BELGIAN ADVISORY COMMITTEE ON Bioethics

Opinion no. 55 of 13 May 2013 on the treatment of patients with multidrug-resistant tuberculosis from a public health perspective

Content of the opinion

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I. Referral and scope of the opinion

In a letter of 7 November 2012, Mrs Laurette Onkelinx, Minister for Social Affairs and Public Health [*Ministre des Affaires sociales et de la Santé publique*], referred to the Belgian Advisory Committee on Bioethics [*Comité consultatif de Bioéthique*] a question concerning the "treatment of patients with open pulmonary tuberculosis. [...] Patients suffering from open pulmonary tuberculosis represent a major risk of contamination for the people with whom they are in contact. Given the increasing prevalence of these patients, I am considering taking, with the federated entities, specific action regarding the provision of care and the therapeutic approach for this group of patients and to combat the disease in general.

I hereby ask you to issue a detailed and reasoned opinion on the ethical and legal aspects of combating tuberculosis as it appears at present, in the light of the evolution of the epidemiology, the phenomenon of multidrug resistance and the precarious social situation of some of the patients concerned. In particular, I would ask the Committee to give its opinion on any measures aimed at restricting the freedom of the patient, and any compulsory treatment measures and procedures in the context of which it is possible to organise and facilitate a directly supervised treatment programme.

I am currently considering, in addition to the standard treatment involving hospitalisation, the possibility of supporting a specific facility offering medical, care and social supervision, provided by the hospitals which have particular expertise in treating this type of patient."

In its plenary session of 10 December 2012, the Committee decided to take this request into consideration and to assign it to a working committee (CR 2012-3).

The working committee focused its review on the following aspects of the request which was sent to it: the medical aspects (Part II), and in particular the phenomenon of multidrug resistance and the epidemiological information; the legal and regulatory context associated with the diagnosis and treatment of patients with multidrug-resistant tuberculosis (Part III); the economic, social and political aspects (Part IV), the ethical aspects (Part V), and, finally, the conclusions and recommendations (Part VI).

The screening and the general prevention of multidrug-resistant tuberculosis are complex issues which can only be alluded to in this opinion. These public health challenges merit in themselves significant developments which could, where appropriate, be the subject of another opinion.

II. Medical aspects

1. The different types of tuberculosis

Tuberculosis is a communicable infectious disease whose outcome is very often fatal. It is caused by various strains of mycobacteria, principally by *Mycobacterium tuberculosis* (Koch's bacillus[1] or KB).

Tuberculosis is generally a pulmonary infection, although in 15 to 20% of cases the infection can spread outside the lungs and affect other organs (visceral pleura, brain, lymphatic system (particularly the ganglions in the neck), and the genito-urinary system). In that case, it is referred to as *extra-pulmonary tuberculosis.* Patients whose immune system is weakened (immunosuppressed patients) and young children are very sensitive to the extra-pulmonary form of tuberculosis.

There is also an acute and widespread form of the disease which is called *miliary tuberculosis*. This form, which is contagious, is very serious and particularly feared as it can be both intra- and extra-pulmonary.

We should also point out that, in addition to active pulmonary tuberculosis, there is a "dormant" form of the bacillus in the infected person (this is referred to as latent tuberculosis). This explains why the disease can sometimes flare up several months or even years after the contamination took place.

2. Screening

Screening for tuberculosis by intradermal injection of tuberculin (Mantoux test) remains positive after the BCG (Bacillus Calmette-Guérin) vaccination. In the event of a positive tuberculin sensitivity test (in an individual who has not had a BCG vaccination), it is necessary to carry out lung x-rays on the patient for five consecutive years (front and side x-rays). In the event of a positive lung x-ray, it is necessary to isolate the germ (tubercle bacillus) via gastric intubation after the patient has fasted and to identify the acid-fast bacterium. If the result is positive, a therapeutic cocktail of drugs must be administered.

3. The therapeutic options

Tuberculosis can be treated with first-line drugs (isoniazid and rifampicin). Multidrug-resistant tuberculosis (MDR) is a form of tuberculosis which is resistant to isoniazid and rifampicin. But there is also an extensively drug-resistant tuberculosis (XDR) which is

[1] *Mycobacterium tuberculosis* was identified and described for the first time in 1882 by Robert Koch, which earned him the Nobel prize in 1905.

resistant not only to isoniazid and rifampicin but also to any fluoroquinolone and to at least one of the second-line injectable drugs (amikacin, kanamycin and capreomycin).
The drug-resistant strains of *Mycobacterium tuberculosis* are the result of spontaneous genetic mutations. The resistance is also caused by the inadequate use of tuberculostatic treatments such as monotherapy or the addition or a single drug into incorrect therapeutic regimens. The transmission of such resistant strains to another individual may result in that individual also developing a form tuberculosis which is resistant to treatment.

There is no effective vaccine. The BCG vaccine is an attenuated tubercle bacillus intended to stimulate human immunity. This vaccine does not offer sufficient protection and makes screening with tuberculin tests impossible. In South Africa, where the incidence of tuberculosis is very high, an equally high incidence of tuberculosis can be observed despite BCG vaccination, which demonstrates that the protection remains inadequate.

Studies are underway in order to develop new vaccines which will replace the BCG vaccine. New drugs to tackle the multidrug-resistant forms of tuberculosis seem to give better therapeutic results. Thus, bedaquiline appears to be a very promising drug in the fight against tuberculosis.

4. Contagion

In order to understand the public health challenge which tuberculosis represents, it must be remembered that a tuberculosis patient may be contagious for other people and that a contaminated person may or may not develop the disease immediately (patients with latent tuberculosis do not develop or transmit the disease). The Belgian *Fonds des Affections Respiratoires* [Respiratory Disease Foundation][2] considers that a person contaminated by the Koch bacillus has a 10% probability of moving to the disease stage during his lifetime (and very soon after infection for half of these people) whereas this risk increases to 10% per year for a person infected with the human immunodeficiency virus (HIV).
A person suffering from non-resistant active pulmonary tuberculosis will be contagious for a further 15 days or so after the start of his treatment.
People receiving treatment must regularly provide a sputum sample for culture. It is generally accepted that three negative cultures are a reasonable indication that the person being treated is no longer contagious.

Transmission takes place by all possible means of emission through the mouth or nose

[2] The FARES is an *association sans but lucratif* [non-profit organisation] (ASBL) which is dedicated to preventing smoking and to preventing and monitoring tuberculosis and chronic respiratory diseases. Visit the website: http://www.fares.be

(coughing, sneezing, spitting, singing, kissing, etc.). Upon each emission, the person emits droplets of around 0,5µ to 5,0µ in diameter which can transmit the disease. A sneezing fit, for instance, releases around 40,000 droplets. Inhalation of around ten bacteria is sufficient to transmit the disease. A carrier of active pulmonary tuberculosis who is not treated can infect between 10 and 15 people, or even more, per year. It should be noted that 22% of the risk of infection is caused by prolonged, frequent and close contact with the carrier of the infection. Transmission relies on a number of factors, such as the number of times the carrier splutters, the duration of the exposure, the virulence of the *Mycobacterium tuberculosis,* the immune status of the receiver, and even the efficiency of the ventilation in the place where the person lives. Therefore, everyone can contract tuberculosis. Children, old people, people with other diseases and people living in a confined environment or in a precarious socioeconomic situation are groups who are particularly vulnerable to contamination.

