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## **REPORT**

with recommendations to the Commission on protecting European healthcare workers from blood borne infections due to needlestick injuries  
(2006/2015(INI))

Committee on Employment and Social Affairs

Rapporteur: Stephen Hughes

(Initiative – Rule 39 of the Rules of Procedure)

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## MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

### **with recommendations to the Commission on protecting European healthcare workers from blood borne infections due to needlestick injuries (2006/2015(INI))**

*The European Parliament,*

- having regard to Article 192 of the EC Treaty,
  - having regard to Rules 39 and 45 of the Rules of Procedure,
  - having regard to Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work<sup>1</sup>,
  - having regard to Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work<sup>2</sup>,
  - having regard to Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work<sup>3</sup>,
  - having regard to the Commission communication on the practical implementation of the provisions of the Health and Safety at Work Directives (COM(2004)0062),
  - having regard to the European Competitiveness Report 2004 (SEC(2004)1397),
  - having regard to the Commission communication on adapting to change in work and society: a new Community strategy on health and safety at work 2002-2006 (COM(2002)0118),
  - having regard to its resolution of 24 February 2005 on promoting health and safety at the workplace<sup>4</sup>,
  - having regard to the report of the Committee on Employment and Social Affairs (A6-0137/2006),
- A. whereas needlestick injuries may lead to the transmission of more than 20 life-threatening viruses, including hepatitis B, hepatitis C, and HIV/Aids, and thus presents a serious public health problem,

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<sup>1</sup> OJ L 183, 29.6.1989, p. 1.

<sup>2</sup> OJ L 393, 30.12.1989, p. 13.

<sup>3</sup> OJ L 262, 17.10.2000, p. 21.

<sup>4</sup> OJ C 304 E, 1.12.2005, p. 400.

- B. whereas the prevalence of hepatitis B, hepatitis C, and HIV is increasing, and the United Nations programme to combat AIDS (UNAIDS) has reported that there are over 40 million cases of HIV and over five million cases of hepatitis C worldwide,
- C. whereas independent studies have shown that the majority of needlestick injuries can be prevented by better training, better working conditions, and the use of safer medical instruments,
- D. whereas the existing European legislation protecting health workers from needlestick injuries has proved ineffective in practice,
- E. whereas there is a serious shortage of healthcare staff, and studies in France and Great Britain have shown that one of the main reasons why the care profession is unattractive is because of the daily risks involved; and whereas the Commission's 2004 competition report (SEC(2004)1397) recognised the growing lack of workers in the health sector as a matter of particular concern for the European Union,
- F. whereas the Commission has delivered consistently disappointing responses to Parliamentary Questions posed by various Members of the European Parliament, highlighting the need for urgent and concrete steps for the protection of healthcare workers,
- G. whereas the Commission should be reminded that such action will be in line with the initiative for better regulation, including the amendment of legislation that has proved ineffective,
- H. whereas concern regarding the life-threatening occupational risks faced by healthcare workers from contaminated needles has been brought to the attention of the Commission on several occasions, most recently in Parliament's abovementioned resolution of 24 February 2005, which calls for a revision of Directive 2000/54/EC to address specifically the risk arising from work with needles and medical sharps,
- I. whereas no proposal within the meaning of Article 39(2) of the Rules of Procedure is in preparation, more than 12 months following Parliament's request for legislative improvement, and whereas during that time, about one million additional needlestick injuries are likely to have been suffered by healthcare workers in the EU, many of which could have been avoided; whereas some of these injuries will lead to infection with potentially fatal blood-borne viruses and many more will cause healthcare workers and their families months of anguish of not knowing whether or not they have contracted a life threatening infection,
  - 1. Requests the Commission to submit to Parliament within three months of the date of adoption of this resolution on the basis of Articles 137 and 251 of the Treaty, a legislative proposal for a directive amending Directive 2000/54/EC;
  - 2. Notes that the model effective in Germany to date, in combination with experience from Spain, could form the basis for a legislative proposal;

3. Calls on the Commission to develop common EU standards for reporting and recording needlestick injuries;
4. Confirms that the recommendations respect the principle of subsidiarity and the fundamental rights of citizens;
5. Considers that the requested proposal will have no financial implications.
6. Instructs its President to forward this resolution and the accompanying recommendations to the Commission and the Council.

