this should be the case, when. What is essential, therefore, is to give the population the necessary information and competencies in order to enable it to react correctly in case of pandemic. If we start this preparation too far in advance, before phase 6, we are likely to obtain the reverse effect and, in the end, see the population deny the eventuality of a pandemic. When a person is warned with too much insistence against the imminence of a danger which never happens, it is highly likely this person will ignore this danger.

In phase 3, this above all means informing the population of viral infections in general and of the preventative behaviour to be adopted in order to avoid the spread of the virus. Recent general campaigns (in winter 2008-2009), similar to the one implemented a short time ago on the spread of the seasonal flu virus, are important in order to prepare the population for a pandemic. The members of the Committee feel that active citizens must be encouraged as of now to stay at home if they feel ill or have the flu, going against their usual reflex; denying the symptoms, some go to work anyway and thus become veritable vectors of the spread of the virus. With regards the general prevention against viral epidemics, it is desirable not to limit oneself to simple "information campaigns" but to involve the general public more directly, *inter alia* via associative life, in order to encourage mutual consideration of the issue. Despite all the effort already made to explain that viral and bacterial infections must not be treated in the same way, it seems useful to return once again to this point. It must be clear for everyone that antibiotics are useless against viral infections, whereas antipyretics will relieve patients and they must ensure they drink enough fluids. In case of bacterial complications, the use of antibiotics may be wise.

It is an excellent idea to administer, as indicated in the emergency plan, the prepandemic vaccine to the entire population as quickly as possible (as of phase 5). This vaccine would help the body resist the future influenza better and would hence reduce the risk of mortality. We must however ensure that the majority of people are aware of its effectiveness so that they react to this proposal. An expert interviewed by the Commission on this matter stated that invites would be sent out on the basis of the electoral rolls. Children would be vaccinated at

school. We may ask ourselves about the communication implemented in respect of those who do not enjoy Belgian nationality and people in this country illegally, in order to encourage them to be vaccinated. The emergency plan specifies in fact that all persons staying on Belgian territory enjoy equal rights in terms of medical assistance in case of pandemic: this position is not only legitimate from an ethical standpoint, but also practical, in order to reduce the risk of contamination among the population. The same expert, interviewed by the Commission, confirmed that the vaccination of people staying in Belgium illegally was indeed planned.
If the vaccination is not a proposal but an obligation, we need to consider the measures to be taken against people who refuse to have it and the means available to apply these measures. Finally, given that the prepandemic vaccination cannot guarantee complete prevention, we have to ask ourselves if, from an ethical standpoint, it can however be imposed (by adhesion to the principle of required solidarity), especially given that little will be known of the possible undesired side effects.

Whilst the Belgian influenza plan provides for specific measures for the hospital establishments (see above), there is little question of precautions to be taken in all other establishments and institutions, whether closed or not, where promiscuity is high and where sanitary conditions are sometimes mediocre. Here we are thinking in particular of prisons, but also rest homes (RH) and rest and care homes (RCH), as well as all the various care homes or convalescence homes. We feel it opportune that in each of these institutions an adapted pandemic plan is pre-established on a joint basis, in order to restrict the dangers of contamination between those staying in these homes and to ensure optimum treatment, which requires, in addition, specific training of each personnel. Of course, for the good of the majority, we must not exclude restricting the access of outside visitors
and it would also be useful to provide special sections in them to accommodate the persons contaminated by the virus, with the hope of avoiding its spread. It seems essential to the members of the Committee to reflect on the treatment of patients thus institutionalised whilst respecting to the utmost their fundamental rights and the principle of equality of these rights with those of all other citizens.

2.b. Cooperation of the healthcare professions

No more than for the civil population, the emergency plan does not seem to doubt the good will of doctors (generalists) to make themselves available to patients within the framework of a pandemic. We expect societies of generalist doctors to promote and organise this availability.

With regard to the general availability of doctors, healthcare workers and all persons who, due to their profession, come into contact with contaminated patients, the Committee feels that it has to look at the moral dilemmas with which these persons would be confronted, basing itself on general ethical considerations. Due to this same availability towards patients affected by the pandemic, they run, in one way or another (regardless of the preventative measures they adopt), a higher risk of contamination than ordinary citizens. Their professional obligations may therefore conflict with their family obligations - at two levels. In parallel to the serious emotional consequences, their potential death may have an indirect catastrophic material impact for their children and/or their partner. Given the risk of contamination they represent, they may also put the life of their partner and their children in danger.

The members of the Committee think that the State must pay the necessary attention to this issue. Just like is done in other countries, particularly further to the SARS epidemic, appropriate measures must be taken to assure financially the life of the healthcare providers, so that their family does not suffer from the serious material repercussions of their positive commitment to society if they die from influenza or lose their ability to earn. On the other hand, we have to ensure that, during the pandemic, active healthcare workers or other persons exposed to increased risks of contagion within the framework of their profession do not have to be in direct contact with their partner or their children. It seems appropriate to create, *inter alia*, an accommodation infrastructure, either for the healthcare providers or for their families.

