EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Consumer Affairs
Cosmetics and Medical Devices

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M/467 EN

Standardisation mandate addressed to CEN and CENELEC: modification and completion of EN 60601-2-52 to prevent entrapment of children and of adults with an atypical anatomy in medical beds and entrapment of children in medical cots

I OBJECTIVE

This mandate requests the modification and the completion of EN 60601-2-52 to prevent entrapment of children and of adults with an atypical anatomy in medical beds. The completion might also be achieved by a new standard.

II BACKGROUND

Several Member States reported about severe incidents including casualties caused by medical beds with bars. The victims were children or adults with an atypical anatomy. The French Competent Authority Afssaps recorded, since 2005, 5 accidents of children, who were fatally injured having been entrapped in the rails of their "adult" medical bed.

It appears from a first analysis undertaken by the Member States Competent Authorities that the current set of standards is not adapted to the needs of children or adults with an atypical anatomy. EN 60601-2-38, EN 1970 on adjustable beds for disabled persons, and the new standard EN 60601-2-52 do not foresee a maximum distance for the bars that is small enough to prevent accidents.

According to Competent Authorities representatives, a part of the safety problem is due to the fact that medical beds for adults are not appropriately labelled as being designed only for adults with a normal anatomy. Users are therefore not always aware of the risk of medical beds for young patients or for adults with an atypical anatomy. Hospital administrations do not always see a need to buy medical beds which are appropriate for children or for adults with an atypical anatomy. Clear labelling of the targeted patient groups for ordinary medical beds could reduce the risk of inappropriate use of ordinary medical beds for children or for adults with an atypical anatomy.

Competent Authorities representatives also stated that there is a need for the development of requirements for medical beds and cots for children and adults with an atypical anatomy.

III MOTIVATION AND NEEDS

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By executing this mandate, CEN and CENELEC shall ensure that:

- medical beds that are in conformity with EN 60601-2-52 are not erroneously deemed appropriate for children and for adults with an atypical anatomy (Part A);

- there are technical requirements available for medical beds which can be safely used for children and for adults with an atypical anatomy (Part B);

- requirements are established for medical cots, the safety issue being very much the same as for medical beds (Part C).

IV DESCRIPTION OF THE MANDATED WORK

This mandate relates to the modification and the completion of EN 60601-2-52 to prevent accidents of children and of adults with an atypical anatomy in medical beds.

For children of the age up to 3 years, medical cots are used in parallel to medical beds. Medical cots can cause the same danger of entrapment as medical beds. CEN and CENELEC are invited to examine whether it is appropriate to cover medical cots, be it in a new standard completing EN 60601-2-52, in the amendment to EN 60601-2-52 or in an amendment to EN 716-1 and EN 716-2 on children's cots and folding cots for domestic use.

Part A

A modification of the standard EN 60601-2-52 should be designed to assure conformity of this standard with the Essential Requirements of Directive 93/42/EEC. The modification shall ensure that medical beds that are in conformity with EN 60601-2-52 are not erroneously deemed appropriate for children and for adults with an atypical anatomy.

Such an amendment might contain the following elements:

- Obligation to determine the age range and height range of patients for whom the medical bed can be safely used.

- Obligation to label for which patients the medical bed cannot be safely used.

Part B

This aspect of completion shall ensure that there are technical requirements available for medical beds which can be safely used for children and for adults with an atypical anatomy. The completion can be achieved via integrating requirements for medical beds designed for children and for adults with an atypical anatomy into EN 60601-2-52 or, alternatively, by developing a new standard. The completion can also be reached by a combination of the two. In this case, CEN and CENELEC would integrate requirements for medical beds designed for adults with an atypical anatomy into EN 60601-2-52 and develop a new standard for medical beds designed for children. CEN and CENELEC are free to decide on the appropriate path.

The Nordic countries have already adapted EN 1970 to the medical needs for the 4-11 year-old children in a document called "Nordic Requirement Specification - Adjustable beds for disabled children" which was published in 2001. CEN and CENELEC shall take account of this document in the standardisation work covered by this mandate.

To reduce the spaces between the bars to < 65mm for all medical beds falling under EN 60601-2-52 might be regarded as the safest solution. If this was to be done, no distinction needs to me made between beds for adults and beds for young and atypical patients. This solution would prevent that medical beds for adults cause incidents when used for young and atypical patients against the instructions for use of the manufacturer. However, some experts seem to claim that certain health protocols need greater space between the bars than 65mm. CEN and CENELEC are invited to investigate whether this solution is suitable.

At the end of the work for Part B, CEN and CENELEC are invited to investigate whether the (labelling) obligations established in Part A have to be modified or to be made more precise, e.g. by referring to the requirements established in Part B.

Part C

It is necessary also to cover medical cots by one of the EN standards. EN 716-1 and 716-2 contain requirements for cots (length between 900 and 1400mm) in the domestic area. These cots are intended for children (from 0 to 3 years old) who cannot pass over a 600 mm high rail. The scope of these standards could be extended to medical cots provided the requirements specific to medical use are taken into account. Alternatively, a new standard, complementing EN 60601-2-52, could also encompass medical cots.

Whatever solution is chosen, CEN and CENELEC are invited to investigate whether it is necessary to identify and to label for which patients the medical cots cannot be safely used.

V EXECUTION OF THE MANDATE

CEN and CENELEC are requested to communicate to the Commission, within three months of the acceptance of the mandate, a work plan for the execution of the abovementioned standardisation task, indicating whether the development of a new standard is deemed necessary.

CEN and CENELEC are requested to provide regular progress reports to the Commission each year after the acceptance of the mandate indicating any possible difficulties encountered.

CEN and CENELEC will accomplish the Part A of the mandate within 12 months from accepting the mandate and will deliver the resulting standards in its working languages.

CEN and CENELEC will accomplish Parts B within three years from accepting the mandate and will deliver the resulting standards in its working languages.

CEN and CENELEC will accomplish Part C within three years from accepting the mandate and will deliver the resulting standards in its working languages.

CEN and CENELEC may combine Parts B and C provided that this does not lead to a delay.

When executing the standardisation tasks covered by this mandate, CEN and CENELEC are requested to take due account of feedback from the stakeholders. Priority shall be given to the fast execution of this mandate if the execution of the mandate within the framework of the Vienna and Dresden Agreements might lead to a delay.

Acceptance by CEN and CENELEC of this mandate starts the standstill period referred to in Article 7 of Directive 98/34/EC of 22 June 1998 (OJ N° L 204/37 of 21 July 1998).

CEN and CENELEC will forward the titles of the standards in all the languages of the European Union.

VI BODIES TO BE ASSOCIATED

As appropriate, CEN and CENELEC will invite the representative organisations of consumers' interests (ANEC), patients (EPF), workers (ETUI-REHS), hospital and healthcare services (HOPE) and small and medium-size enterprises (NORMAPME) to take part in the standardisation work.