It emerges from these various factors that the medical knowledge needs to be further strengthened and developed in several areas: making the technology available to refine still further the diagnosis between the different forms of tuberculosis, more detailed information on the link between multidrug-resistant tuberculosis (MDR) and other diseases such as AIDS, the intervention of more powerful antibiotics, and so on.

5. The epidemiological information

5.1. The global situation

According to the World Health Organisation (WHO), "[i]n 2011, 1.4 million people died due to TB, with the greatest per capita death rate in Africa. Multidrug-resistant TB (MDR-TB) presents a major threat, with an estimated 630,000 people ill worldwide with this form of TB today"[3].

According to the WHO's Global Tuberculosis Report 2012[4], "(t)he Millennium Development Goal (MDG) target to halt and reverse the TB epidemic by 2015 has already been achieved. New cases of TB have been falling for several years and fell at a rate of 2.2% between 2010 and 2011. The TB mortality rate has decreased 41% since 1990 and the world is on track to achieve the global target of a 50% reduction by 2015. Mortality and incidence rates are also

[3] http://www.who.int/mediacentre/news/releases/2013/tuberculosis_threat_20130318/fr/index.html l consulted on 20 March 2013.

[4] This Report brings together the data reported by Member States during the annual data-gathering rounds. In 2012, a total of 182 Member States and 204 countries and territories, accounting collectively for more than 99% of the cases of tuberculosis worldwide, sent data to the WHO. The Report is available at: http://www.who.int/tb/publications/global_report/fr

falling in all of WHO's six regions and in most of the 22 high-burden countries that account for over 80% of the world's TB cases. (...) However, the global burden of TB remains enormous. (...) Global progress also conceals regional variations: the African and European regions are not on track to halve 1990 levels of mortality by 2015".
Tuberculosis also affects children. In its Report, the WHO estimates that there were 0.5 million cases and 64,000 deaths in children in 2011.

The WHO's Global Tuberculosis Report 2012 emphasises that "[p]rogress in responding to multidrug-resistant TB (MDR-TB) remains slow. While the number of cases of MDR-TB notified in the 27 high MDR-TB burden countries is increasing and reached almost 60 000 worldwide in 2011, this is only one in five (19%) of the notified TB patients estimated to have MDR-TB. In the two countries with the largest number of cases, India and China, the figure is less than one in ten; scale-up is expected in these countries in the next three years. (...) Worldwide, 3.7% of new cases and 20% of previously treated cases were estimated to have MDR-TB. India, China, the Russian Federation and South Africa have almost 60% of the world's cases of MDR-TB. The highest proportions of TB patients with MDR-TB are in eastern Europe and central Asia".

Combined treatment for tuberculosis and HIV

The WHO advocates a combined approach to tackling tuberculosis and HIV. In its Global Tuberculosis Report 2012, the WHO indicates that in "2011, there were an estimated 8.7 million new cases of TB (13% co-infected with HIV) and 1.4 million people died from TB, including almost one million deaths among HIV-negative individuals and 430,000 among people who were HIV-positive. TB is one of the top killers of women, with 300,000 deaths among HIV-negative women and 200,000 deaths among HIV-positive women in 2011. (...) Almost 80% of TB cases among people living with HIV reside in Africa."

According to the Global Tuberculosis Report 2012, "[g]lobally, 40% of TB patients had a documented HIV test result and 79% of those living with HIV were provided with co-trimoxazole preventive therapy in 2011. Interventions to detect TB promptly and to prevent TB among people living with HIV, that are usually the responsibility of HIV programmes and general primary health-care services, include regular screening for TB and isoniazid preventive therapy (IPT) for those without active TB. The number of people in HIV care who were screened for TB increased 39% (2.3 million to 3.2 million) between 2010 and 2011".

5.2. The situation in Belgium[5]

In Belgium, cases of active tuberculosis have to be declared to specific bodies: the FARES (*Fonds des Affections Respiratoires*), the VRGT (*Vlaamse Vereniging voor Gezondheidszorg en Tuberculosebestrijding*), and the health inspectorates of the French and Flemish Communities and of the Common Community Commission [*Commission Communautaire Commune*] of the Brussels Region. At the end of each year, the declarations from these different sources are pooled to validate the epidemiological results obtained in the three Regions. They are also necessary in order for Belgium to be able to participate in the European Tuberculosis Surveillance Network, managed jointly by the ECDC (European Centre for Disease Prevention and Control) and the WHO (World Health Organisation).
The Belgian Tuberculosis Register [*Registre belge de la tuberculose*] 2011 produced by the FARES[6] presents the results of this pooling of the epidemiological data and also mentions the results of the treatment of the cohort of tuberculosis patients recorded in 2010.

According to this Report, 1,044 cases of tuberculosis were declared in Belgium in 2011, which corresponds to an incidence of 9.5 per 100,000 inhabitants, in other words an incidence under the threshold of 10 cases/100,000, as was the case from 2007 to 2009.
According to the FARES Report, the incidence in Brussels (31.4/100,000) was higher than in Flanders (6.6/100,000) and in Wallonia (7.8/100,000). With the exception of the capital, tuberculosis has been decreasing in Belgium since 1994.
The incidence of tuberculosis in large towns of more than 100,000 inhabitants was four times higher than in the small entities because the at-risk populations are concentrated in these large entities. In 2011, the towns with the highest incidence were Brussels, Liège, Antwerp and Charleroi. During the previous 10 years, there had not been any significant variations in the incidence in the various towns apart from in Brussels and Liège.

The FARES Report notes that 67.5% of the patients in the Register had no history of tuberculosis and could be regarded as new cases of tuberculosis, whereas 5.7% of the recorded cases did have a history of tuberculosis. In more than a quarter of cases (26.8%), the history was unknown. This proportion was particularly significant in 2011.
More than a third (38.3%) of the tuberculosis cases listed in 2011 were aged between 25 and 44. The average ages varies by region (Brussels: 31; Flanders: 38; Walloon: 40) and by nationality (non-Belgian: 32; Belgian: 46).

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[5] The figures presented in this Opinion under this point 5.2., "The situation in Belgium", come from the Belgian Tuberculosis Register 2011 (FARES *asbl*, March 2013).
[6] Each year, the FARES makes a Belgian Tuberculosis Register available to the public (http://www.fares.be). The 2011 Report is available at: http://www.fares.be/documents/Regtbc2011.pdf.

According to the FARES Report, children aged under 5 ran a greater risk of developing tuberculosis when they were contaminated. They represented 4.6% of the total number of cases declared (in other words 48 cases) and 56.5% of the 0-14 year-olds. The incidence in this group was higher among the non-Belgians (30.8/100,000) compared with the Belgian natives of the same age (5.0/100,000). Among the non-Belgians, the age bracket in which tuberculosis was most present was the 15-29 year-olds whereas among the Belgians the age bracket was higher (in 2011, the over-75s were more affected by the disease than the 0-14 year-olds).
In 2011, 52.1% of the cases in the Register were of foreign nationality (54.6% in 2010). This proportion was markedly higher in the Brussels Region (63.3%) compared with the figure in Wallonia (47.8%) and in Flanders (45.6%). The Moroccan nationality was the most represented (16.4%) among the foreigners listed in the Register.
The incidence among the Belgians was 5.1/100,000 in 2011. It was almost 10 times higher among individuals of foreign nationality (48.6/100,000) but if the asylum-seekers and illegal immigrants were excluded the difference was less marked (29.5/100,000). The FARES Report concluded that, among non-Belgians, the incidence had fallen significantly in Belgium and in Flanders and Brussels but not in Wallonia where it had remained stable. Excluding the asylum-seekers does not alter these trends.