3. Availability of resources and personnel

3.a. Availability of hospital beds and their supervision

The resources a country has are not infinite and even in situations where a danger of death weighs over the population it is essential to ensure that the survivors always have the resources necessary to enjoy a correct standard of living. However, a cost-benefits analysis must be carried out in order to determine, if any, the "disproportionate" expenses - we are thinking, for example, of the relative pointlessness of building new hospital infrastructures in anticipation of a potential pandemic - and the more minor financial costs, designed to launch measures enabling the expansion of a potential pandemic to be countered and/or better health protection to be offered to certain professional categories essential for the smooth running of society.

Extending the hospital capacity seems to be an excessive measure, since no one knows where the healthcare personnel should be found. Often, the hospitals already lack personnel and a pandemic would certainly not spare this professional category.

3.b. Availability of ventilators and their management

The purchase of a higher number of ventilators seems less extravagant, even if it represents a major budgetary investment. Ventilators are durable investment goods and may always be used after the pandemic. Even outside pandemic periods, this apparatus is sometimes lacking. Handling ventilators also requires competent personnel and since we usually bank on a relative shortage of healthcare personnel in case of pandemic, this expenditure is perhaps no that wise.

3.c. Availability of masks

Things seem different in respect of masks, even if their protective effectiveness has not actually been proven. Masks also have a very long storage period and in case of surplus, those stored for the pandemic are not lost. Their cost is also low. The State plans stocks of surgical and respiratory masks.

3.c.1 Surgical masks

As previously explained, surgical masks do not protect those wearing them against contamination but prevent contaminated persons from contaminating others. These are

therefore "altruistic masks". All contaminated persons must wear them, whether they are treated at home or if they are staying in a hospital or another institution.

The creation of local "healthcare" contact points seems justified to relieve the emergency services of hospitals and prevent, as best as possible, the contamination of non-contaminated persons in the waiting rooms of surgeries. Within the framework of such a structure, people presenting influenza symptoms must however travel and go out in the street, even take the train, the bus or the underground to reach the local contact point. First of all, it seems wiser to centralise the consultations of the patient at home as much as possible. In other words, we need to be able to count on a maximum number of mobile generalist doctors and organise an on-call service at the local contact point. We may nevertheless assume that a certain number of generalist doctors will also be non-available, whether or not they are infected with the disease. Persons who have to travel to the contact point and who have already developed influenza symptoms represent an obvious risk of contamination: they must consequently have surgical masks before the diagnosis is made. It hence seems desirable to issue these masks as a preventative to all persons staying on the Belgian territory.

Within the framework of fighting the spread of the virus, the main problem resides in the fact that a person is already contagious 24 hours before the appearance of the symptoms. No one can therefore confirm with certainty that this person is not already in the process of spreading the virus. Just like the measures taken in Asia during the SARS epidemic, it may be useful to impose the wearing of surgical masks on all persons who leave their home, as well as in companies, schools, authorities and other similar establishments once phase 6 starts. This measure seems wise as of phase 4 in air planes and trains that transport persons coming from countries already affected by the pandemic. At family level, it is also recommended to have surgical masks ready to wear as of the appearance of the first symptoms in order to avoid, as far as possible, contaminating other family members.

The emergency plan reports a stock of 32 million surgical masks, which represents approximately 3 masks per person. Given that the mask has to be disposed of after wearing it, this number seems to be insufficient. According to estimates, 30% of the population could be contaminated and develop the disease. In Belgium, 3 million people should therefore have surgical masks for seven days approximately in order to avoid the spread of the virus. The number of masks has been obviously established on this basis. The members of the Committee do however feel that one should not underestimate the value of masks as a general prevention measure. They hence support the idea of generalising the making available of surgical masks for the entire population.

3.c.2 Respiratory masks

Unlike surgical masks, the so-called respiratory masks (type FFP2) protect those who wear them against the virus. Their effectiveness is however limited to a few hours (from 2 to 4 maximum, depending on the source of information).

They are deemed to protect healthcare professionals against the virus, both in the outpatient sector and in the hospitals. We have already explained that the availability and working aptitude of generalist doctors were crucial. Given the frequency of their contacts with patients, we think that they should enjoy maximum protection against viral transmission during phase 6, even as of phase 4, if they are called by persons presenting influenza symptoms. Wearing a respiratory mask therefore seems recommended for any contact with a person suspected of

being contaminated as the virus is transmitted in the form of micro-droplets. If the patient coughs or sneezes during the examination, the risk of contamination is patent.

There is a comparable risk in the hospital sections where patients infected by influenza are admitted. Even in the absence of specific examinations related to a microbial aerosol risk, the personnel treating them may be infected by micro-droplets if the patient coughs or sneezes. Since it should be reasonably expected that hospitals will be overcrowded, it is hence imperative to advise against any exposure to the risk of contamination which would directly lead to a reduction in operational staff in all the professional categories concerned.

