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### **Assessing the risk of shortage or an actual shortage in the supply of blood or blood components as a result of an influenza A (H1N1) pandemic**

15 December 2009

#### **1. INTRODUCTION AND ISSUE**

On 25 November 2009, the Superior Health Council (SHC) received a letter from the Cabinet of the Minister of Social Affairs and Public Health, which was followed by a note from the Federal Agency for Medicines and Health Products on 30 November 2009. The latter concerned the criteria and methodology to use in assessing the risk of a shortage of blood donations caused by an influenza A(H1N1) pandemic.

The European Commission Directive 2009/135/EC of 3 November 2009 allows temporary derogations to certain eligibility criteria for whole blood and blood component donors in case of a risk of shortage directly caused by the influenza A(H1N1) pandemic. These temporary derogations concern, on the one hand, reducing the minimum haemoglobin levels in donors from 125 grams per litre of blood to 120 grams per litre of blood in women and from 135 grams per litre of blood to 130 grams per litre of blood in men. On the other, the deferral period of no less than 2 weeks after the disappearance of symptoms in donors with an influenza-like illness is replaced by a one-week deferral period (SANCO, 2009).

The Royal Decree of 6 December 2009, which transposes this European Directive into Belgian law, states that "*l'avis du Conseil Supérieur [de la Santé] précise notamment l'ampleur du risque de pénurie, ou de la pénurie réelle de sang ou de composants sanguins* (i.e. "the advisory report of the Superior Health Council clarifies, in particular, the extent to which there is a risk of shortage or an actual shortage of blood or blood components") and the SHC "*décrit également les critères et la méthodologie utilisés pour évaluer cette nécessité*" (i.e. "also describes the criteria and the methodology used to assess this need"). This Decree stipulates that "*Le Roi fixe la date [...] dès qu'il constate, après avis du Conseil Supérieur de la Santé, que les quantités de sang et de composants sanguins disponibles atteignent de nouveau un niveau suffisant*" (i.e. "the King sets the date (...) as soon as He notes that the blood and blood component supplies reach sufficient levels again and after having received the advice of the Superior Health Council"). This last point is not dealt with in this advisory report because of its lesser urgency.

In spite of the intensive campaigns for the recruiting and retaining of blood donors, the blood establishments frequently face supply difficulties (Custer et al., 2004; Boulton, 2008; Eder et al., 2009). Reduced donor availability or increased hospital demand can have a very significant impact on the blood supply. Yet there is little agreement about what constitutes a shortage.

The postponing of non urgent surgical interventions or transfusions and the transfusing of Rh D positive red cell concentrates to Rh D negative recipients are signs that indicate that there are supply difficulties or even shortages. An American inquiry (Klein & Anstee, 2005) has revealed that 12.6 % of the investigated hospitals (138 out of 1,086) have postponed elective surgical interventions for at least one day and that 18.9 % of them have had to postpone blood transfusions. Another study has revealed the existence of seasonal fluctuations in the blood demand (Nightingale et al., 2003). After year-long attempts to reduce the use of blood components by drawing up recommendations for more targeted indications for transfusion, the ageing of the population will predictably result in an increased need for blood in the coming years, with even more frequent shortages as a corollary (SHC, 2009b).

In addition to this, there is the conundrum posed by the need to combine safety and availability. Indeed, the criteria concerning the temporary exclusion of donors are constantly on the increase and play an ever more significant role in blood component supplies. In Custer (2004), a one-year study carried out in a regional blood transfusion centre, the medical selection resulted in over 14 % of potential donors being deferred for a short or lengthy period of time. Low haemoglobin levels were the most common reason for donor deferral as regards women in all age groups (generally speaking, 53 – 67 % of the deferrals for first-time donations and up to 75 – 80 % for later donations).

The blood component supply is a crucial element in our healthcare system. The impact of a pandemic on transfusion needs is difficult to assess and unpredictable (WHO-BRN, 2007; EBA, 2009). Therefore, the SHC had recommended that an emergency plan be implemented in order to prepare for this possibility. This plan aimed at optimally co-ordinating the hospitals' demand for blood components with their delivery by the blood establishments (SHC, 2007, 2008). Meanwhile, the SHC has continued to draw up advisory reports on recruiting donors and ensuring the safety of blood components (e.g. SHC, 2008, 2009, 2009b).