In 2011, according to the FARES Report, the percentage of men with tuberculosis was higher (64.1%) than for women, whatever the region and nationality.

In 2011, the location of the tuberculosis was mainly pulmonary (71.6%). Cases where the extrathoracic ganglia were affected was the second most frequent form of the disease (9.5%). Among the serious forms of tuberculosis, 15 cases of meningitis were listed (including 2 in children aged under 5 years) and 31 cases of miliary tuberculosis. Of the 747 patients with pulmonary tuberculosis, 45.2% were positive based on a direct analysis of their sputum (which indicates increased contagiousness) and 78.6% based on culture. For the majority of the patients whose culture was positive (95.2%), the first-line treatment (isoniazid and rifampicin) was sufficient. Resistance to at least one first-line drug was 7.6%. The FARES Report stresses that resistance, of whatever type, was generally higher among foreigners and among patients who had a history of tuberculosis.

In 2011, according to the FARES Report, a fifth (20.5%) of the cases in the Register had the status of asylum-seeker or illegal immigrant. This proportion was higher in Wallonia where the number of reception centres has been increased (27.1%) compared with the Brussels Region (21.1%) and Flanders (15.6%). Individuals in precarious situations represented 38.9% of all the cases declared in 2011 in the Wallonia-Brussels Federation. The proportion of prisoners among the cases declared nationally (3.1%) was very close to the figure for the

homeless (2.7%). People who had had recent contact (within the previous 2 years) with contagious tuberculosis patients represented 11.8% of the cases declared in Belgium in 2011. Finally, the Report points out that 4.2% of the cases in the Register were HIV-positive. This proportion was higher in the Brussels Region (5.7%) compared with the figure in Flanders (3.6%) and in Wallonia (3.3%).

The FARES Report provides the results of the treatment of the 2010 cohort. The proportion in which there was a favourable outcome from the treatment one year after starting the treatment among patients with pulmonary tuberculosis confirmed by culture was 75% in Belgium but varied in the three Regions: 81.3% in Flanders, 71.7% in Wallonia and 71.2% in the Brussels Region. These figures are nowhere near the standard of 85% advocated by the WHO. Among the explanations for this difference in results, the Report highlights a very significant proportion at national level of people who abandoned treatment (13.5%) but which soars in the Brussels Region (21.6%) where the patients treated are usually lost to follow-up or more frequently return to their country of origin. This percentage is 10.5% in Wallonia and 8.5% in Flanders.
The proportion of cured patients in identical among the Belgians (75.6%) and the non-Belgians (74.3%).

A. Screening

Tuberculosis is a notifiable infectious disease. All GPs and laboratory doctors are obliged to notify the regional authorities of any suspected disease within 24 hours. If it is a contagious case, an investigation will be set up by the staff at the FARES and the VRGT and/or the regional health inspectors, during which all the contacts of the sick person will be examined for the purpose of detecting any contagion. In the event of recent contagion, a preventive therapy programme will be implemented.

A.1. Active screening among at-risk groups[7]

In Belgium, systematic screening is applied to the at-risk groups which are: detainees (upon entry, after 3 months and annually thereafter); the homeless (on an annual basis wherever possible); asylum-seekers and new arrivals (at the time of seeking asylum, after 6 months and after 12 months; in Wallonia, also after 18 and 24 months, insofar as this is feasible), intravenous drug-users[8]; individuals who, in their professional lives, are prone to coming into contact with at-risk persons.

[7] The information appearing in this section is available at: http://www.vrgt.be/tuberculose/informatie_voor_professionelen/risicogroepen.
[8] Individuals receiving methodone substitution treatment in a recognised centre are screened. If it is the GP who prescribes their substitution treatment, there is, at present, no check on the presence of tuberculosis.

A.2. Passive screening (spontaneous consultation)

The medical services and the doctors who work with at-risk groups refer people whose symptoms suggest tuberculosis to lung specialists for a more detailed examination. In each province there are health centres run by the VRGT and the FARES which offer free consultations and which perform tests and screening.

A.3. Screening in the context of occupational health

Where a contagious case is discovered in a business, the company doctor carries out an investigation within the business to assess the risks of contamination. Based on this risk analysis, the decision may be taken to screen the employees (or the medical staff) every 6 months or on an annual basis[9].

B. Information on the hospitalisation of patients with multidrug-resistant tuberculosis in Belgium

During the period 2008-2011[10], 69 patients with multidrug-resistant tuberculosis were screened: 57 of them were hospitalised a total of 85 times, for a total duration of 1,181 weeks of hospitalisation. The total hospitalisation period varied from 13 to 21 weeks and the duration of a hospitalisation period ranged from 12 to 14 weeks. These 57 patients were hospitalised in 14 hospitals, but the CHU [University Hospital] Saint-Pierre in Brussels had a total of 64.7% of the hospitalisation periods and 66% of the weeks of hospitalisation. Among these 57 patients, 12 had extensively drug-resistant tuberculosis (XDR) and had an average hospitalisation period of 43 weeks. Given the worsening resistance profiles in Belgium, the hospitalisation period became longer during the period 2005-1011.
A quarter of the hospitalisations lasted for more than 21 weeks and 10% of the hospitalisations lasted for more than 33 weeks. The longest hospitalisation lasted for 76 weeks.

An example of hospital treatment of tuberculosis patients

The CHU Saint-Pierre[11] in Brussels is a reference centre for tuberculosis treatment. The majority of the tuberculosis patients who are admitted there come from Eastern European

[9] The Royal Decree of 22 January 2013 extended the recognition of tuberculosis as an industrial disease to some new occupations. The police, airports and sea ports, asylum reception centres for illegal immigrants and the homeless, and social workers now enjoy the same recognition as staff working in the health care and scientific research sectors.
[10] The figures in this paragraph come from a letter sent to the Committee by the *SPF Santé publique, Sécurité de la Chaîne alimentaire et Environnement* [Federal Public Service of Public Health, Food Chain Safety and Environment] to which Hilde Jansens, Michèle Gerard, Renaat Peleman, Willy Peetermans and Steven Callens contributed.
[11] The Committee would like to thank Dr. Yves Van Laethem from the CHU Saint-Pierre for the information provided on the treatment of tuberculosis patients in his hospital.

countries (particularly the carriers of XDR tuberculosis), and to a lesser extent from North Africa. These patients are mostly men who have left their wives and children in their country of origin. A very small proportion of these patients come to Belgium with the sole aim of receiving treatment, since their drug resistance cannot be treated in their own country.
The isolation of the patients takes place in negative pressure rooms, in other words rooms which have an airlock between two doors in which the air from the room is sucked out, thus preventing it from spreading to the outside. These rooms contain various conveniences (bathroom, toilet, telephone, television, etc.). The CHU St-Pierre has 30 negative pressure rooms[12] grouped on one floor, of which around half are intended for tuberculosis patients and the other half for patients with other contagious diseases. The hospital admits 6 to 10 tuberculosis patients per year. The medical staff who are in contact with the patients protect themselves by wearing a mask. Patients who have to undergo medical examinations which require them to leave their negative pressure room also move about with their mouth and nose covered with a mask.
In the near future, the hospital is planning to construct a special on-site unit in which the entire space will be at negative pressure. This will allow tuberculosis patients who have gone past the acute crisis stage of their disease to leave their room (with or without a mask depending on the risk of contagion they pose) and to come into contact with other patients in their unit. In addition to medical and psychological monitoring where necessary, the patient will benefit from measures aimed at his future social integration (language and IT courses, etc.).