It is also desirable to offer optimum protection to workers from the social or home care sector, who have to look after sick people living alone (buying drugs, delivery or preparation of meals, etc.). If we want to avoid sick people going to the pharmacists to buy antipyretics for example, or even to the baker, the fruit and vegetable market or the butcher, we have to ensure that they benefit from effective home help. But these professionals, just like volunteers, hence put their own life or that of their nearest and dearest in danger.

The emergency plan plans the building up of a stock of 6 million respiratory masks. If we start from the hypothesis that no healthcare provider works at night, which is obviously absurd, 100,000 healthcare providers will have respiratory masks for 10 days. The pandemic may however last for several months - up to two years according to some sources - and, as already explained, the healthcare providers are not the only professional category that have to benefit from specific protection. Neither can we forget the protection of the cleaning and administrative personnel of hospitals and of the local contact points. The stock of respiratory masks hence seems insufficient. The members of the Committee feel that it is necessary to consider a considerable increase in the stocks of respiratory masks, especially given that here there cannot be a question of waste since the stored masks have a long storage period on the one hand and, on the other, their cost is not excessive.

3.d. Availability of antiviral drugs

The emergency plan only provides for the use of antiviral drugs for the treatment of pandemic influenza symptoms and not for their prophylactic use. Public health specialists and scientists are not of the same opinion with regards the usefulness of antiviral prophylaxis. According to sources, antiviral prophylaxis could lead to a reduction in morbidity of between 30 and 70%.

Nederlandse Gezondheidsraad does not support prophylaxis (publication 2005/05, p. 13). It is only when patients become symptomatic that antiviral drugs can be useful for them because they will have already been able to develop antibodies and will be more resistant during a latter attack. Within the framework of a prophylactic use of antivirals, no antibody can be developed and individuals are therefore never immunised against the virus. If a localised outbreak site of contaminated persons is discovered, Nederlandse Gezondheidsraad nevertheless recommends (p.12) administering antiviral drugs as post-exposure prophylaxis. "The aim is to slow down the pandemic, or even to nip it in the bud" (our translation).

For its part, the Finnish Advisory Committee on Bioethics supports short term prophylaxis for people living under the same roof as a contaminated person or who are in contact with sick people.

An expert interviewed by the Commission felt that not only was it necessary to provide the respiratory masks necessary for the healthcare workers - a point of view also supported by the Advisory Committee - but that these latter should also have a constant dose of prophylactic antivirals in order to fight absenteeism for disease in their ranks and protect them effectively against the risks to which they are exposed. This point is controversial as the actual protective effectiveness of such prophylaxis is not established with certainly and healthcare workers perhaps have an interest in developing antibodies against the virus as quickly as possible. The members of the Committee are however of the opinion that it is the responsibility of the healthcare professional to decide whether or not he or she wishes to have drugs as a preventative measure.

The potential usefulness of generalised prophylaxis must be examined, taking account of the moment a country enters phase 4 and the timeframe it must reasonably have in order to have an adequate amount of the pandemic vaccine. If the virus has already developed for a certain time far from Europe and if we had several months to manufacture a vaccine enabling the majority of the population to be vaccinated, the argument related to the formation of antibodies is no longer valid and it seems advisable to administer antivirals as a prophylactic until vaccination. If there is, however, a great shortage of pandemic vaccine, it is essential that the majority of people can develop natural defences against the virus.

The emergency plan provides for a stock of antiviral drugs that is sufficient for treatment of only 30% of the population. In this respect, it should also be remarked that the effectiveness of stored antivirals reduces over time, even in the best storage conditions. According to some sources, the expiry time is one year, according to others, the drug stays effective for longer. At the end of the day, we also do not know the exact therapeutic value of the antivirals available. Even though it is impossible to evaluate with certainty the prophylactic value and the therapeutic effectiveness of antiviral drugs, the members of the Advisory Committee feel that it would be irresponsible, ethically, not to be able to treat certain contaminated people due to a shortage of drugs and that neither would it be legitimate to deprive healthcare professionals of the possibility of taking Tamiflu® or oseltamivir for prophylactic reasons if they so wish.

Purchasing antiviral drugs is however deemed very expensive, especially given that the stock has to be renewed regularly due to the risk of relapse. Officially, Tamiflu® is only manufactured by Roche and Relenza® by GSK. These antiviral drugs are sold by these firms throughout the world. Roche and GSK may find it difficult to honour their orders. Given that these companies have a protected patent for these two products, no other firm can compete with them.

An expert interviewed by the Select Commission did nevertheless state that discussions have been under way for years on tri-therapy for persons contaminated with the AIDS virus. Financial accessibility to treatment for developing countries encouraged the WTO (World Trade Organisation) to interpret the Agreement on TRIPS (Trade-Related Aspects of Intellectual Property Rights) so as to support the rights of the members of the WTO to protect public health and, in particular, to promote access to all drugs (Doha Declaration of 14 November 2001).