This advisory report assesses the risk of shortage or the actual shortage in the supply of blood and blood components as a result of an influenza A(H1N1) pandemic. It is based on the preliminary findings concerning the very recent evolution of the A(H1N1) influenza pandemic and the opinion of the experts.

## 2. ADVICE

The SHC recommends that a risk of serious shortage or an actual shortage directly caused by the influenza A(H1N1) pandemic should be notified as soon as one of the following situations occurs:

- the incidence of influenza-like illnesses reaches 200 per 100,000 population per week, with 30 % of the samples testing positive for the A(H1N1) virus (*risk of shortage*);
- the supply level drops to the critical threshold of 5,000 red cell concentrates of all blood groups (*real shortage*);
- the supply level drops to the critical threshold of 2,500 group O red cell concentrates (*real shortage*).

Preliminary observations: these threshold values have been calculated by taking into account an **immediate** implementation of the derogations provided in the Royal Decree. If these derogations require some time to implement, a warning procedure needs to be set up on the basis of the decline in blood establishment supplies and/or the increased demand from the healthcare establishments.

The SHC takes the view that the derogations provided should be implemented in a co-ordinated fashion. Similarly, there will also need to be several accompanying measures taken concerning donor recruitment as well as the use of blood by healthcare establishments, in order to provide the blood establishments and blood transfusion centres with assistance in their difficult task of managing the supplies during such a major crisis situation.

Taking into account the urgency of this request for advice and the uncertain evolution of the A(H1N1) pandemic, the recommendations and conclusions must be adapted according to the evolution of the situation.

Because the supply of blood components is a **critical** factor in our healthcare system, the SHC advises that all means of communication between the surveillance centres and all actors in blood transfusion should be enhanced and optimised (IPH, blood establishments, FAMHP, healthcare establishments, SHC).

Many of these recommendations also apply when there is either a risk of shortage or an actual shortage as a result of an epidemic or a pandemic caused by another highly contagious disease.

