STATUTORY INSTRUMENTS.

S.I. No. 507 of 2009

EUROPEAN COMMUNITIES (QUALITY AND SAFETY OF HUMAN BLOOD AND BLOOD COMPONENTS) (AMENDMENT) REGULATIONS 2009

(Prn. A9/1815)

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EUROPEAN COMMUNITIES (QUALITY AND SAFETY OF HUMAN BLOOD AND BLOOD COMPONENTS) (AMENDMENT) REGULATIONS 2009

I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Commission Directive 2009/135/EC[1] of 3 November 2009 allowing temporary derogations to certain eligibility criteria for whole blood and blood components donors laid down in Annex III to Directive 2004/33/EC[2] in the context of a risk of shortage caused by the Influenza A(H1N1) pandemic, hereby make the following regulations:

1. These Regulations may be cited as the European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2009.

2. In these Regulations, "Principal Regulations" means the European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005 (S.I. No. 360 of 2005).

3. Regulation 9 of the Principal Regulations is amended by inserting the following paragraphs after paragraph (2):

"(2A) Subject to paragraphs (2B)(*c*) and (2D), a blood establishment may, in relation to the donation of blood, if confronted with a serious risk of shortage or an actual shortage in the supply of blood and blood components directly due to the A(H1N1) Influenza pandemic, on a temporary basis do one or both of the following:

(*a*) by way of derogation from point 1.2 of Annex III to Commission Directive 2004/33/EC, reduce the minimum haemoglobin levels in donors blood to no less than 120 g/l for females and 130 g/l for males;

(*b*) by way of derogation from point 2.2.1 of Annex III to Commission Directive 2004/33/EC, apply a deferral period of no less than 7 days after cessation of symptoms of a flu-like illness.

(2B) A blood establishment, in relation to the proposed implementation, or the implementation, of any of the derogations referred to in paragraph (2A)—

[1]OJ L288, 4.11.2009, p. 7
[2]OJ L 91, 30.3.2004, p. 25

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 18*th December*, 2009.

(*a*) shall notify the IMB without delay of the measures it intends to take or has taken pursuant to that paragraph,

(*b*) shall notify the IMB of its justifications as to the necessity of the measures referred to in subparagraph (*a*), notably as to the extent of the risk of shortage, or of the actual shortage, of blood and blood components, including a description of the criteria and methodology used to assess that necessity, and

(*c*) shall, as soon as, according to the criteria and methodology referred to in subparagraph (*b*), the supply of blood and blood components comes back to a sufficient level, terminate any such implementation of any of those derogations and notify the IMB of any such termination.

(2C) The IMB shall—

(*a*) inform the Commission without delay of the measures referred to in paragraph (2B)(*a*),

(*b*) communicate to the Commission the justifications referred to in paragraph (2B)(*b*), and

(*c*) inform the Commission of any termination referred to in subparagraph (2B)(*c*).

(2D) Paragraphs (2A) to (2C) shall expire on 30 June 2010.".

4. Regulation 22(1) of the Principal Regulations is amended by inserting "(except Regulation 9(2C))" after "Regulation 5(1), 9".

L.S.

GIVEN under my Official Seal,
11 December 2009.

MARY HARNEY,
Minister for Health and Children.

EXPLANATORY NOTE

(This note is not part of the instrument and does not purport to be a legal interpretation.)

The measures provided for in this Directive are designed to respond to a temporary situation related to the specific Influenza A(H1N1) virus. They will assist in easing, on an exceptional and temporary basis, some of the eligibility criteria for donors with regard to certain technical requirements for blood and blood components in order to increase the blood supply.

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