## **ANNEX TO THE MOTION FOR A RESOLUTION: DETAILED RECOMMENDATIONS AS TO THE CONTENT OF THE PROPOSAL REQUESTED**

### **1. BACKGROUND**

- 1.1 A needlestick injury occurs when the skin is accidentally punctured with a needle that is potentially contaminated with a patient's blood. Contaminated needles can transmit more than 20 dangerous blood borne pathogens, including hepatitis B, hepatitis C and HIV. The majority of these injuries are suffered by nurses and doctors, but other medical staff are also at significant risk, as are auxiliary staff such as cleaners and laundry staff and other downstream workers.
- 1.2 Approximately 10% of workers in the EU are employed in the health and welfare sector with a significant proportion employed in hospitals. This makes healthcare one of the biggest employment sectors in Europe. Work related accident rates in the healthcare and social services sectors are 30% higher than the EU average<sup>1</sup>. High on the list of hazards are exposures to biological agents especially HIV and the hepatitis B and C viruses.
- 1.3 Percutaneous injury from hollow-bore blood-filled sharp objects is the primary route through which healthcare workers occupationally acquire blood borne and potentially fatal diseases. It is estimated that there are 1 million needlestick injuries in Europe each year<sup>2</sup>
- 1.4 High risk procedures include blood collection, IV cannulation and percutaneously placed syringes. Small amounts of blood can result in potentially life threatening infection. The risk of infection is dependent on various factors, such as the infection status of the patient, the virus load of the patient, the immune status of the staff member, the depth of the wound, the volume of blood transferred, the time between receiving and disinfecting the wound and the availability and use of post-exposure prophylaxis.
- 1.5 The prevalence of these infections is considerably higher in the healthcare setting than in the general population<sup>3</sup>.

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<sup>1</sup> See COM(2002)0118.

<sup>2</sup> a) EPINet Data. Dee May RGN, DMS. Period of Study: July 2000 to June 2001.

b) Surveillance of Occupational Exposures in Italy: the SIROH program, Gabriella De Carli, Vincent Puro, Vincenzo Puro, Giuseppe Ippolito, and the SIROH group, SIROH, 6 – 2002.

c) EPINet Spain, 1996 – 2000. Hernandez – Navarrete MJ, Arribas – Llorent JL, Campins Marti M, Garcia de Codes Ilario.

d) Risk of Hepatitis C Virus Transmission following Percutaneous Exposure in Healthcare Workers, 2003 – G De Carli, V Puro, G Ippolito, and the Studio Italiano Rischio Occupazionale da HIV (SIROH) Group.

<sup>3</sup> a) (University of Wuppertal) Hofmann F, Kralj N, Beie M. Needle stick injuries in healthcare - frequency, causes and preventive strategies. Gesundheitswesen. 2002 May; 64(5):259-66.

b) Schroebl S., Infektionsrisiko durch Nadelstichverletzungen für Beschäftigte im Gesundheitsdienst, in Dokumentationsband über die 40. Jahrestagung der Gesellschaft für Arbeitsmedizin und Umweltmedizin e.V., Rindt-Druck, Fulda 2000; fortgeführt und ergänzt, persönliche Mitteilung.

- 1.6 The risk of hepatitis B can be reduced by vaccination and, if administered rapidly post exposure prophylaxis can lower the risk of HIV transmission. For hepatitis C, however, such measures are not helpful.
- 1.7 Studies have shown that the use of safer instruments can significantly reduce the number of needlestick injuries. Independently of this measure, regular training and organisational measures can also significantly lessen the number of needlestick injuries. Therefore, as well as the use of appliances with safety features, emphasis should be placed on organisational measures such as established working procedures, training and instruction of workers and raising awareness of risky activities<sup>1</sup>.