### 3. FURTHER DETAILS AND ARGUMENTATION

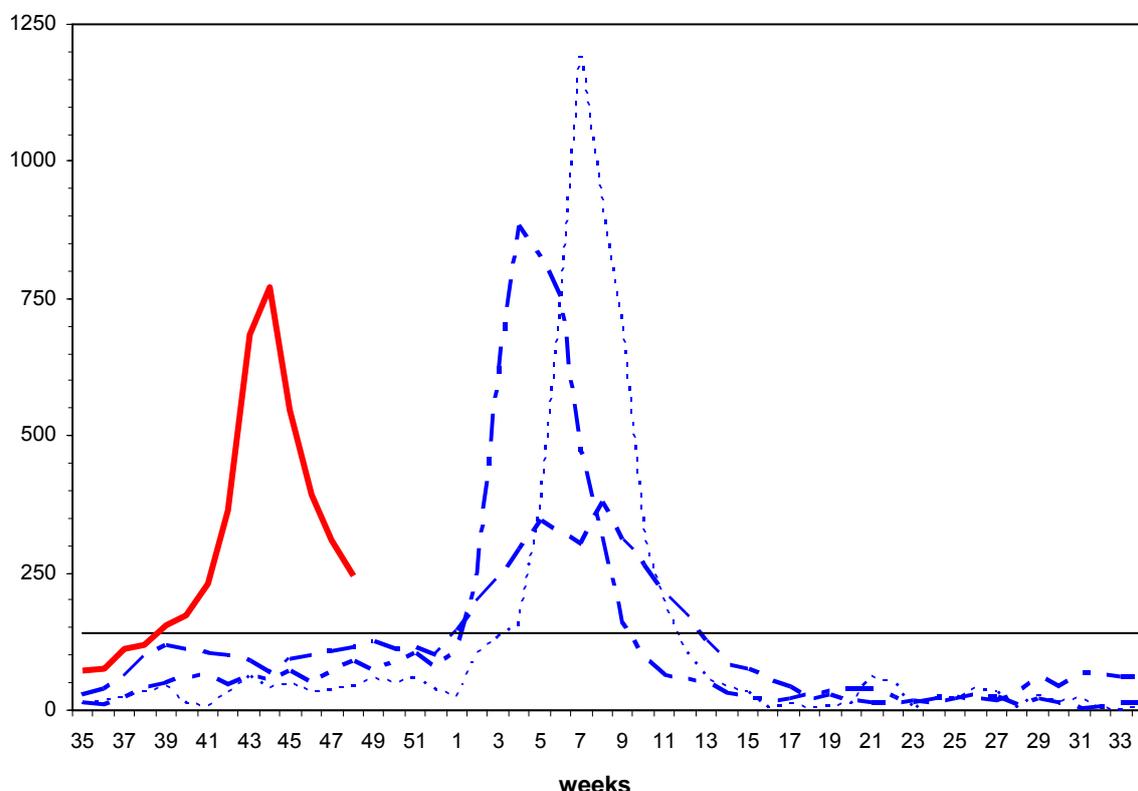
#### 3.1. Methodology

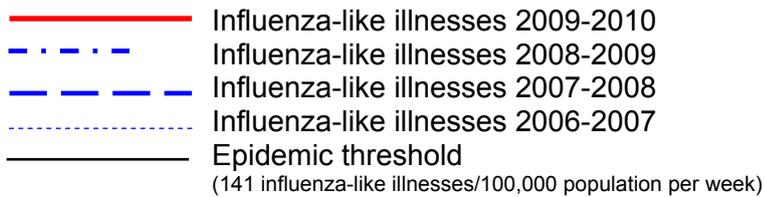
This advisory report is based on the assessment of the data concerning both the management of the red cell concentrate supplies and of epidemiological findings during the recent Influenza A(H1N1) pandemic in Belgium in the autumn of 2009, as well as on the opinion of the experts.

#### 3.2. State of affairs regarding the influenza A(H1N1) pandemic in Belgium in the autumn of 2009

In Belgium, the epidemic threshold for influenza was reached in early October (week 40). The incidence of the influenza-like illnesses increased until late October (week 44) and then became less intense between week 45 and late November (Fig. 1).

**Fig 1.** Evolution of the incidence of influenza-like illnesses (IPH, 2009).





The virus that is currently circulating is the A(H1N1) 2009 virus. In early December, nearly 36 % (23/64) of the samples still tested positive for the influenza A virus (Table 1 and Fig. 2). This result suggests that it cannot be ruled out that the circulation of the influenza virus among the population will rise again.

**Table 1.** Virological surveillance of the tested samples (IPH, 2009).

Week	w40	w41	w42	w43	w44	w45	w46	w47	w48	w49
Number of samples	194	276	367	485	259	194	147	148	104	64
A/H1 new variant	42	86	152	265	148	112	62	54	34	21
A/others	12	19	33	72	41	22	13	6	4	2
B	0	0	0	0	0	0	0	0	0	0
% A/H1v positive	21,6	31,2	41,4	54,6	57,1	57,7	42,2	36,5	32,7	32,8
% Influenza positive	27,8	38,0	50,4	69,5	73,0	69,1	51,0	40,5	36,5	35,9

The three criteria for an epidemic (IPH, 2009) are still valid:

- 1) the number of consultations > the epidemic threshold of 141 consultations per 100,000 population;
- 2) > 20 % of the samples taken by the sentinel doctors in case of influenza-like illnesses seem to test positive for the influenza virus;
- 3) in the neighbouring countries, there is at least a moderate influenza activity.