In practice, this means that a country that does not have the necessary funds to buy patented drugs can grant a mandatory licence to import generic versions. The Agreement on TRIPS did however define restrictions concerning the production and exporting of basic products, which

are also protected by a patent in the potential exporting country. On 30 August 2003, the General Council of the WTO handed down a decision authorising the countries whose manufacturing capacities in the pharmaceutical sector are insufficient or non-existent to make effective use of mandatory licences to import generic versions of patented drugs. In principle, only the patent holder can grant the right to use its invention to a third party. It grants a licence to this third party. There is a mandatory licence when the State authorises a third party to use the invention without the agreement of the patent holder.

Several "rich" countries, including Belgium, have declared then that they would not use this possibility. According to an expert interviewed by the Commission, this declaration may be considered a pious intention and nothing could, in case of need, prevent Belgium from using this system of mandatory licences and from importing oseltamivir (generic) originally from India, for example, at a significantly lower price.

The members of the Committee feel that, if a shortage of antiviral drugs occurs during a pandemic, the State must use the system of mandatory licences if it does not have the financial resources to buy the necessary patented specialities or if the pharmaceutical companies are unable to respond quick enough to demand.
As specified by the Nuffield Council[16], if the industry is unable to respond to the needs of the population and the health of this is in danger, it is acceptable for the State to use this type of process.

4. Decisions on the use of resources

4.a. Prioritisation and de-prioritisation, in principle

"Prioritisation" here means that in case of a shortage of resources, some people or categories of people are treated "as a priority". Such a scenario will present itself in all likelihood during the administering of the pandemic vaccine, which will not undoubtedly be manufactured in sufficient quantities to vaccinate the entire population. Prioritisation may also be essential if several persons need a ventilator at the same time, but only one machine is available.

By "de-prioritisation" we mean that, for a defined treatment, some persons obtain a lower priority than others. This could even imply that in some situations, persons who already benefit from a treatment are deprived of it in favour of others. Within the framework of some hospital treatments, if there are not enough ventilators, it may thus be decided to make a ventilator already used by one patient available to a new-comer if it is felt that the latter would gain more benefit from it. Even if the person placed on the ventilator is in fact prioritised, we speak of "de-prioritisation" of the other patient.

In principle, all human beings have equal rights and, as emphasised by the Finnish Advisory Committee for Health Ethics, "there are no "correct" answers to the questions related to prioritisation in case of pandemic". From an ethical standpoint, neither are there any "correct" answers to questions related to de-prioritisation. However, the ethical principles must also be able to be applicable and force majeure prevails in certain circumstances. From a utilitarian

[16] Report “Public health: ethical issues”, paragraphs 2.47-2.50, 5.26, 5.16-5.25, 6.18-6.31 and 8.24, see www.nuffieldbioethics.org

standpoint, a majority of the population has everything to gain from some professionals remaining operational in case of pandemic, such that their prioritisation seems legitimate.

In the domain of public health also, priority criteria are applied. Some categories of patients may receive some drugs free of charge or benefit from a more advantageous reimbursement. The aim is generally to offer better protection to the weakest patients. Article 12.1 of the International Covenant on Economic Social and Cultural Rights[17] ("the right to the highest attainable standard of physical and mental health") provides that all healthcare establishments, goods and services must be available for everyone and in particular the most vulnerable and marginal groups of population.

If the resources are lacking and if reasonable effort has been made to overcome this shortage, some people will have to be de-prioritised in favour of others.

Specialists in catastrophe medicine have learnt to react according to the principle of triage, taken from battlefields and war medicine. When a catastrophe occurs (a natural catastrophe, a plane crash, a serious train accident), they determine, where appropriate, who can be treated effectively or not in accordance with their vital prognosis. Depending on the type of catastrophe, the nature of the wounds, the number of victims and the type of damage caused, as well as the existing healthcare infrastructure and its availability, some patients are de-prioritised in favour of other patients.

In ordinary medical practice, de-prioritisation does not generally occur, even if doctors specialised in intensive care are sometimes faced with dilemmas when all nearby beds are occupied. Most often, it is usual to grant priority then to the youngest patients, as long as their prognosis has real chances of being positive.

If there is a pandemic outbreak, the resources available will not be inexhaustible. Even if we start from the principle that the State will stock up on a lot more respiratory masks and will have doses of antivirals for the entire population, even antivirals designed for prophylactic use if such a scenario were deemed to be wise, it may be the case that the number of hospital beds is insufficient to deal with all demands. The number of ventilators available will necessarily restrict the accessibility of healthcare. Depending on morbidity and the speed by which the virus spreads and, consequently, the number of sick people, decisions may have to be made involving de-prioritising some people in favour of others, who have more chances of survival.

It is judicious to reflect carefully on questions related to the concepts of prioritisation and de-prioritisation in case of pandemic if we want to avoid faux pas at the height of the crisis. As written by the Minister, it seems actually desirable to define a framework within which the healthcare professionals may find an answer to the questions they have to ask themselves in some cases of force majeure. Such a scenario must preferably be drawn up with the active collaboration of the population. Tools to help decision-making must be able to be made available to the multidisciplinary treatment teams.