## 2. CURRENT LEGISLATION

- 2.1 Directive 2000/54/EC (the seventh individual directive within the meaning of article 16(1) of Directive 89/391/EC) contains provisions designed to protect workers from risks related to exposure to biological agents at work. The following provisions are particularly relevant in this context:
- Biological agents are classified into four groups according to their level of risk infection (Article 2).
  - In the case of any activity likely to involve a risk of exposure to biological agents the employer must carry out a risk assessment (Article 3).
  - Where it is not technically practicable to prevent exposure to risk, the risk must be reduced to as low a level as necessary to protect adequately the health and safety of the workers concerned. This includes individual protection measures, drawing up plans to deal with accidents and safe collection, storage and disposal of waste (Article 6).
  - Procedures for taking, handling and processing samples of human or animal origin must be established (Article 8).

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<sup>1</sup> a) Advances in Exposure Prevention; vol. 3, no. 4; Libourne study GERES day\_09/2001.

b) Mendelson MH, Chen LBY, Finkelstein LE, Bailey E, Kogan G. Evaluation of a Safety IV Catheter Using the Centers for Disease Control and Prevention (CDC) National Surveillance System for Hospital Healthcare Workers Database. In 4<sup>th</sup> Decennial International Conference on Nosocomial and Healthcare-Associated Infections 2000 (March 5-9). Atlanta, Georgia.

c) Four-year surveillance from the Northern France network' American Journal of Infection Control. 2003 Oct;31(6):357-63. Tarantola A, Golliot F, Astagneau P, Fleury L, Brucker G, Bouvet E; CCLIN Paris-Nord Blood and Body Fluids (BBF) Exposure Surveillance Taskforce.

d) Louis N, Vela G, Groupe Projet. Évaluation de l'efficacité d'une mesure de prévention des accidents d'exposition au sang au cours du prélèvement de sang veineux. Bulletin Épidémiologique Hebdomadaire 2002 ;51 : 260-261.

e) Younger B, Hunt EH, Robinson C, McLemore C. Impact of a Shielded Safety Syringe on Needlestick Injuries Among Healthcare Workers. Infection Control and Hospital Epidemiology 1992; 13: 349-353.

f) Abiteboul D, Lolom I, Lamontagne F, Tarantola A, Deschamps JM, Bouve Et, and the GERES group. GERES (Groupe d'étude sur le risque d'exposition des soignants aux agents infectieux). AES : Peut on se protéger ? Enquête multicentrique sur les AES des infirmier(e)s de Médecine et réanimation. GERES Day, Hospital Bichat June 2002 Paris.

- Appropriate measures must be taken in health and veterinary care facilities in order to protect the health and safety of workers concerned (Article 5).

2.2 Council Directive 89/655/EEC concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of article 16 (1) of Directive 89/391/EEC) is also relevant. Article 3 imposes an obligation on the employer:

- to ensure that work equipment is suitable for the work to be carried out and may be used by workers without impairment to their health and safety;
- to pay attention to the specific working conditions and hazards posed by the use of the equipment in question;
- to take measures to minimise the risks.

In addition, Workers should receive information and training on the use of work equipment and any risks which such use may entail (Article 6 and 7).

### **3. WHY A LEGISLATIVE SOLUTION IS NECESSARY**

3.1 While the existing legislation should, theoretically, address the risk of needlestick injuries, in practical terms, this has not been the case. The Commission communication on the practical implementation of the Health and Safety at Work Directives (COM(2004)0062) specifically references problems with the public sector including hospitals.

3.2 Guidelines, awareness campaigns and other non-legislative initiatives can only make a partial contribution; they should be used in addition to directives<sup>1</sup>;

3.3. The 2004 European Competitiveness Report (SEC(2004)1397) acknowledges the escalating shortage of healthcare workers as a cause for concern throughout Europe. There are many reasons why healthcare may not be seen as an attractive career, but the occupational safety risks that are present in the workplace are certainly a contributing factor.

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<sup>1</sup> E.g. The TRBA 250 (Technical Requirements for Biological Agents) was published in Germany in October 2003, detailing specific recommendations to prevent medical sharps injuries, including the use of medical technology that incorporates needle protection. One of the aims of the TRBA 250 is to reduce infections from needlestick injuries. Therefore apart from the introduction of safer systems, it recommends alternative procedures for safer handling of cannula. The professional association rules for safety and health at work (BGR/TRBA 250) provide help for enterprises. If they keep to the techniques described here they can assume that they have complied with the requirements of the biological substances regulation (presumed effect, conformity effect). As the requirements are worded as technical rules, however, using terms such as 'should', rather than defining mandatory requirements, they have had little practical impact.