**Fig 2.** Evolution of the virological surveillance (IPH, 2009).

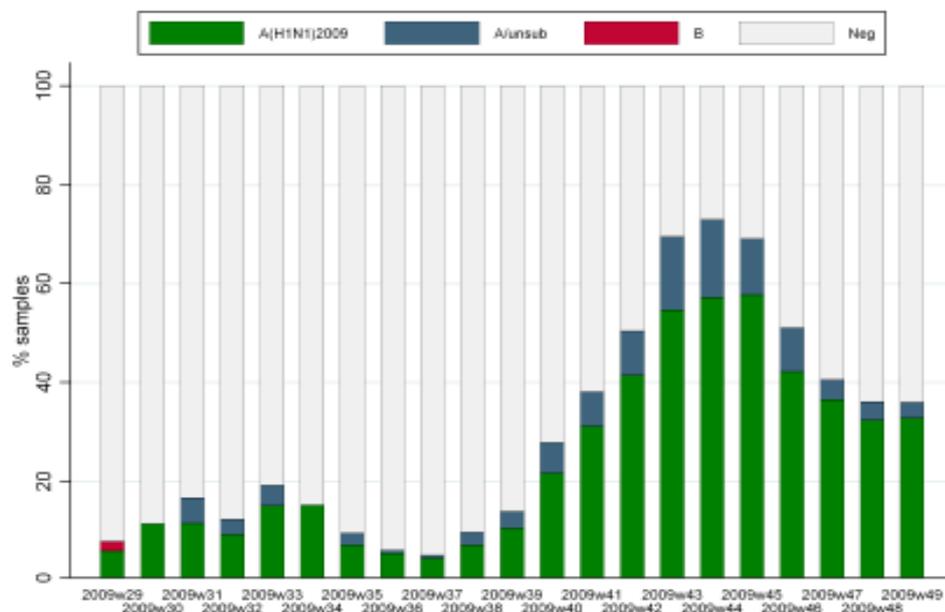


Figure 6: Virology: Evolution of the percentage of virus types among GP's samples

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### 3.3. Impact on the blood component demand

In countries like Belgium, where a great deal of attention is paid to good transfusion practices and a judicious use of blood components (SHC, 2010), each restriction on the use of these components during an influenza pandemic will require a special effort from all those concerned (cf. SHC, 2007). Consequently, there could not really be predicted to be any decline in the demand in Belgium, contrary to what was assumed by several prevention plans for influenza pandemics (e.g. EBA, 2009), except if elective surgical interventions were postponed.

The influence of seasonal influenza epidemics on blood demand is insignificant (Zou, 2006; Kamp et al., 2010). In sharp contrast, the new serious clinical forms, which are a direct consequence of the pathogenicity of the A(H1N1) virus against the respiratory system, require intensive treatment, which in turn leads to a potential increase in the use of blood components (WHO, 2009). Reviewing the cases recently reported to the World Health Organisation (WHO, 2009) has shown that this concerns a new type of influenza that involves lengthy stays in an intensive care unit. Some 15 % of all hospitalised influenza patients are said to be admitted into intensive care units (WHO, 2009b).

### 3.4. Criteria and methodology for analysing the extent of the risk of shortage or the actual shortage of blood and blood components

Assessing the blood component requirements in the Belgian blood establishments is exclusively grounded on the red cell concentrate supply. This approach is based on the following two facts: a) frozen plasma can be kept for a long time at low temperature (COE, 2008; SHC, 2010); b) there can be a great deal of variation in the supply of blood platelets, which are kept at room temperature for less than a week (SHC, 2008).

Under normal circumstances, optimal supplies in blood establishments suffice to provide hospitals with red cell concentrates for about one week. It should be pointed out that both the overall supply and the supply of group O red cell concentrates are important. This can be accounted for by the fact that group O patients can only receive red blood cells of the same blood group, whereas group O red blood cells can be administered to all patients. This possibly helps to explain why it is more difficult to keep a sufficient supply of group O blood.

The blood supply reaches critical levels when either the total red cell concentrate supply or the group O red cell concentrate supply available in blood establishments no longer suffice to supply the hospitals for a half-week period.

The quantity of red cell concentrates that are required to supply hospitals for one week can be roughly evaluated by dividing the total number of red cell concentrates provided to the hospitals in 2008 by the number of weeks in one year ( $514,210 : 52 = 9,889$  a week).

On the other hand, though 45 % of the Caucasian population have group O blood, this is not in keeping with the statistics for the distribution of these concentrates. Indeed, some 50 % of the units distributed are group O units (for the Belgian data in 2009, see Table 2).

**Table 2.** Distribution by blood group of the red cell concentrates provided by the Dienst voor het Bloed, Rode Kruis – Vlaanderen (DVB) (Blood Service – Red Cross Flanders) and the Service du Sang, Croix-Rouge de Belgique (SFS) (Blood Service – Red Cross Wallonia) .

