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Public Health and Risk Assessment
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Blood Regulatory Committee on quality and safety of blood
28 October 2009
SUMMARY REPORT

The Regulatory Committee established by Directive 2002/98/EC discussed a draft Commission Directive allowing temporary and exceptional flexibility of eligibility criteria of blood donors in the context of the influenza A (H1N1) pandemic.

All Member States were present except Czech Republic which was represented by Slovakia.

Following questions by Member States, the Commission clarified the points below:

- Some Member States commented that the draft measures could have a wider scope than the specific risk of blood shortage due to Influenza A(H1N1). The Commission explained that the draft measure is exclusively focused on this risk as being the only justification for an urgent measure. Furthermore, the opinion given by the ECDC on 9 October 2009 was strictly limited to A(H1N1). These issues raised by the Member States will be addressed at the next meeting of Competent Authorities for blood and blood components, which should take place in December 2009.

- The draft measure contains conditions as regards the use of the proposed flexibility and does not prejudge the provisions of article 4.2 of Directive 2002/98/EC stating that the Directive shall not prevent a Member State from maintaining or introducing in its territory more stringent measures which comply with the provisions of the Treaty.

- The draft measure would not apply beyond 30 June 2010. By that date, additional data will be available on the evolution of the pandemic and on the possible availability of seasonal vaccines with Influenza A(H1N1) strain for the autumn 2010. The proposed measure will be reviewed in the light of such new elements.

- The Commission and EMEA are in contact to address the impact of this proposed measure on the Plasma Master File required for manufacturing of plasma derived medicinal products.

The Commission took note of the reservation expressed by Germany and Austria regarding correlation tables referred to in article 2.1 of the proposed measure. It was agreed that these parallel discussions should not delay the adoption of the proposed urgency measure.

The Commission asked for the opinion of the Regulatory Committee on the proposed draft measure. The Regulatory Committee gave a unanimously favourable opinion on the proposal for a Commission Directive allowing temporary derogation to certain eligibility criteria for whole blood and blood components donors laid down in Annex III to Directive 2004/33/EC in the context of a risk of shortage caused by the Influenza A(H1N1) pandemic.

Chair of the Committee

Patricia Brunko,
Head of Unit SANCO C6