The problems encountered most frequently by the staff treating tuberculosis patients at the CHU Saint-Pierre are: the language barrier; difficulties in making the patient accept the forced isolation (it can happen – rarely, however – that some patients leave the hospital or walk around the corridors without permission); verbal and even physical violence from patients who refuse isolation; problems with making the patients understand that they must follow their treatment programme scrupulously and often for several months. This treatment may take place by intravenous injection or through drug-taking which is supervised by a member of the medical staff.

III. Legal and regulatory context[13]

1. Introduction

The central legal issue is clearly raised in the WHO guidelines on human rights and the

[12] In general, hospitals have only 2 or 3 rooms of this type and some have none at all.
[13] The Committe is very grateful to Mr Lieven Dejager, coordinator of the Committee's scientific secretariat, for gathering all the legal information appearing in this Part III.

involuntary treatment of extensively drug-resistant tuberculosis[14]:

" Public health is sometimes invoked to limit the exercise of human rights. Therefore, interference with freedom of movement when instituting quarantine or isolation for a communicable disease such as MDR-TB and XDR-TB may be necessary for the public good, and could be considered legitimate under international human rights law. A key factor in determining if the necessary protections exist when rights are restricted is that each one of the five criteria of the Siracusa Principles[15] (6) must be met:

- the restriction is provided for and carried out in accordance with the law;
- the restriction is in the interest of a legitimate objective of general interest;
- the restriction is strictly necessary in a democratic society to achieve the objective;
- there are no less intrusive and restrictive means available to reach the same objective;
- the restriction is based on scientific evidence and not drafted or imposed arbitrarily i.e. in an unreasonable or otherwise discriminatory manner.

Even where the restrictions are authorised to protect public health, they should be of a limited duration and subject to review and appeal."

The WHO considers that, where voluntary measures are not effective, the authorities responsible for public health must be able to apply the rules, and that constraint must always be considered the last resort.

More specifically, the WHO claims that "communicable diseases legislation and TB regulations can limit the right to freedom of movement (in case of isolation or quarantine[16] of an infectious person), can limit the right to autonomy and self-determination (in case of compulsory testing, screening, examination and treatment) and can limit the right to privacy (in case of compulsory contact tracing or patient retrieval)".[17]

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[14] http://www.who.int/tb/features_archive/involuntary_treatment/fr/index.html (consulted on 4 February 2013).

[15] Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights. E/CN.4/1985/4, annex. *25 Questions and Answers on Health and Human Rights*, Geneva, World Health Organisation, 2002 (Health and Human Rights Series No. 1, July 2002, p. 20), available online at the following address: http://www.who.int/hhr/activities/Q&AfinalversionFrench.pdf (consulted on 4 February 2013).
The Council of Europe mentions in relation to people with mental health disorders the need to ensure that the isolation is always in proportion to the risks posed. See on this subject the *Recommendation Rec(2004)10 of the Committee of Ministers to member States concerning the protection of the human rights and dignity of persons with mental disorder*, and the *Recommendation CM/Rec(2009)3 of the Committee of Ministers to member states on monitoring the protection of human rights and dignity of persons with mental disorder*.
(http://www.echr.coe.int/ECHR/FR/Header/Case-Law/decisions+and+judgments/HUDOC+database, consulted on 17 May 2013).

[16] On the issue of quarantine, see Bloem D., Nazarian M. and Grigorieff G. V., "*La quarantaine médicale humaine, réflexions juridiques, éthiques et sanitaires sur une pandémie* [Human medical quarantine, legal, ethical and health considerations as regards a pandemic]", in *Médecine et droit, Questions d'actualité en droit médical et en bioéthique*, 2007, Louvain-la neuve, Anthemis.

[17] World Health Organisation (WHO). *Good practice in legislation and regulations for TB control: an indicator of political will (WHO, 2001)*, p. 15.
http://whqlibdoc.who.int/hq/2001/WHO_CDS_TB_2001.290.pdf (consulted on 4 February 2013).

In this context, there is increasing talk of " health public order".[18]

2. Rules of international law[19]

- Article 5 of the European Convention on Human Rights and Fundamental Liberties (ECHR) states:

"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 states:

"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 wellbeing 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 WHO International Health Regulations (IHR) 2005 constitute an international legal instrument which is legally binding for 194 countries, and in particular for the Member States of the WHO. Its aim is to help the international community to prevent the acute public health risks which may spread beyond borders and constitute a worldwide threat by taking the necessary action. The current IHR[20], which entered into force on 15 June 2007, states that countries must notify the WHO of certain disease outbreaks and certain public health events. Countries are also obliged to bolster their current monitoring and action capabilities in favour of public health.

- Directive 2004/38/CE of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States provides for the possibility of limiting the right of entry

[18] See Genicot G., *Droit médical et biomédical*, Brussels, Larcier, collection of the Faculty of Law at the University of Liège, 2010, p. 142-144 and the literature quoted therein.
[19] The rules of international and national law are partly the same as those cited in Opinion no. 48 of 30 March 2009 on the Belgian operational plan for an "influenza pandemic" (see www.health.belgium.be/bioeth, left-hand column under "Opinions").
[20] To be consulted at www.who.int/csr/ihr/fr; the original International Health Regulations were signed in Geneva on 25 May (Moniteur Belge of 11 October 1952).

and of residency for reasons of public order, public safety or *public health* (our italics)[21].

3. Belgian federal legislation and regulations: this point hasn't been translated

4. Législation et réglementation des Communautés: this point hasn't been translated

5. Some examples of problems encountered on the ground

Having consulted several experts on the ground, it appears that the exercise of constraint is not necessary in the majority of situations. In certain cases, it is necessary to insist that the individuals begin a course of therapy in order to prevent any transmission of a potentially fatal infectious disease such as multidrug-resistant tuberculosis. Constraint is necessary in some exceptional cases *which are, nevertheless, observed each year*.

To the question "Do you consider that you have sufficient legal instruments to be able to combat tuberculosis effectively?", most of these managers give a negative response:

- either the so-called legislative framework is not suitable:

Thus, work is currently in progress, within the Wallonia-Brussels Federation, on a decree intended to replace the Royal Decree of 1 March 2971 which is still in force.

- or there are problems in terms of implementation.

In cases where treatment and isolation may be obligatory, providing, of course, that a number of peripheral conditions are met (Flemish Decree of 21 November 2003 and Order of the Brussels-Capital Region of 19 July 2007), this obligation often appears "unenforceable" in practice:

- Sometimes, the police are unfamiliar with the legal basis of such an intervention, and without police intervention there is no binding force in practice.
- By law, a patient with multidrug-resistant tuberculosis may not, in principle, be admitted to a prison infirmary because the person in question has not committed any act punishable by imprisonment.
- A non-custodial hospital is not equipped to constrain on site the patients who are to be treated. This is possible only with police surveillance, yet some police forces do not wish to carry out this type of task, sometimes for legal reasons (cf. the first point above) and sometimes for practical reasons.

[21] In the annex to Council Directive 64/221/CEE of 25 February 1964 on the co-ordination of special measures concerning the movement and residence of foreign nationals which are justified on grounds of public policy, public security or public health, repealed by Directive 2004/38/CE, tuberculosis of the respiratory system which is active or liable to progress was mentioned as a disease which could endanger public health. This annex no longer appears in Directive 2004/38/CE.

- A psychiatric hospital sometimes has a secure department, but this, naturally, is not organised, equipped or suitable for the treatment of tuberculosis.