Blood group	DVB	SFS
A	41,19 %	40,55 %
AB	2,29 %	2,46 %
B	7,09 %	7,82 %
O	49,54 %	49,16 %
including O- and O+	9,33 % 40,21 %	9,46 % 39,70 %

The reasons are as follows:

- 1) the recipient population is not purely Caucasian; thus, patients with sickle-cell anaemia, who require large quantities of red blood cells, are of African descent, with 60 % of Africans having group O blood;
- 2) since O units are considered to be “universal donors”, they are also used by non-O recipients (especially those with group B blood);
- 3) if a patient’s blood group is unknown, group O red blood cells are administered until it is (this can lead to the use of several O units). Some hospitals give O blood when they do not have two separate blood type determinations at their disposal before the transfusion;
- 4) hospital emergency units need to have two Rh D negative group O units at their disposal, which causes further unbalance in the group O/other groups ratio. Moreover, hospitals that don’t have a blood bank of their own but have an agreement with a delocalised blood bank do have a supply of Rh D negative concentrates of group O at their disposal;

- 5) when phenotyped blood is needed, group O units are automatically used because blood from regular type O donors is preferentially/almost exclusively phenotyped (in order to make it possible for these units to be given to all recipients);
- 6) group O units are used for transfusions during the neo-natal period or *in utero* (cf. recommendations in the transfusion guide of the SHC, 2010);
- 7) CMV negative units contain group O blood (so as to enable all recipients, irrespective of their blood group, to use them);
- 8) the supplies of irradiated red blood cells belong to group O for the same reason as for CMV.

### **3.5. Establishing the thresholds below which there is a risk of shortage or an actual shortage of blood and cellular blood components**

#### **a) In terms of the red cell concentrate supplies**

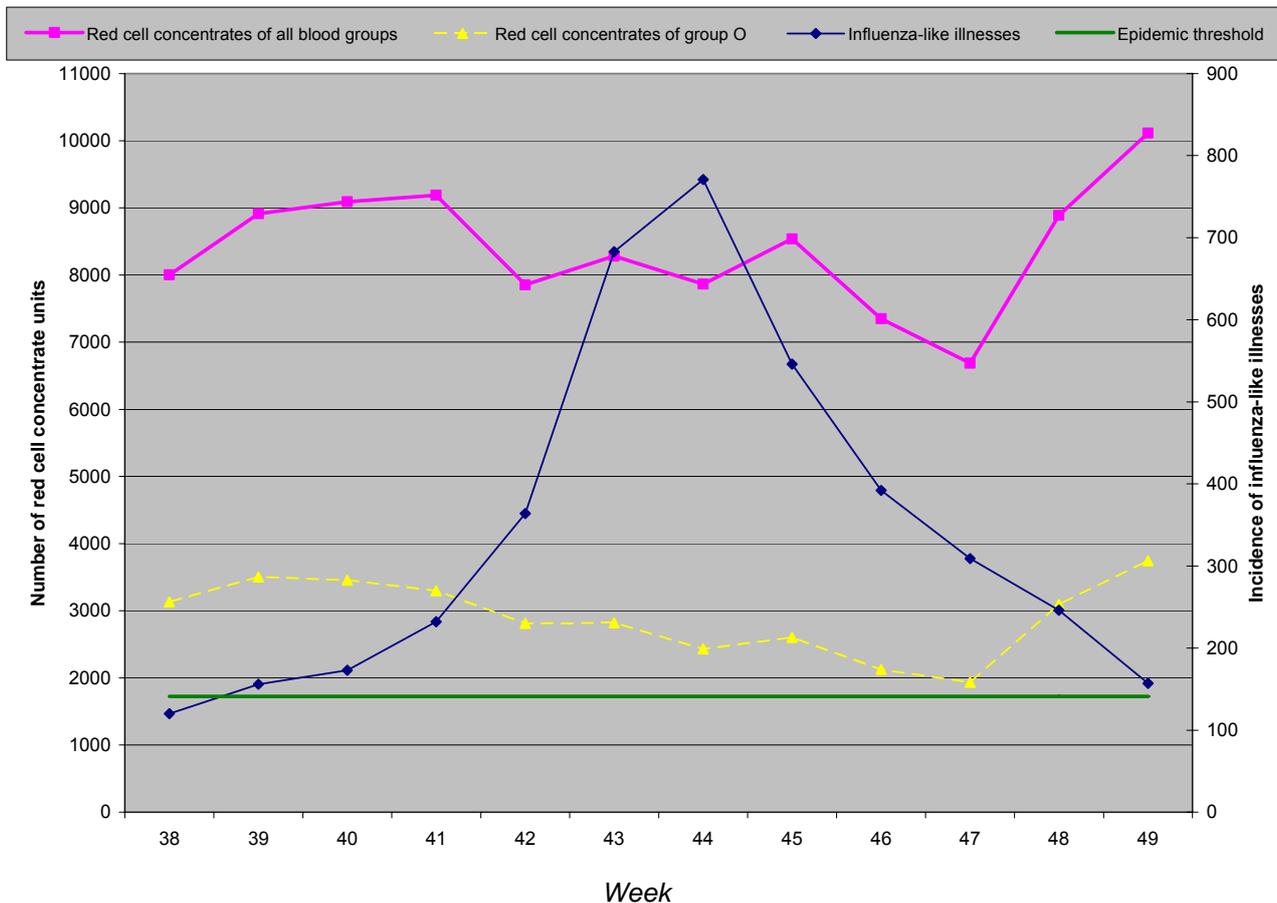
Faced with the spectre of an influenza pandemic in 2007, the SHC had “*attiré l’attention des autorités sur la nécessité de créer une structure nationale afin de garantir le traitement des patients présentant le besoin clinique le plus élevé. Dès que les premiers cas d’infection s’établissent sur le territoire, un plan national visant à assurer un approvisionnement national maximum pour les transfusions indispensables est essentiel*” (i.e. “the SHC had drawn the attention of the authorities to the need to provide a national structure to guarantee that patients with the greatest clinical need receive treatment. As soon as the first cases of infection occur in this country, it is of crucial importance that there should be a national plan in place for ensuring maximum national supply levels in the event of vital transfusions”) (SHC, 2007).

