



Decision of April 26th 2010

Determining specific conditions of use, putting into service, placing on the market, distribution, import and export, for the reinforcement of the safety of the children put in medical beds equipped with bed rails,

The Director general of the French Agency for the Safety of Health Products ,

With regards to part five of the French Public Health Code and in particular articles L.5311-1, L.5211-1, L.5312-1;

With regards to standards NF EN 716-1 and NF EN 716-2 pertaining to children's cots and folding cots for domestic use, stating that the effective diameter of the holes, and the distance between two structural elements, must be less than or equal to 65 mm;

With regards to standard NF EN 1970 pertaining to adjustable beds for disabled persons, amendment 1 of standard NF EN 60601-2-38 pertaining to particular requirement for the safety of electrically operated hospital beds, and standard NF EN 60601-2-52 pertaining to particular requirements for basic safety and essential performance of medical beds;

With regards to the decision of July 30th 2008 about the medical cots;

With regards to the notice of the National Committee for the safety of Medical Products, dated December 2nd 2009;

With regards to the responses provided by manufacturers and professional organisations to the consultation of February 5th 2010;

Considering that, within the framework of medical devices vigilance system, four serious accidents which have occurred in 2005, 2007, 2008 and 2009, were notified to the AFSSAPS, concerning children, from 3 to 6 years old, becoming trapped between the bars, or between the mattress support platform and the lowest bar of the medical bed rail; that in the four cases, the body of the child, except his head, passed through the spaces between 110 and 128mm; that a fifth accident occurred in 2008, by trapping of the neck of a 11-year-old child between the headboard and the plank that had been added to fill in the space, for lack of suitable device; that the above-mentioned five accidents led to the death of the children;

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

Considering that the risk of such trapping is inherent to bed rails whose bar spacing allows children's limbs and body to pass, but not the head;

Considering that standards NF EN 1970, NF EN 60601-2-38 Amendment 1 and NF EN 60601-2-52 pertaining to medical beds give safety requirements for bed rails for adults and are based on anthropometric data based on patients tall(er) than 146cm or old(er) than 12 years; that these standards therefore do not apply to the children who are smaller than 146cm;

Considering that there is no safety standard about the medical bed rails suitable to children with a height lower than 146cm; that the safety level required for the medical bed rails for these children shall not however be inferior to the level required for smaller children put in cots; that in the sense that, it is advisable to refer to the above-mentioned standards NF EN 716-1 and NF EN 716-2 pertaining to children's cots and folding cots for domestic use;

Considering that medical bed rails for children smaller than 146cm, with a space between the bars and/or the space between the mattress support platform and the lowest bar of the medical bed rail bigger than 65 mm are still, to this day, placed on the market, put into service, distributed, imported, exported; that beds equipped with rails with a space between the bars and/or the space between the mattress support platform and the lowest bar of the rail bigger than 65 mm are still, to this day, used for children smaller than 146cm;

Considering consequently that there is reason to enforce safety requirements to all medical beds equipped with rails for children smaller than 146cm, imported, exported, distributed, put into service and placed on the market from the date of publication of the present decision;

Considering taking into account the size of the concerned installed field, the fraction of beds that currently fail to meet these requirements, current works by many manufacturers to develop suitable solutions, the material impossibility to immediately bring into compliance all the concerned bed within the healthcare facilities, the communities and in the field of devices managed by providers for the rental at home and the consequences concerning the organisation within the above-mentioned healthcare facilities, communities and providers, the users must make due diligence to plan the upgrade or the replacement of the beds equipped with rails as rapidly as possible depending on the availability of necessary devices and, at the latest, by March 1st 2011.

Decides,

Article 1 – Medical bed rails for which the manufacturer claims a use for children smaller than 146cm, placed on the market, put into service, distributed, imported or exported, shall present a space between two elements of structure within the rail and between the mattress support platform and the rail, smaller than or equal to 65mm as per the test defined by NF EN 716-2 standard from the date of publication of the present decision.

Article 2 – For the bedding of children smaller than 146cm in medical beds equipped with side rails, whether they are in a healthcare facility, a community or at the patient's home, the side rails will have to present a space between two elements of structure within the side rail and between the mattress support platform and the side rail, smaller than or equal to 65mm as

per the test defined by NF EN 716-2 standard. This requirement can be reached by the use of a side rail in compliance with the technical specifications described in Article 1 or the use of a side rail brought into compliance by its manufacturer by any suitable means. This compliance must be effective at the latest, by March 1^{er} 2011.

Article 3 - The director of medical devices evaluation and the director of inspection and companies are responsible for enforcing the present decision each for what he is concerned, which will be published in the *Official Gazette* of the French Republic.

Drawn up in Saint-Denis, on April 26th 2010