In practice, therefore, the obligation is often theoretical and impossible to implement.

However, some examples were also cited, highlighting the rapid intervention of the burgomaster, the medical inspector of the *Service de l'Inspection de la santé de la Commission communautaire de la Santé de Bruxelles-Capitale* [Health Inspectorate of the Community Health Commission of the Brussels-Capital Region] and the police.
Better information, communication and collaboration between the aforementioned players seems a necessity, therefore, in addition to creating an adequate legal framework.

IV. The social, economic and political dimensions of the forced isolation and treatment of a patient with multidrug-resistant tuberculosis

1. Two examples

The Andrew Speaker case

In 2007, the "Andrew Speaker" case was widely reported in the American press because it epitomised all the difficulties encountered by the national and international health authorities in isolating a person with multidrug-resistant tuberculosis. This case is also exemplary because it portrays a patient who did not have any particular socioeconomic problems and because it highlights the importance of the patient's individual responsibility.

In January 2007[22], Andrew Speaker underwent some medical examinations which revealed an anomaly in his lungs. However, his sputum analysis was negative for tuberculosis. In March 2007, a bronchoscopy indicated that he was positive for tuberculosis. He was then prescribed the standard regimen of first-line drugs for this disease. Some sensitivity tests were carried out to identify the specific type of disease in question. Speaker notified the Fulton County TB Clinic of his intention to travel outside the United States in May. The results of the sensitivity tests indicated that Speaker was suffering from multidrug-resistant tuberculosis (MDR). The Fulton County Health Department (FCHD) discussed this illness with Speaker, his family and his personal doctor and urged Speaker not to undertake his

[22] For a detailed account of the "Andrew Speaker" case, we refer to the article by David P. Fidler, Lawrence O. Gostin and Howard Markel: "Through the quarantine looking glass: drug-resistant tuberculosis and public health governance, law, and ethics", *Journal of Law, Medicine & Ethics*, winter 2007, vol.35:4, p. 616-628.

international trip. The FCHD made inquiries regarding the legal options for preventing travel by a patient infected with untreated MDR.

However, without the knowledge of the various players in the public health field, Speaker brought forward his departure from Atlanta to Europe. The US Customs and Border Protection issued a national alert against Speaker. In the meantime, another result of a test carried out on Speaker by the US Centers for Disease Control and Prevention (CDC) revealed that he was suffering not from MDR but rather from extensively drug-resistant tuberculosis (XDR). There then began a race pursued by the American health authorities to locate Speaker in Europe. They managed to make contact with him in Italy and issued him with a ban on travelling on a commercial airline because his illness constituted a serious threat to the other people. The CDC investigated the possibility of treating this infection and of repatriating Speaker to the United States. But Speaker continued to travel and flew to Prague and then from there to Montreal.

The CDC requested that Speaker should not be permitted to enter the United States, made contact with the Italian health ministry and informed the World Health Organisation that the Speaker situation constituted a public health emergency of international concern, with reference to the International Health Regulations of 2005. At the end of May 2007, Speaker left Canada by car and crossed the border into the United States. The CDC managed to locate him in New York through his mobile telephone. He was then ordered to go Bellevue Hospital in New York. A federal isolation mandate and then a federal provisional quarantine notice were issued against him. No such federal quarantine order had been used since 1963. On 31 May, Speaker was transported at his own expense to the National Jewish Medical Center in Denver. In the meantime, the CDC began to look for the passengers with whom Speaker had come into contact during his various flights, which required international cooperation. In mid-July, some of the passengers who had made the trip from Prague to Montreal in Speaker's company filed a complaint.

Speaker had an operation at the end of July. After the removal of part of the infected lung, he was declared non-contagious and free to move as he pleased.

It was from 28 May that the media seized on the Speaker story. Firstly, because Speaker's account of the events differed from that of the CDC, and, secondly, because, on 3 July, some subsequent tests carried out on Speaker revealed that he did not in fact have XDR but rather MDR. These factors fuelled a debate about what had actually happened, about the impact of an MDR or an XDR diagnosis on the measures to be taken to protect public health, on the responsibilities of the various players, and, in general, on the way in which the situation was handled nationally and internationally.

The case of a Georgian man suffering from multidrug-resistant tuberculosis and in an illegal situation in Belgium

From time to time, the press takes up the sometimes tumultuous journeys of foreign tuberculosis patients in Belgium. Thus, in 2002, a Georgian man who arrived in Belgium illegally hit the headlines because he had been released when he was at risk of transmitting the tuberculosis from which he was suffering.

The man was in a centre for asylum-seekers in Bruges. A medical examination revealed that he had a multidrug-resistant form of tuberculosis. He was then placed in isolation in the secure centre and was given the appropriate antibiotics. A few days after the diagnosis was made, the *Office des étrangers* [Immigrant Office] issued him with an order to leave the territory within five days as he was in an illegal situation. *"In practice, this means taking him to the railway station. There is no check to verify whether he actually leaves the country. The man would be a contagious bomb travelling around our cities without any medication or supervision"*[23].

The centre for asylum-seekers was concerned about this injunction and the man was hospitalised. However, the Georgian man announced his desire to leave the hospital. The doctors tried in vain to persuade him of the need to follow his treatment programme and not to leave the hospital. With sufficient drugs for only one month of treatment, the man nevertheless decided to leave the hospital. There was no news of him. Was he continuing to take his drugs scrupulously? Had he stopped his treatment?

The difficulties raised by these two cases are expressed in the form of conflicting injunctions: the person has to be expelled *and* he has to be kept in the territory in order to isolate him and treat him; the person has to be treated *and* he himself has to be persuaded of the need to take care of himself and in particular to continue his treatment over the long-term; the isolation of a patient who has become non-contagious has to be ended and he has to be given back his freedom of movement, *and* he has to undergo regular medical checks and therefore have his freedom of movement limited. These conflicting requirements demonstrate different interests: those specific to protecting public health and those that fall within the private sphere of the individual. We will return to this opposition and the means to overcome it.

[23] Quoted in *La Libre Belgique* (http://www.lalibre.be/actu/belgique/article/74869/un-georgien-tuberculeux-erre-peut-etre-en-belgique.html) consulted on 22 March 2013.

2. Isolation and quarantine: definitions and objectives

The transmission of the infectious agent may take place during the incubation period of the disease or during its manifestation but may also re-emerge if the treatment is followed incorrectly or is interrupted. This last point implies that, in addition to isolation, monitoring the patient during his treatment is necessary to ensure his complete recovery.

The transmission of MDR is boosted by confined environments – public transport of a certain duration (plane, ship, train, bus, etc.) – and by the presence of groups of people who come into contact frequently for social, economic, professional (hospital, etc.) or legal (prison, etc.) reasons.

Although in everyday language the terms "isolation" and "quarantine" are used synonymously, they do have different meanings[24]. Isolation means segregating people who have a contagious disease. Quarantine means segregating (formerly for 40 days) people who may have been exposed to a contagious disease with the aim of determining whether they are ill and, where necessary, to prevent transmission of the disease during the incubation period. The *Dictionnaire médical* [Medical Dictionary], meanwhile, defines quarantine as a period of isolation "imposed on people from areas or countries in which certain contagious diseases are prevalent"[25].

Today, the diagnosis of tuberculosis has become more refined, which implies that, for the most part, isolation of a person is used rather than quarantine.

Isolation and quarantine are the consequences of the exercising of an authority's power to detain individuals, possibly against their will, for public health reasons. The objective is to counter the spread of the contagious disease and to limit its impact on the health of the population. These measures constitute the best means of public health protection where therapeutic actions are no longer effective, do not exist, or are not available.

