

EUROPEAN PARLIAMENT

2004



2009

Committee on Petitions

20.02.2009

NOTICE TO MEMBERS

Subject: **Petition 0637/2008 by Pawel Szczepanski (Polish), and one co-signatory, on safe one-way syringes**

1. Summary of petition

The petitioner, who works at the Poznan University of Medical Science, stresses that, in spite of the medical progress and cooperation via HELICS (a surveillance network for infections caused in the health sector), iatrogenic infections are still a serious problem throughout the world. He considers that one of the reasons for this is one-way syringes, the shape of which permits the transmission of infection. Referring to Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control, and the provisions governing the tasks of the Centre, he therefore calls on the European Parliament to ensure that this serious public health problem is addressed.

2. Admissibility

Declared admissible on 16 October 2008. Information requested from Commission under Rule 192(4).

3. Commission reply, received on 20 February 2009.

The petitioners claim that there is a design fault in disposable syringes. The claimed fault relates to syringes where the diameter of the plunger is equal to or slightly smaller (by about 0.1 – 0.2 mm) than the internal diameter of the syringe cylinder. This type of construction makes it possible, according to the petitioners, for the plunger to touch the internal sterile surface of the syringe cylinder. The petitioners claim that, when preparing injections using

soluble medicines (for example, antibiotics), it is necessary to move the plunger up and down a number of times. When doing so, it might happen that the plunger is pulled out and is contaminated, for example, by being touched by a hand. If the contaminated plunger is pushed into the cylinder again, this contaminates the inner surface of the cylinder, which then contaminates the drug in the syringe. The petitioners claim that this might lead to transmission inter alia of the Hepatitis C Virus (HCV).

The petitioners declare having presented the issue to the Polish authorities without success. They now call upon the European Parliament to take all necessary steps to withdraw the faulty syringes from sale in EU countries.

Observations

The petition could be understood literally as a call for product withdrawals. However, it has to be noted that only the Member States are in charge of "withdrawing" potentially harmful medical devices from the market. Member States are in charge of this in accordance with articles 8 and 14 b of Directive 93/42/EEC on Medical Devices. If understood in this way, the European Parliament as much as the other European Institutions are not the right addressee. Both are not empowered to undertake the requested action. Supposedly the claimed risk exists, it will be up to the Member States to take measures.

The petition could also be interpreted as a call for a modification of EU legislation to prevent this type of infection. This call would be justified if the current EU legislation did not adequately cover the risk described in the petition. However, the current EU legislation does adequately cover this risk. Section 7.2 of Annex I to Directive 93/42/EEC states: "The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product." Furthermore Section 13.1. of the same Annex contains provisions on the information to be supplied for the safe use. As it is impossible to legislate with particular requirements for several thousands of different medical devices, the European Union cannot set-up more concrete requirements for each of the product types. Accordingly, it cannot do more at the level of legislation.

The petition could further be understood as a call for modification of the relevant Harmonized Standard in as much as the development of Harmonized Standards takes place under control of the European Union. The Commission services have verified the content of the applicable standard which is EN ISO 7886-1:1997 "Sterile hypodermic syringes for single use – Part 1: Syringes for manual use (ISO 7886-1:1993, including Technical Corrigendum 1:1995)". In its section 12.1, it is written "*.... it should not be possible easily to withdraw the plunger completely from the barrel*". Thus the main requirement for the protection against a contact between the hand and the sterile part of the plunger is taken into account in the standard. Equally Section 16.3. f) requires "*information for handling, storage and transportation of the contents*" (of the packaging) from the manufacturer. Accordingly, at the level of standardization, what can be done has been basically done. Nonetheless, the Commission services will invite the relevant standardization body CEN, on the occasion of the next

revision of the standard, to investigate whether it is appropriate to add an additional sentence for the case when the plunger is pulled out of the barrel of the syringe.

The Commission services recognize that the contact between the hand of the healthcare professional and the plunger of the syringe could possibly be a source of contamination with hand carried infection (Staphylococcus infection). Therefore, the Commission is developing a Commission Communication and a proposal for a Council Recommendation on patient safety, including the prevention and control of healthcare associated infections, which, *inter alia*, recommends Member States to put in place specific measures for the prevention and control of healthcare associated infections.

However, it is extremely unlikely that the inadequate use of the syringe as described by the petitioners will lead to infection by the Hepatitis C Virus (HCV). HCV is spread primarily by direct contact with human blood. Transmission through blood transfusions that are not screened for HCV infection, through the re-use of inadequately sterilized needles, syringes or other medical equipment, or through needle-sharing among drug-users, is well documented. Other modes of transmission such as practices using percutaneous procedures can occur if inadequately sterilized equipment is used. HCV is not spread by casual contact (1). All reported cases of HCV cross contamination in health care settings are related to surgery or unsafe injection practices (re-use of injection materials or contamination of multiple dose vials) (2,3,4,5,6,7). Thus the problem of contamination by HCV is related to the contact with blood or other body fluids, not with hands, and could therefore be avoided by appropriate behaviour from healthcare professionals.

Conclusion

There is no action needed at the level of the European institutions. The appropriateness of a sentence obliging the manufacturers to warn users against pushing the plunger of a syringe back into the cylinder once it has been out will be examined by the standardization body in charge which is CEN. It is up to the Member States to verify whether individual syringes placed on the market fulfill the legal requirements and are safe. Any kind of action described here will not resolve the issue of contamination by HCV which is related to the contact with blood or other body fluids.

References

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