[17] International Covenant on Economic, Social and Cultural Rights of 19 December 1966, executed in New York and approved by the Belgian Law of 15 May 1981 (Belgian Official Gazette of 6/7/1983) and "General Observation 14" 22nd session, Geneva, 25.4.2000.

4.b. Prioritisation

4.b.1 Prioritisation of certain professional categories

During phase 6, it seems essential to protect the professionals and volunteers who take care of the sick. The treatment of sick people falls on their shoulders and the inability to work due to illness in their ranks may put the lives of others in danger.

Some other healthcare professionals further come into close contact with potential carriers of the virus. We are particularly thinking about dentists. The wearing of respiratory masks therefore also seems recommended for this professional category, recalling once again that these masks only guarantee optimum protection for a few hours.

Pharmacists also come into contact with a very high number of potential carriers of the virus. It seems more than desirable that pharmacies remain open for the population in general but also for patients infected by influenza who have to continue to have antipyretics and potentially analgesics, as well as antibiotics in case of co-morbidity with a bacterial infection or even other drugs.

We also have to think about other fundamental needs of society. Insofar as we wish to avoid the paralysis of society as a whole, it seems interesting not to force all parents to stay at home with their children. It therefore seems important to protect the teaching personnel who, through their job, are in contact with children spreading the virus. The same rule applies for healthcare providers in the social sector. People who work in rest homes must be protected against the virus if we want to avoid the closing of these homes for lack of personnel, with all the social repercussions which might result from this.

In the commercial sector also, we have a huge interest in ensuring that there is enough personnel to keep shops open, particularly food stores. However, traders also come into contact with a large number of people and we cannot start from the principle that everyone will take optimum precaution measures so as not to contaminate others.

Given the large number of travellers transported, bus drivers and tram drivers may also be contaminated and we have to ensure that public transport continues to operate.

It hence seems desirable to offer adequate protection to these different professional categories, particularly by making available the necessary respiratory masks and, where need be, antiviral prophylaxis, even if we readily admit that the dignity of an individual cannot be measured by the yardstick of their social usefulness.

In other sectors, the professionals are not exposed to a greater risk of contamination, but their presence in "the field" is however just as essential for the smooth running of society. We are thinking, *inter alia*, of firemen, policemen, people who work in the distribution of energy, all categories of professionals who occupy key positions.

4.b.2 Prioritisation for vaccination using the pandemic vaccine

If we are lucky enough to have the pandemic vaccine during the prepandemic period in Belgium, nothing enables us to confirm that there will be enough doses available to be able to vaccinate the entire population - to the contrary. If the pandemic vaccine is only available

during the pandemic phase, it is more than likely that it will be impossible to vaccinate all citizens.

Once again, it will have to be determined to whom the vaccine must be administered as a priority. The WHO[18] is already interested in the question and suggests prioritising healthcare workers and field workers from other basic (social) services, persons for whom it is deemed they represent an increased risk of spreading the virus, as well as people whose health is precarious or for whom an infection is likely to be fatal.

It is difficult to determine who has to be vaccinated as a priority. In fact, we have no vision of the risks of mortality related to certain groups of people. Will the virus be more dangerous for the elderly than for the young? Would persons suffering from pulmonary and/or cardiovascular diseases be more severely affected or not? It seems prudent to wait until we have additional epidemiological data before adopting the final prioritisation models.

For the time being, we can state a few general things on this matter, by repeating that there is no "correct" answer to this question. We can already state that people who have acquired natural resistance will, of course, be de-prioritised. If it becomes obvious that some groups of the population run a greater risk of infection and mortality, they will be prioritised provided that these are people with a certain quality of life. In the Minnesota Pandemic Ethics Project (see below), it is advised against taking account of the quality of life, mainly because the assessment of this criterion by the healthcare provider may be very subjective. It does nevertheless seem reasonable to offer the healthcare provider the possibility of taking this into account, to a certain extent and together with other criteria. Hence, the prioritisation of patients in palliative care seems hardly wise, just like that of persons of unsound mind, above all when their mental state is combined with psychic problems, as is often the case. Likewise, it seems hardly sensible to prioritise people suffering from immunity depression, since the vaccination does not guarantee better resistance in this case.

When establishing the prioritisation criteria, it is fitting to take account of at least two sometimes antagonistic ethical standpoints: the utilitarian and the egalitarian. Even if each individual has, ethically speaking, identical rights to protection, it is still nevertheless necessary to ensure that society can continue to function, as we have already explained. We are not talking here of maintaining economic profitability, which is no longer a priority in the case of a pandemic. We mean that in this case account has to be taken of the actual social functions of everyone, so that the healthcare providers and the persons involved in the manufacturing of the vaccine and its transportation can continue to work, but also so that the other basic needs are satisfied. The simple prioritisation of children, for example, due to the "fair innings" principle, only holds water if a sufficient number of adults also survive to get the wheels of society working at the social, commercial educational, cultural, scientific and medical level, etc. We will present below (4d) the Minnesota Project which, according to the members of the Advisory Committee, respond best to our ethical considerations.

