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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Health Law and International

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Blood Regulatory Committee
28 September 2009
SUMMARY REPORT

The Regulatory Committee, established by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Council Directive 2001/83/EC, was convened on 28 September 2009 to assess the potential impact of the A/H1N1 influenza pandemic on supply and demand of blood for transfusion, and to address possible related regulatory consequences at Community level.

The purpose of that meeting was to gather information from the Member States on the measures/contingency plans they are considering in case the blood supply is at risk because of the A/H1N1 influenza pandemic affecting both donors and the staff of national blood services.

In advance of the meeting, the Commission had prepared a working paper providing background information on the following points to be addressed during the meeting of 28 September:

- Overview of the potential impact of a pandemic on the blood supply in the European Union;
- Identification of the best instruments to correct this potential impact and maintain this supply;
- Analysis of the potential conflicts between these instruments and the minimum standards for blood and blood components set by the European legislation.

Several supporting documents were provided to the participants, originating either from some Member States authorities or from the European Blood Alliance.

Discussions during the meeting confirmed that in case of a severe A/H1N1 influenza pandemic, there could be a net shortage of blood/blood components of approximately 10-15 %, depending on the Member State.

Some elements of the contingency plans prepared by the Member States fall under Directive 2002/98/EC and its implementing Directives. Two of these were identified as being levers to increase blood supply on an exceptional and temporary basis in case of severe shortage:

(1) Donor deferral period after recovery of a flu-like illness

The Commission Directive 2004/33/EC requires that two weeks (14 days) must elapse between end of flu-like symptoms in a prospective donor and the donation event (Annex III.2.2.1).

A majority of Member States considered that reducing this period to 7 days would be the lever with the most effect on admissibility of donors during an acute A/H1N1 influenza pandemic. One Member State was also considering the possibility of reducing the buffer period to 5 days after the end of the symptoms.

The Member States and the Commission agreed to request a risk assessment from the European Centre for Disease Control and Prevention (ECDC) on the reduction from 14 days to 7, or even 5 days of the donor deferral period after recovery of a flu-like illness. *[Post meeting note: the request to ECDC was sent by the Commission on 1 October 2009].*

(2) Haemoglobin levels in donors' blood prior to donation

Annex III.1.2 of the Commission Directive 2004/33/EC specifies that the thresholds for haemoglobin levels in donor's blood lies at 125g/l for women and 135g/l for men. There was a consensus among the delegations that in the context of an A/H1N1 influenza pandemic these levels could be reduced to 120 and 130 g/l respectively for women and men, without putting at risk the health of the donors.

Based on the input provided by the Member States during the meeting and the results of the risk assessment performed by the ECDC, the Commission will consider whether further steps are appropriate.

The conclusions of this meeting will be kept under review.

Chair of the Committee

Ms Patricia Brunko,
Head of Unit SANCO C6