As a result of these recommendations as well as the emergence of the pandemic A(H1N1) virus in Belgium, the Federal Agency for Medicines and Health Products (FAMHP) and the blood establishments in the country have agreed that the former should be informed about the blood supplies in each blood establishment on a weekly basis, starting from September 2009. This provides an overall view of the blood supplies, which makes it possible to keep track of both the total amount of blood that can be provided and that of each blood group (see Figure 3).

According to the calculations of the FAMHP and taking into account the modification concerning the portion of red cell concentrates that belong to group O, the critical supply levels (i.e. sufficient supplies for half a week) therefore amount to 4,944 units of red cell concentrates of all blood groups, whereas the necessary supply of group O red cell concentrates is 2,442 units (i.e. 49.4 %). It should be noted that these calculations do not take into account the weekly variations observed in the blood component distribution (Kamp et al., 2010).

As regards the implementation of the criteria proposed, it is worth pointing out that, at the end of week 46, the levels of group O red cell concentrates had dropped below the critical threshold, i.e. sufficient quantities to cover the needs for half a week (see Figure 3).

**Fig. 3.** Evolution of the red cell concentrate supply levels (overall levels and group O levels) as well as that of the incidence of the A(H1N1) influenza illnesses in Belgium in the autumn of 2009. The left and right hand scales express the number of red cell concentrate units (absolute number) and the weekly incidence of influenza-like illnesses per 100,000 population, respectively.



**Note:** Since the data concerning the supply levels we have at our disposal are incomplete, we have kept the values for which the DVB and the SFS data were available (these two centres together provide more than 93 % of the Belgian supplies).

b) In terms of the incidence of the influenza-like illnesses among the general population

It will be noted that this shortage was predictable on account of reduced donor availability (viz. a 5 to 10 % reduction in the number of expected donors (Olivier Bertrand – SFS, pers. comm.)) and the dwindling red cell concentrate supplies from week 41 onwards, i.e. during the second week after the epidemic threshold of 141 influenza-like illnesses/100,000 population a week (see Figure 1 and Figure 3) had been crossed. This turning point occurred at 1.6 x this threshold. At that moment, 31.2 % of the samples tested positive for the influenza A(H1N1) virus (see Table 1 & Fig. 2).

These fluctuating supplies reflect the varying success of the massive campaigns for the recruiting of donors that were launched by the blood establishments in response to this tightening in the supply levels.