[18] "Ethical considerations in developing a public health response to pandemic influenza", see: www.who.int/csr/resources/publications/WHO_CDS_EPR_GIP_2007.2

4.c. De-prioritisation

The problem of de-prioritisation is posed above all for certain hospitalised patients. It may be deemed necessary to de-prioritise some of these patients in favour of others, with regards the treatment or the putting on ventilators. This de-prioritisation should ideally be based on certain tools that help with decision-making, which offer reference points and weighting criteria to healthcare personnel when they have to make difficult collegial decisions. Indeed, it is important that the decision to deprive a patient of a ventilator in favour of another is taken collegiately, even if it remains the final responsibility of the doctor in charge of that department.

The members nevertheless think that we have to consider the ethical implications of de-prioritisation in secondary and tertiary healthcare. The steps to follow do however vary. The "fair innings argument" favours young patients, starting from the principle that they have more right to more years of life than those who have already lived for a certain amount of time.
The Swiss Advisory Committee on Bioethics advocates a "first come, first served" policy, at least in an initial phase. If it is no longer possible to treat everyone in a second phase, those who are the worst must continue to receive treatment. Finally, in a third phase, if it has become impossible to help all severely infected patients, priority has to be given to those who have the best chances of survival through treatment. This way of proceeding corresponds *grosso modo* to the approach usually used in the intensive care services and from the point of view of the Advisory Committee.

With regards the use of antiviral drugs for the treatment of symptomatic patients, de-prioritisation (or prioritisation) measures are not recommended.
If a shortage of antivirals occurs, some patients will eventually be "pushed aside" if other people are infected before them by the pandemic disease. The Committee supports the idea that all patients capable of being treated (less than 48 hours after the appearance of symptoms) can be treated. To this end, we have to ensure that we can always have sufficient amounts of antivirals available and that the stock is added to when needed (see above).

4.d. The "Minnesota Pandemic Ethics Project

The members of the Advisory Committee can rally to the "Minnesota Pandemic Ethics Project" [19] drawn up by the "Minnesota Center for Health Care Ethics" and the "University of Minnesota Center for Bioethics", in collaboration with the interested citizens and representatives of associative life.

The ethical framework proposed in the Minnesota Pandemic Ethics Project attempts to respond to three objectives: to protect the population's health, namely to reduce mortality and serious morbidity; to protect public safety and civil order; to treat people fairly, recognising the moral equity of all. The measures taken must seek to reduce disruption to the basic

[19] D.E. Vawter et al, "For the good of us all: ethically rationing health resources in Minnesota in a severe influenza pandemic", Preliminary Report for the Minnesota Pandemic Ethics Project, January 30, 2009, Minnesota Center for Health Care Ethics & University of Minnesota Center for bioethics + companion report: D.A. DeBruin, "Implementing ethical frameworks for rationing scarce health resources in Minnesota during severe influenza pandemic", January 30, 2009 (to be consulted via www.ahc.umn.edu/mnpanflu).

healthcare, public health, public safety and other critical infrastructures. The measures taken must hence try to reduce significant group differences in mortality and serious morbidity and, where possible, ensure everyone has decent access to the resources available. But they must also reciprocate to groups accepting high risk in the service of others.

As long as there is not a sufficient amount of vaccines to vaccinate the entire population, people who have overcome the disease and developed antibodies are not vaccinated. People allergic to the vaccine - to eggs for example, if the vaccine is cultured from eggs - are not vaccinated. Immunosuppressive people are not considered, neither are patients for whom there is every reason to presume that they will die shortly from another disease or for whom there are other satisfactory protection measures.

The priority criteria consist of varying combinations of the following characteristics: high risk of flu-related mortality and serious morbidity; good or acceptable response to resource; key role in performing basic health care, public health, public safety or other critical functions ("key workers"); risk of infection by professional exposure; risk of transmitting flu to groups presenting a high risk of flu-related mortality or morbidity; possibly age.

With regards the distribution of the scarce reserves of pandemic vaccines, the Minnesota Pandemic Ethics Projects proposes a two-track approach. The first makes recommendations with regards the distribution of the vaccine to "key workers", while the second suggests the approach to be used within the general public. The breakdown of the number of vaccines between these two "tracks" must be determined by epidemiological factors during the pandemic itself. In Minnesota, the size of the group of "key workers" is estimated at approximately 5% of the population.

If there is only a very limited number of vaccine doses available, only "key workers" presenting a disproportionate high risk (for example, members of staff working in an intensive care unit where influenza patients are treated) are vaccinated. In this phase, no vaccine is administered to persons in the general population.

If there is a slightly higher number of vaccine doses available, the doses available are distributed among the "key workers" with a high risk of exposure (for example, healthcare workers in direct contact with patients whom themselves present a high risk of morbidity and mortality). In the general population, the vaccine is distributed to persons with a very high risk of serious illness and death from whom one can expect they have good immunological response to the vaccine.