For a long time, the management of communicable diseases has taken place in particular through measures involving the isolation of individuals or of groups, as recorded in various historical sources (the Old Testament, Hippocrates, Galen, the decrees of Emperor Justinian, etc.). The relationship between travel and the spread of certain diseases is also well known. Thus, it is no coincidence that, in the 14th century, the city of Venice implemented a regulation preventing, if necessary and for 40 days, a ship's crew, passengers and goods

[24] See, for example, the distinction made by the *Dictionnaire médical* (under the coordination of J. Quevauvilliers and A. Fingerhut, Paris, Ed. Masson, 3rd edition, 2001) and by the Centers for Disease Control and Prevention (USA) at http://www.cdc.gov/quarantine/.
[25] Quevauvilliers J. and Fingerhut A. (eds.), *Dictionnaire médical*, Paris, Ed. Masson, 3rd edition, 2001, p.827, article "Quarantine".

from disembarking in the city. This was the "quarantenara", or quarantine. In 1403, the municipality of Venice made the island of Santa Maria di Nazareth the first lazaret (*lazzaretto* is a corruption of *Nazareto*), a place where contagious patients were placed in quarantine.

At the end of the 19th century and particularly during the first half of the 20th century, the sanatorium (*sanatorius*: *curative*) was the ideal way to treat tuberculosis patients and, above all, to prevent them from contaminating those around them. Usually situated in the mountains or by the sea, the mission of the sanatorium was to offer a cure for tuberculosis patients involving fresh air and sunshine. Isolated and subject to strict hygiene, these patients were able to rest away from the polluted air of the cities.

In the 19th century, the nations of Europe sought to harmonise their quarantine implementation policy for plague or cholera patients. This initiative was the result of taking various parameters into account.

One of these parameters was the progress of medical knowledge. In the 19th century, the germ theory argued by Pasteur explained contagious diseases by contamination due to an external micro-organism. It was therefore necessary to protect oneself by avoiding contact with the patient. In general, the isolation decision depended on the available knowledge about the disease – its causes, its prevention, its therapies, its cure – and the perception by the community of the disease and the infected patient.

Another parameter was the consideration given to economic and commercial interests. In the 19th century, the European countries which had colonies were anxious to maintain the free movement of people and goods. The fact that germ theory was being called into question by some scientists, in favour of managing the contagious disease by cleaning up the environment rather than by isolating people, provided an argument for those who were concerned about guaranteeing the movement of individuals solely for commercial and economic interests.

These two parameters – medical and economic – are still valid when taking a quarantine decision, but today they are tempered by taking other considerations into account: the precarious social and economic situation of the individual or of a group, the risk of stigmatisation or discrimination, the shortcomings to be overcome in relation to health policy or housing policy, for instance.

3. The socioeconomic aspects

3.1. The precarious socioeconomic situation of the patients

Multidrug-resistant tuberculosis is often linked to appalling sanitary conditions or substandard housing. Finding a solution in terms of health policy and housing policy is a fundamental aspect of the strategy to combat the appearance and the transmission of MDR[26].

Economic insecurity prompts some people to wait for a critical deterioration in their state of health before consulting a doctor. In Belgium, treatment for tuberculosis is free due to the fact that the costs are covered by the mutual health insurance system. Patients who are not able to receive mutual health insurance can approach the CPAS [*Centres Publics d'Action Sociale* – public social services centres] for direct or urgent medical assistance. As for people who are unable to call on either mutual health insurance or the CPAS, they have been able to have their costs met by BELTA-TBnet[27] since 2005.

3.2. The financial investment necessitated by public health protection measures

The deprivation of liberty represented by placing an MDR patient in isolation or in quarantine must be balanced with the economic costs of this treatment. Protection of public health justifies making sufficient funds available to cover the costs related to the isolation and care of the patient and to the protection of the medical staff. Other financial costs are to be envisaged if the health authorities wish to screen people infected with MDR or those who have been in contact with a patient, or undertake public information campaigns.

Faced with a patient who does not follow his treatment programme correctly and who risks developing the disease again, and therefore endangering others, there are several possible solutions, each of which has a specific cost: either isolate him by force, or set up an arrangement to monitor him at home or offer him a financial incentive to follow the medical instructions.

From a strictly economic point of view, a quantified assessment of these various options is necessary in order to come to a decision, and, in principle, none of them should be rejected.

From the ethical point of view, protecting public health is incalculable in absolute terms. But the idea of, as it were, "buying" a patient's responsibility towards his treatment through a

[26] See, for example, on this subject Lebas J. and Chauvin P. (eds.), *Précarité et santé* [Insecurity and health], Paris, Flammarion, 1998.
[27] Further information is available at the following address: http://www.belta.be/.

financial incentive does provoke an ethical consideration.

In fields other than health, a fine can be imposed on a person who does not assume his responsibilities, and a person, group or business can be financially encouraged to act responsibly. It could, therefore, be assumed that a financial incentive to follow a treatment programme fits into this approach: just as support is provided, through financial incentives, for behaviours which do not pollute the environment, for example, financial support could be offered for the responsible attitude of a patient towards the health of others. In different ways, pollution and MDR endanger the health, or even the life, of a potentially significant number of people. One difference may, however, be important from the ethical point of view: MDR is transmitted by the actual body of the patient, by the substances (cough, sputum) which issue from it, and this directly involves his responsibility and his personal physical freedom as regards the spread of the disease. Simple contact with the patient's infected substances or constantly frequenting the place where he lives can be sufficient for the transmission of MDR. By his very presence, the patient can be a source of contamination, and this engages his ethical duty to follow a treatment programme or to isolate himself in order to protect the health of others. Not harming, and therefore adhering fully to the curative treatment programme, is an imperative whose ethically restrictive force should mean that it is possible to manage without a financial incentive.

But an ethical constraint may not be respected, this possibility being moreover inherent in the *ethical* nature of this type of constraint. It is, therefore, a question of analysing the reasons that motivate the patient not to be aware of the obligation of not harming or not to want to meet the requirement of this imperative. There may be many causes, including ignorance, socioeconomic insecurity, fear or psychological problems, etc. Seeking the causes rather than failing to deal with the roots of the problem through financial incentives seems to be the most beneficial attitude for both patient and society. Not following the treatment programme can be interpreted as one of the possible manifestations of difficult social integration.

4. Stigmatisation and discrimination

As D.F. Musto[28] points out on the subject of placing AIDS patients in quarantine, an epidemic affecting the underprivileged social classes or individuals on the margin of society is often "the grain of sand from which the pearl of moralism forms".
During the MDR epidemic in the 1990s, some sections of the population of New York – people with mental health disorders, or drug-users or the homeless – were required to follow

[28] Musto D.F., "Quarantine and the problem of AIDS", *Milbank Quarterly* 64, 1996, Supplement 1, p.106.

a supervised treatment programme (a person checked that the patient was actually taking his drugs), while other financially well-off groups avoided this measure[29].

To avoid any discrimination or stigmatisation, specific information on a person's state of health is essential. A medical diagnosis must confirm that the person is actually infected with MDR, or would be liable to be infected with MDR again if the treatment was interrupted, or has been exposed to MDR. The diagnosis of a proven or possible MDR infection suggests that the person's state of health constitutes a danger to public health and that he must therefore be isolated.

