Decision of July 30th 2008

Determining the special manufacturing, import, export, marketing (free or for a price) and use of medical beds, commonly referred to as medical "cot-beds"

The Director of the French Agency for Health Product Sanitary Safety,

With regards to part five of the Public Health Code (PHC) and in particular articles L.531 1- 1, L.5211-1, L.5312-1;

With regards to order no. 91-1292 of December 20th 1991 pertaining to the prevention of risks resulting from childcare articles 2 and 4, defined by the notice published in the Official Gazette of the French Republic, no. 0083, dated April 8th 2008 - text no. 116 pertaining to the application of this order;

With regards to standards NF EN 716-1 and NF EN 716–2 pertaining to fixed and folding body beds for domestic use with children of between 900 and 1400 mm in height, stating that the effective diameter of the holes, along with the distance between two structural elements, must be less than or equal to 65 mm;

With regards to the notice of the National Commission for medical devices, dated June 11th 2008;

With regards to the responses to the consultation of manufacturers and professional organisations of July 9th 2008;

Considering that five accidents, occurring in 2002, 200 and 2006 were notified to the AFSSAPS in the context of materiovigilance, concerning children becoming trapped between the bars, or between the headboard and the first bar of the medical cot-bed rails, in spaces of between 80 and 110mm, where their entire body, with the exception of their head, had been able to pas.

Considering that, though the above-mentioned accidents occurred with spaces of between 80 and 110mm, the risk of trapping is inherent to cot-beds whose bar spacing allows children's limbs and body to pass, but not the head, which is the case when spacing exceeds 65mm; that the dimension of 65mm has furthermore been retained in the context of the above-mentioned standards pertaining to fixed and folding body beds for domestic use with children;

Considering the risk of death or of serious clinical consequences that may arise from such trapping, the child being suspended with no support, in a position of strangulation with breathing difficulties;

Considering that cot-beds for medical use with bars spaced by more than 65mm are still, to this day, manufactured, imported, exported, marketed and used;

Considering that the required safety level for the medical use of cot-beds must not be lower than that required for domestic use; that in this respect, the NF EN 716-1 and NF EN 716-2 standards, pertaining to fixed and folding body beds for domestic use with children, should be used as reference in order to ensure a similar safety level for medical cot-beds;

Considering that this safety requirement must be applied to all medical cot-beds manufactured, imported, exported and marketed from the date of publication of the present decision; that considering the fraction of beds currently in use that fail to meet this requirement and the material impossibility of immediately replacing the concerned beds in the healthcare establishments, these latter must make due diligence to plan their replacement as rapidly as possible and, at the latest, by May 1st 2009.

<div align="center">

Decides,

</div>

Article 1 - Medical cot-beds must present a space, between bars or between the headboard and the bed rail, smaller than or equal to 65mm as per the test defined by the NF EN 716-2 standard.

Article 2 - The manufacture, import, export and marketing (free or for a price) of cot-beds for medical use, must conform to the requirements of article 1 from the date of publication of the present decision.

Article 3 - The use of medical cot-beds must conform to the provisions of article 1 from May 1st 2009.

Article 4 - The director of inspection of medical devices and the director of establishments are each responsible for enforcing the present decision, which shall be published in the *Official Gazette* of the French Republic.

Drawn up in Saint-Denis, on