When there is an increased availability of doses, the irreplaceable "key workers" are vaccinated independently of their personal risk of death or complications. Other "key workers" treating persons with a high risk of complications are also vaccinated.
The vaccine is distributed to people from the general public who run a high risk of death or serious complications.

When even more doses are available, the entire batch of vaccines is assigned for the general public. This stage gives priority to two groups: people with a high risk of flu-related complications who have an *acceptable* immunological response (as opposed to "good") and, potentially (if age is accepted as an acceptable criterion), groups of children with a moderate risk.

Finally, and before the generalised vaccination, priority is given to adults who have a moderate risk of flu-related complications and an *acceptable* immunological response. If the age criterion is not accepted to define the ranking of priorities, all persons (regardless of their age) presenting both a moderate risk of flu-related complications and an immunological response to the vaccine that is presumed acceptable, fall into this sample.

The authors of the Minnesota Project feel that the best way of distributing scarce resources fairly consists of combining, on the one hand, a segmentation of the population according to a given hierarchy and, on the other hand, a random distribution process (lottery) within each sample. The hierarchy is determined on the basis of clinical and non-clinical considerations.
The clinical considerations are factors determined by the risk of serious flu-related complications, provided that a given person can be expected to react favourably to the resources implemented.
The non-clinical considerations include "reciprocity", a key role played in society, on the one hand, and age on the other.

"Reciprocity" means that some groups which, due to the exercising of their activities (professionally or as volunteers), accept running a big risk of infection, receive to a certain degree favourable treatment through the assignment of rare resources to protect them or treat them.

The idea of also according priority to persons who play an irreplaceable role in the fulfilment of functions presenting a vital need for society, can be defended insofar as the lives of many others may depend on the capacity of these "key workers" to continue to assume their functions.

Once the key groups and the categories of the general population to be prioritised for clinical reasons have been defined, inside these two groups, as long as there are enough vaccines available for everyone, it is possible to refine the selection by introducing new criteria such as, for example, age group. It may be decided to give equal opportunity per age group. In each age group (children, adolescents, young adults, mature adults, the elderly) we decide to vaccinate the same percentage of people. However, it is still possible that we will have to select once again inside these different groups. In the Minnesota Project, it is proposed to use chance in the selection and submit this to a lottery type procedure. One could rely on a system widely used in certain types of research where to have a sample that is representative of a population one selects from an alphabetical list e.g. every third person or one could create a basic random selection system.

If the arbitrariness of random selection may encounter reticence from an ethical stand point - the CNNE (the French National Advisory Committee on Ethics) explains them in its aforementioned opinion - it has not however been proven that another selection method is fairer or more equitable in a situation of precariousness. The members of the Committee are not opposed to this, on principle.

5. Intra- and international solidarity

As indicated in the "Bellagio Statement of Principles"[20] in July 2006, socially and economically disadvantaged groups and individuals are almost always the worst affected by epidemics.

In accord with the Bellagio Group, the members of the Committee feel that the solidarity measures required at each phase, prepandemic and pandemic, have to be taken in order to avoid a pandemic and, if this attempt fails, the chances of survival of everyone has to be increased.

With regards the prepandemic phase, it is already obvious that not all countries eliminate all the avian flu outbreak sites with the same zeal. Likewise, the infection outbreak sites are not reported with the same level of detail throughout the world. In the developing countries, citizens often think initially of their economic survival before considering the health risks they incur, both for their own life and for that of others. The elimination of a dozen potentially contaminated chickens in an African village condemns the owners to famine. In the richer countries, poultry breeders know that if they report an outbreak site, they will lose their entire breeding stock and some hence think twice before doing so. In some regions, where birds are part of the tourism offering, they are ready to conceal potentially infected birds in order to avoid a deterioration of the economic situation in the region!

To prevent a pandemic, it therefore seems not only desirable for all interested parties to understand the real danger of avian flu outbreak sites, but also for the State to cover the losses suffered by these interested parties. In the richer countries, it should also be ensured that the regions affected by these losses are protected against economic recession. In the developing countries, it is essential to protect both individuals and the local economy.

The means that can be considered to cover the said losses depend, of course, on the financial possibilities of the different States. These possibilities vary considerably throughout the world. International solidarity hence seems the only ethical answer. And this solidarity is even more desirable given that it could fight the appearance of a pandemic: it therefore also has a practical meaning.

During phase 4, when the inter-human transmission of the virus is ascertained, the entire world has an interest in that these human infectious outbreak sites do not spread beyond the borders of the country concerned. Not all countries, however, have the means required to fight an epidemic. Like Nederlandse Gezondheidsraad, we are inclined to propose that all patients and persons who have been in contact with them are treated in-the-field using antivirals. The problem of the difference in financial resources is also posed. The richer countries once again have everything to gain from contributing to an adequate treatment of the first people infected, wherever they are in the world.