Thus, the social status of a person or his insecure or non-standard lifestyle may suggest that he will probably be more prone to MDR than another person, but this insecure or non-standard social status is not a sufficient reason to override the rights of this person.

5. The national and international dimensions of public health

Effective management of the issue of the spread of MDR requires the implementation of regulations at various political and legal levels (regional, national, European and global). These regulations cover the apprehending, isolation or quarantine and release of a person or of a group of people who are carriers of MDR and also the treatment of the disease. One of the aspects of the complexity of managing this issue is determining which status of a communicable infectious disease, depending on its origin and its level of threat to public health, requires the activation of which type of regulation, and for how long. The response to this question must also be periodically adapted to the new medical knowledge regarding diagnosis and treatment of the communicable disease.

The national and international regulations must, naturally, be aimed at ensuring that the disease does not spread, by prohibiting the contagious person from entering or leaving a territory, and must also provide for treatment for this disease in the place where it has been located, the sovereignty of each State being absolute on this point. The international coordination essential for managing the spread of the disease requires infrastructures and a budget.

MDR can be contracted by people of an average social, economic and educational level, as demonstrated in the Andrew Speaker case mentioned above, but for the most part it is present in poor populations, who have other diseases (AIDS, in particular) and who have little or no access to a public health system in their country of origin. International cooperation as regards transfer of knowledge and technologies and setting up efficient care structures

[29] Dubler N.N., Bayer R., Landeshan *et alii, The tuberculosis revival: individual rights and societal obligations in a time of AIDS*, New York, United Hospital Fund, 1992.

and effective health policies is a central aspect of managing MDR.

V. The ethical dimensions of the forced isolation and treatment of a patient with multidrug-resistant tuberculosis

From a medical point of view, the isolation of a person with multidrug-resistant tuberculosis may last from 3 to 6 months and the duration may reach 9 months for cases of extensively drug-resistant tuberculosis (XDR).

As mentioned in Opinion no. 48[30] of the Belgian Advisory Committee on Bioethics, Article 10(2) of the Law of 22 August 2002 on patients' rights states – based on Article 8(2) of the European Convention on Human Rights – that no interference is authorised in the exercise of the patient's right to respect for private and family life "unless it is provided for by law *and is necessary for the protection of public health* or for the protection of the rights and freedoms of others". (Our italics).

The competent authority may, for the sake of public health, impose various types of obligation on a person suffering from MDR: an obligation to put an end to a risky behaviour, or to undergo a medical examination, or to be isolated or placed in quarantine. One of the tasks of the public authorities is to manage the tension between protecting public health and respecting the rights of the individual (his physical freedom, his decision-making autonomy, his dignity, etc.).

1. Restriction of freedom

The person's freedom of movement[31] (and the other types of freedoms that depend on it) is suspended during isolation or quarantine. The imposition of this significant restriction on individual freedom must be assessed and justified. If the isolation is necessary as the sole means of preventing the spread of the disease and of protecting the health of the population, other means which do not require this deprivation of freedom can be called on to monitor the patient's treatment once he has become non-contagious. Thus, the patient can take his drugs in the presence of a member of the medical staff and the patient can be

[30] Opinion no. 48 of 30 March 2009 on the Belgian operational plan for an "influenza pandemic", in Devroey P., Dupuis M., Schotsmans P., Stiennon J.-A., *Les avis du Comité consultatif de bioéthique de Belgique* [The opinions of the Belgian Advisory Committee on Bioethics] *2005-2009* Brussels, Bernard Gilson editor, 2010, p.524.

[31] The work *Dwang en drang in de tuberculosebestrijding* published by the Gezondheidsraad néerlandais ("Commissie ethische en juridische aspecten van TBC-bestrijding", Den Haag, Gezondheidsraad 1996/07) offers a particularly clear analysis of the restriction of freedom linked to isolation and to the treatment of tuberculosis.

required visit the doctor periodically for his treatment to be monitored, while also enjoying his freedom of movement. This monitoring of the patient during his treatment is necessary to ensure his complete recovery and to prevent the resurgence of the disease and its threat to public health. Thus, in the *City of New York versus Antoinette R*[32] case, the Supreme Court of the State of New York justified isolation only after evidence that the patient's observance of his treatment programme could not be secured by any less restrictive measures.

The length of the isolation should not exceed the incubation and transmission period of the disease, which may last from a few weeks to a few months.
Deprivation of the freedom of movement and of direct contact, justified on account of protecting public health, must have the least possible effect on person's ability to exercise his other rights and freedoms. Thus, the place of isolation or of quarantine must be healthy and safe. In addition to the treatment specific to MDR, the person is entitled, if necessary, to other medical care, to a proper diet and to accommodation which enables him to live freely, apart from having to comply with the constraints imposed for the sake of public health and from the functioning of the host institution.

2. Consent

Faced with a serious threat to public health, the authorities may legally and ethically isolate an MDR patient or place him in quarantine. The patient may not have perceived the gravity of his state of health and the danger he poses to others. Once in possession of this information[33], he may clearly consent to the constraint imposed but he may also, for a variety of reasons (incomprehension, various fears, etc.) refuse to comply. The medically proven nature of the threat which his state of health represents to public health justifies, from an ethical point of view, him being isolated by force and, therefore, without him having given his consent in advance. The situation is ethically more complicated as far as the treatment is concerned.

The issue of an MDR patient consenting to treatment does not arise in the same way as for certain patients who have a mental illness. The forced treatment of the latter is required for the purpose of re-establishing the autonomy of the person as far as possible. Unlike a

[32] 630 N.Y.S.2d 1008 (N.Y. Sup. Ct.1995).
[33] The law of 22 August 2002 on patients' rights states in its Article 8(2) the content of the information to be given in general to the patient, and provides for the case of refusal of consent: "The information provided to the patient, in order that he can express his consent, as referred to in point 1, concerns the objective, the nature, the degree of urgency, the duration, the frequency, the contraindications, side effects and risks inherent in the intervention and relevant to the patient, the after-care, the possible alternatives and the financial consequences. It also concerns the possible consequences in the event of refusal or withdrawal of consent, and the other information deemed desirable by the patient or by the professional practitioner, where necessary including the legal provisions which must be observed concerning an intervention."

patient with a mental illness, a patient with MDR is, in principle, regarded as a capable and conscious person. His refusal to follow a treatment programme must be respected, under, inter alia, the Law of 22 August 2002 on patients' rights. Under Article 8(1) of this law "the patient is entitled to consent freely to any intervention by the professional practitioner provided that he has received information in advance", and, under point 4 of this same Article, "the patient is entitled to refuse or to withdraw his consent, referred to in point 1, for an intervention".

Consequently, if an MDR patient who does not have any psychiatric problems rendering him incapable of giving his consent refuses a treatment, the health authorities can hold him in isolation to avoid the spread of the disease but cannot force him to receive treatment. From an ethical point of view, as in the analysis offered in point 3.2, "The financial investment necessitated by public health protection measures", it is regrettable that the patient does not follow the treatment for his disease and that this attitude deprives him of his freedom of movement. But, above all, it is necessary to clarify the *reasons* for this refusal. Although this clarification of the refusal of treatment is not required in general, since refusal falls with the patient's exercise of autonomy, it may be useful in the case of MDR[34]. Faced with refusal of treatment, the health authorities have no option other than to require him to be held in isolation to avoid contamination. This isolation has a financial, logistical and human cost since some people in the host institution will have to remain in contact with the patient.