The SHC therefore recommends that a situation in which there is a risk of serious shortage or an actual shortage directly caused by the influenza A(H1N1) pandemic should be notified as soon as one of the following situations occurs:

- the weekly incidence of the influenza-like illnesses reaches 200 per 100,000 population (i.e. 1,42 x the epidemic threshold), with 30 % of the samples testing positive for the A(H1N1) virus (*risk of shortage*);
- the supply level drops to the critical threshold of 5,000 red cell concentrates of all blood groups, i.e. approximately the quantities that are provided to the healthcare establishments during a period of half a week (*real shortage*);
- the supply level drops to the critical threshold of 2,500 red cell concentrates of group O, i.e. approximately the quantities that are provided to the healthcare establishments during a period of half a week (*real shortage*).

The SHC points out that, after the supply of group O red cell concentrates had remained below the critical threshold for two weeks, the blood establishments increased their production, without, however, reaching an optimal level again.

### 3.6. Actual effect of the measures considered

Whether or not there will be a new wave of influenza illnesses caused by the A(H1N1) virus depends on several parameters that are constantly being monitored (Dushoff et al., 2009; Gojovic et al., 2009). At the end of the autumn, there are still many individuals who are liable to develop the illness in Belgium and in its neighbouring countries. It can therefore reasonably be supposed that there will be a new increase in the incidence of the influenza illnesses in the near future. Moreover, given the fact that in tropical areas, seasonal influenza reaches epidemic levels twice every year during the rainy seasons (Leo et al., 2009) and that an early wave caused by the new A(H1N1) virus was noted this autumn, it can be expected that it will soon be re-imported by travellers from these countries.

It is therefore becoming increasingly crucial that strategies to ensure sufficient national supply levels are enhanced and that the respective pandemic plans are updated by analysing all options and scenarios in the light of recent preliminary findings (see especially Zimrin & Hess, 2007; WHO-BRN, 2007; EBA, 2009; HHS, 2009).

#### a) Lowering the authorised haemoglobin levels for blood donations

Based on the calculations of Custer et al. (2004) and Klein & Anstee (2005), implementing the European derogation concerning the haemoglobin levels would increase the number of potential female and male donors by some 10 and 3 % respectively. This is in fact in keeping with the available assessments for the Belgian establishments (see Table 3).

**Table 3.** Proportion of the blood donors who are currently excluded on account of insufficient haemoglobin levels (but max. 5 g/L below the threshold), according to donor gender. Belgian data assessed by the Dienst voor het Bloed, Rode Kruis – West Vlaanderen (DVB-WVI) and the Service du Sang, Croix-Rouge de Belgique (SFS) over the 2008-2009 period.

Donors	DVB-WVI	SFS
men	3,2 %	3,3 %
women	8,9 %	10,2 %

#### b) Shortening of the exclusion period after an influenza-like illness

It is more difficult to assess the extent of the real effect of implementing the second measure allowed by transposing directive 2009/135/EC into Belgian law.

It has not been proven that influenza viruses are transmitted through blood transfusion (Zou, 2006; Likos et al., 2007; Zimrin & Hess, 2007; Arbeitskreis Blut, 2009). Our knowledge concerning the extent of the viremia and the number of asymptomatic cases among carriers of the new pandemic virus is preliminary. Yet, it can be estimated that these are close to the results obtained for seasonal influenza A viruses (Likos et al., 2007; Carat et al., 2008; HHS, 2009). It should be noted that, when there is an A(H1N1) pandemic in the US, donors are deferred for only 24 hours after the disappearance of the symptoms without antipyretics (HHS, 2009). Dependent on the evolution of our specific knowledge on the viremia, the implementation of this measure will, if necessary, be adapted.

### **3.7. Implementation strategy and accompanying measures to deal with a serious shortage**

The impact of the measures considered should be viewed within an overall context of disturbed balance between supply and demand. This disturbed balance, which was noted in the autumn of 2009, may still worsen in the event of a prolonged epidemic wave (15 weeks) and/or the emergence of a highly pathogenic virus. As a result, the SHC takes the view that all measures should be implemented in a co-ordinated fashion. They should be combined with several accompanying measures in order to provide the blood establishments with assistance in their difficult task of managing the supply during such a major crisis situation. Because of the way in which transfusion is organised in Belgium, these accompanying measures have to be applied at two levels: at the level of the blood establishments, so as to increase the offer of blood components, and at that of the healthcare establishments in order to limit the use of blood components to the strictly necessary.