Finally, if the pandemic becomes a reality, we have to ask ourselves if the principle of equality also applies outside our borders. Can we take the risk of seeing some groups of the population entirely decimated or even more disadvantaged from an economic standpoint? These questions are posed with even more acuity given that we know that in some countries

[20] www.hopkinsmedecine.org/bioethics/bellagio

or continents, indigenous population groups have hardly - even no - resistance against influenza and will perhaps be even more sensitive to the avian flu virus. Don't the principle of equality and the principle of precaution rightly designate these groups as being priorities for the administering of the vaccine, as long as they can be reached? In any case, the countries where such tribes still live must reflect on the means of protecting them from contamination and of treating them as effectively as possible if they are contaminated.

V. Conclusions and recommendations

In response to the questions asked by Mrs Onkelinx, Minister of Public Health, the members of the Committee feel that the population must before anything else know how to react in case of an epidemic and, above all, what measures it has to take, individually, to avoid an epidemic. The population must also be made aware that, in some cases, the resources available are not unlimited and that some people may be de(prioritised) within the framework of treatment or vaccination.

To be able to count on the adequate collaboration of the population staying in Belgium, it seems desirable to involve it at much as possible in the decision-making on matters of prioritisation and de-prioritisation. Here the Committee refers to the project established in Minnesota, which came to light due to the collaboration of groups of citizens and representatives of associative life. The Committee is favourable to the idea of establishing such collaboration in Belgium, taking account of the need to represent also the groups who live on the fringe of society, particularly people in the country illegally and the homeless.

It is desirable to prioritise healthcare workers, i.e. personnel who are professionally or voluntarily in contact with patients infected by influenza. However, these people must be able to rely on measures going beyond prioritisation. It seems appropriate to do what is necessary to protect their family against the risks of contamination they represent, likewise against the devastating consequences which their inability to work or - *a fortiori* - their death would entail.
Other keys workers also have to be prioritised since the maintenance of basic infrastructures is in the interest of society as a whole.

Further, the Committee thinks that, first of all, all possible resources must be deployed to avoid and/or restrict the spread of the disease. It supports the building up of sufficient stocks of surgical and respiratory masks to avoid contamination. From an ethical standpoint, it seems indeed unacceptable to spare on these expenses, since these resources will always be able to be used after the pandemic, if appropriate, and their generalised use may limit the spread of the disease, which will perhaps enable avoidance of all or part of the potential de-prioritisation of hospitalised patients.

The Committee considers that it is imperative to recall in this opinion that the early eduction of young generations in hygiene, in particular but not exclusively of hands, remains not only an effective and economic means of salubrity but, furthermore, a measure of essential civil education.

It also seems desirable to encourage all generalist doctors to administer the anti-pneumococcic vaccine to their patients, which may mean they avoid the more frequent complications of influenza.

Further, it is necessary to consider the legal provisions related to the placement in quarantine or in isolation of persons: these provisions are not always clear and are partly based on federal legislation and partly on the regulations of the Communities. It is recommended to develop the "Influenza framework law" sufficiently early so that haste in a situation of crisis can be avoided.

If a large part of the population is affected by the influenza pandemic, despite all these precautionary measures, the members of the Committee think that everything should be put in place to care for those sick at home and provide them with the necessary doses of antiviral drugs. And if it appears that the stocks built up are insufficient to treat all contaminated patients, the members think that the mandatory licence possibility has to be used in order to procure the cheapest ozeltamivir as quickly as possible. The members support the idea that the possibility is given to carers to decide themselves whether or not they wish to take antivirals prophylactically.

If hospitals are overcrowded or lack ventilators, the most severely affected patients will be prioritised. Priority will then be given to those who have the best chances of survival.

The Committee demands that the budget required is provided for buying the pandemic vaccination as soon as it is available, wherever it is in the world. If only small amounts of vaccination are available, the members propose - just as what has been defined in Minnesota - adopting a two-track policy: the healthcare providers and key workers who are probably not yet immunised and who should react well to the vaccination are prioritised. When it is certain that a sufficient amount of key workers are protected so that the fundamental needs of society can be satisfied, a proportional number of other key workers and ordinary citizens are vaccinated, depending on the risk of morbidity and mortality they present at that time. Within two groups, the selection can be made on the basis of a random selection principle, until the entire population can be vaccinated.

Finally, the Committee supports the idea that part of the budgets available have to be devoted to epidemiological research on the one hand and organisational research into healthcare on the other, on a wide scale.

It also seems pertinent to encourage research into general medicine, particularly in the domain of primary healthcare and the application of the measures of the operating plan decreed by the authorities in view of a pandemic or any other health crisis.

The opinion was prepared by select commission 2008-2 consisting of:

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- Mr M. Van Ranst, Extraordinary Professor, Head of the "Clinical and Epidemiological Virology" department of the KULeuven and Interministerial Influenza Delegate
- Mr Ph. Burette, lecturer at the University Department of General Medicine, Faculty of Medicine - University of Liège
- Mr D. de Beer, lecturer at the Faculty of Law at the Saint-Louis University Faculties in Brussels.

The working documents of select commission 2008-2 - question, personal contributions of the members, minutes of meetings, documents consulted - are stored as Annexes 2008-2 at the Committee's documentation centre, where they may be consulted and copied.

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