More fundamentally from an ethical point of view, and given the socioeconomic context in which this type of disease tends to develop, clarifying the refusal of treatment will make it possible, where appropriate, to identify any difficulties (psychological, social, economic, etc.) outside the purely medical field and outside the source of the person's appalling state of health.

MDR is one of the diseases which require global and multidisciplinary treatment of the patient. This treatment, which is aimed at the social integration of the person, is the counterpart of the initial social isolation action taken by the health authorities for the sake of protecting public health. The radical nature of the initial isolation action is offset by the social recognition implied by the second action. The privilege accorded justifiably to the collective well-being in the initial action is balanced by the attention paid to the individual and to his rights in the second. Thus, the ethical tension between protecting public health and individual rights becomes a protective and respectful link on both sides.

[34] See, on this point and in this sense, Opinion of the Committe no. 53 of 14 May 2012 on the refusal of medical care by a pregnant woman which has an impact on the fœtus.
Note that, while considering the possibility of refusal of treatment on the part of the patient, the law on patients' rights also calls for the patient's co-operation. This means that it is desirable to seek this co-operation by trying to understand the grounds for the refusal.

3. Privacy and confidentiality

In this opinion, we are considering solely the isolation and treatment consequences of detecting and preventing MDR rather than the family, social and professional consequences. Withdrawal from social life, particularly where it is involuntary and where it has been achieved by force, reveals the person's state of health and subjects the existence of that person and his family members to general view. The confidentiality which marks the doctor-patient bond is destroyed. Faced with a communicable infectious disease which endangers public health, the doctor is obliged to break the contract of confidentiality which ordinarily binds him to his patient. As a reminder, the Law of 22 August 2002 on patients' rights states in its Article 10(2) that no interference is authorised in the exercise of the patient's right to respect for privacy "unless it is provided for by law and is necessary for the protection of public health or for the protection of the rights and freedoms of others".

In the case of interception of passengers who have MDR or who have been in contact with a patient, the transport companies[35] may be required by the national or international health authorities to provide information on their passengers. They may also be required to collect, keep safe and transmit under certain conditions information relating to the health of the passengers, particularly those with MDR. Finally, they may receive instructions to prevent the departure from or the arrival in a territory of a passenger with MDR. These various possible actions by the transport companies must be carefully evaluated from an ethical point of view. It is a question of preventing passengers from being required to disclose personal information regarding their state of health to transport companies but also of preventing a situation in which information which has significant impact on the health of others fails to reach the health authorities. It is not within the objectives of this opinion to consider in more detail this ethical balance between the privacy of passengers, the protection of public health and the activities of businesses.
Isolation may promote a discriminatory attitude towards the patient and sever his social and professional ties or accentuate his marginalisation. Providing information to his family members and, where appropriate, to his employer (to prevent a loss of salary or a dismissal) is essential to avoid these damaging consequences.

[35] A situation in which an MDR patient is in a confined space for a certain period of time (such as travelling by air or lengthy train or bus journeys, etc.) promotes contamination.

VI. Conclusions and recommendations

1. In Belgium, multidrug-resistant (MDR) tuberculosis and extensively drug-resistant (XDR) tuberculosis are currently diseases which are, for the most part, present in towns where there are concentrations of populations who are socioeconomically insecure, and which arise partly from immigration.

   The Committee considers that the socioeconomic causes of MDR must be tackled. Particular attention should be paid to healthy living conditions and social and educational assistance, and to providing information to tuberculosis patients regarding the options available for meeting the financial costs generated by their hospitalisation and their treatment.

2. Tuberculosis affects all age brackets, including young children.

   The Committee draws attention to the need for global treatment of children and minors who are isolated on account of their contagion potential. The host structure must, wherever possible, provide psychological, educational and social support for these children who are separated from their families for a time.

3. *The Committee considers that the isolation of a contagious tuberculosis patient must be justified from the medical point of view. This isolation must take place in accordance with the Belgian and international legal and regulatory frameworks. It must, therefore, be reasonable, reviewable according to changes in the patient's state of health and non-discriminatory. The use of restraint, although it may be justified to prevent the spread of the disease, must always be considered a last resort. Since isolation is a deprivation of freedom with serious consequences, the patient must have recourse to legal remedy. But, in view of the danger of contamination and the need to protect public health, this remedy cannot be suspensive and cannot prevent the isolation of the patient.*

4. The total duration of isolation in a hospital for contagious people varies from 13 to 21 weeks but may reach 40 weeks for people with XDR.

   This isolation period requires a financial investment in the host infrastructures and in the commitment of the medical staff.

   The creation within the hospital of an infrastructure dedicated to the treatment of

tuberculosis patients[36] is a solution which has several advantages. The tuberculosis patients are not geographically separated from the rest of the population in general and from the other patients in particular, which prevents them from being stigmatised. This unit, designed in a negative pressure atmosphere and occupying one floor of the hospital, allows the patients to have contact with each other, which is important for these individuals who are often foreigners, alone or socially excluded.

The Committee considers that establishing such an infrastructure must be encouraged and that it should also be carried out in at least two other Belgian hospitals, one in Flanders and one in Wallonia, in addition to CHU Saint-Pierre in Brussels.

5. The FARES Report mentions a very significant proportion of individuals who abandon treatment in Belgium, and particularly in the Brussels region, which favours the appearance of multidrug-resistant forms of tuberculosis and accentuates the risk of contagion.

   Although obligatory treatment is mentioned in certain regulatory texts (see Part III of this opinion), it raises some ethical issues with regard to patients' rights, in particular the issues of being autonomous and of being able to refuse treatment.

   The Committee considers that all means must be implemented to convince the patient of the need to follow his treatment, both for himself and in order to protect others. It accepts that it may be necessary for a member of the medical staff to be present when the patient takes his drugs. But it considers it unjustifiable from the ethical point of view for a patient to be compelled to follow his treatment by force or by intimidation.

   By contrast, the Committee considers that the isolation of a patient who is contagious or who risks becoming so, who does not follow his treatment or does so inadequately, is a justifiable solution from the ethical point of view. Admittedly, isolation is an imposed constraint which undermines the person's freedom of movement, but it is therefore the only possible way to prevent the contamination of others.

6. The regulatory context of tuberculosis is complex in Belgium. According to those involved on the ground (see Part III.5., "Some examples of difficulties encountered in the field"), it seems that it is not always sufficient and that it causes implementation problems, particularly as far as forced isolation is concerned.

   The Committee recommends better information provision, as regards the regulatory

[36] See on this subject Part II, under point 5.2., B *"An example of hospital treatment of tuberculosis patients".*

context, for those involved on the ground and the promotion of more frequent communication between these organisations.

The Committee highlights the need to coordinate efforts to combat tuberculosis at the regional, national and international levels. This pooling of disease-control resources must be accompanied by cooperation with disadvantaged countries as regards transferring knowledge and providing assistance in setting up efficient medical infrastructures for the treatment of tuberculosis patients.

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The opinion was prepared in the Select Committee 2012/3, consisting of:

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A. Velz	M.-G. Pinsart	A. Herchuelz	
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Mrs M. Wanlin, medical director of the FARES
Mr Y. Van Laethem, doctor at the *Service des maladies infectieuses* [Department for Infectious Diseases] at the *Centre Hospitalier Universitaire* [University Hospital] Saint-Pierre in Brussels

The working documents of the Select Committee 2012/3 – request for opinion, personal contributions of the members, minutes of the meetings, documents consulted – are stored as Annexes 2012/3 at the Committee's documentation centre, where there may be consulted and copied.

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This opinion is available at www.health.belgium.be/bioeth, under the "Opinions" section.