#### **a) Measures aimed at maintaining or increasing the offer of blood components**

- provide appropriate information to the general population, so as to put an end to all misunderstandings concerning blood donations during an influenza pandemic; this will specify that

e.g. the influenza vaccines used in Belgium contain no infectious viruses and therefore do not prevent donor candidates from visiting the blood donor clinics;

e.g. the blood establishments take all possible precautions and have tightened up their hygiene measures, so as to protect their donors against possible contamination with the influenza virus during blood collection; specific information is available;

e.g. the fear of donors that they could contract a virus as a result of their blood being collected is unfounded (there had been a huge misunderstanding of this type following the emergence of the HIV virus (Goodnough et al., 1999));

e.g. blood donor clinics should not be looked upon as public meeting points;

- collect two red cell concentrates per apheresis session (SHC, 2008b);
- increase the number of authorised blood donations a year (SHC, 2009);
- increase the obligatory age limit for blood donations. The SHC has recently recommended that the age limit for regular donors be raised from 65 to their 70<sup>th</sup> birthday (SHC, 2009b);
- investigate the possibility of vaccinating the blood donor population (WHO-BRN, 2007). In Belgium, some 275,000 donors are currently aged between 18 and 65;
- promote the use of pathogen reduction for platelet concentrates (SHC, 2008).

#### **b) Measures for saving blood and using blood components judiciously**

- once again draw attention to the task of the Transfusion Committees and adapt/harmonise good transfusion practices (SHC, 2010);
- avoid non-urgent transfusions as much as possible and make the clinical services aware of the importance of making optimal use of the very scarce resources in case of an influenza pandemic (SHC, 2007; Kamp et al., 2010);

- give priority to the indications for transfusion that are of vital importance (SHC, 2010);
- improve the level of achievement of the logistic chain in/around hospital blood banks, mainly by discouraging exaggerated orders and inflated real needs ("shortage gaming" phenomenon) (Sethuraman & Tirupati, 2005);
- strengthen the co-operation between the co-ordinator group of the influenza pandemic plan and the Transfusion Committees within the healthcare establishments (SHC, 2007).

## **CONCLUSION:**

Taking into account the urgency of this request for advice, the lack of perspective and the uncertain evolution of the A(H1N1) pandemic, the recommendations and conclusions in this advisory report must be adapted according to the evolution of the situation.

Preliminary observations: the threshold values have been calculated by taking into account an **immediate** implementation of the derogations provided in the Royal Decree. If the implementation of these derogations requires some time, a warning procedure needs to be set up on the basis of the decline in blood establishment supplies and/or the increased demand from the healthcare establishments.

Many of these recommendations also apply when there is either a risk of shortage or an actual shortage as a result of an epidemic or a pandemic caused by another highly contagious disease.

Because the supply of blood components is a **critical** factor in our healthcare system, the SHC advises that all means of communication between the surveillance centres and all actors in blood transfusion should be enhanced and optimised (IPH, blood establishments, FAMHP, healthcare establishments, FPS Public Health, SHC).

In order to be able to ensure that this advice be acted upon appropriately and because the SHC also has as its task to issue an advisory report concerning the setting of the date at which these temporary derogations can be suspended, the SHC must be informed in "real time" of all useful and reliable information about the blood component supply levels.

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## 5. COMPOSITION OF THE WORKING GROUP

All experts joined the working group *in a private capacity*. The names of the members and experts of the Superior Health Council are indicated with an asterisk\*.

The following experts were involved in drawing up this advisory report:

BAETEN Martine	(transfusion - Dienst voor het Bloed, Rode Kruis - Vlaanderen);
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LAMBERMONT Micheline*	(transfusion - ULB; Service du Sang, Croix-Rouge de Belgique);
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MATHYS Esther	(blood and blood products, virology - IPH);
PEERLINCK Kathelijne	(coagulation and blood vessel disorders - KUL);
SELLESLAG Dominik	(internal medicine, haematology - AZBrugge);
SZABO Bertrand	(transfusion - Cliniques Reine Astrid Malmédy);
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The following experts were consulted:

MUYLLE Ludo*	(blood, tissues and cells - UA; UZA; FAMHP);
WUILLAUME Françoise	(epidemiology - National Influenza Centre, IPH).

This working group was chaired by Véronique DENEYS; the scientific secretary was HÜBNER Roland.