## 4. FINANCIAL IMPLICATIONS

- 4.1 Numerous independent studies have examined the short and long-term benefits of investment in safer working practices and medical devices to prevent needlestick injury and each of these has concluded that, overall, economic savings will be achieved<sup>1</sup>.

## 5. SPECIFIC PROVISIONS

- 5.1 The following provisions need to be inserted into Directive 2000/54/EC:

Article 2, point (ca)            "'medical sharp' shall include hollow-bore needles (such as those incorporated in syringes, lancets, specialised blood sampling devices, winged needles and IV catheters), suture needles, scalpels and other medical cutting implements."

Article 15, paragraph 1, point (ca)        "the risk of injury from needles and other medical sharps that are contaminated with blood."

Article 15, paragraph 2a            )  
"Safe devices to prevent cutting and needlestick injuries should not endanger the patients. Without prejudice to paragraph 2, and with the participation of the doctors responsible, the following specific preventative measures shall be taken in health and veterinary care facilities to protect workers from injuries caused by needles and other medical sharps

- (a) where available, safe and effective systems to minimise the use of cannula should be used, e.g. cannula that remain in the vein;
- (b) on the basis of risk-assessment security devices where they exist will be introduced in a timely fashion giving priority to areas of greatest risk of infection or accidental injury;
- (c) Work practices that pose a risk of needle injury shall be modified to make them safer and recapping needles shall be eliminated;
- (d) all workers - especially those who perform cannulation shall be trained in the safe use and disposal of needles and other medical sharps in appropriate sharps containers, as well as in the proper

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<sup>1</sup> a) A. Wittmann, F. Hofmann, B. Neukirch, Ch. Thürmer, N. Kralj, S. Schroeblner, K. Gasthaus; 'Blood-borne viral infections: causes, risks and prevention strategies', Bergische Universität Wuppertal, May 2005

b) US General Accounting Office, Impact assessment regarding Needlestick Safety and Prevention Act; Nov 17, 2000

c) Evaluation of the Efficacy of a Measure to Prevent Accidental Needlestick Injuries by Using Safety Needles for Venous Blood. Louis Nicole (1), Vela Gilles (2) and the Project Group Cellule d'Hygiène [Hygiene Unit], Centre Hospitalier 06401 – Cannes cedex Département d'Ergonomie [Department of Ergonomics], Centre Hospitalier Cannes

d) 2004 Center for Disease Control Sharps Safety Workbook, USA - Cost of Needlestick Injuries

sealing of waste in these containers;

- (e) if a sharps bin is not in the immediate vicinity of where a needle is used, the worker should carry a disposable tray, which in turn will be disposed of in a clinical waste bin to prevent contamination in the event of blood staining;
- (f) written instructions shall be provided at the workplace and, if appropriate, notices displayed communicating the procedures to be followed in the case of accident or incident involving needles and other medical sharps;
- (g) effective response and follow-up to accidents or incidents including rapid post -exposure prophylaxis shall be carried out;
- (h) all workers who may come into contact with needles and other medical sharps shall be offered vaccination against hepatitis B;
- (i) injuries from needles or medical sharps shall be recorded in a special register;
- (j) by (four years after this resolution's recommended changes to Directive 2000/54/EC come into force), the Commission shall ascertain whether devices with safety features within the meaning of paragraph 2a(b) have been introduced successfully. Studies should be conducted on the extent to which introduction of such devices in areas with high risk of infection have reduced the number of wounds and infections and whether further areas should be included in the field of application of this article. The evaluation will also assess which devices are most effective and acceptable for employees.

Article 15,  
paragraph 2b

The rules shall enter into force two years after their publication in the Official Journal of the European Union;"

## PROCEDURE

<b>Title</b>	Protecting European healthcare workers from blood borne infections due to needlestick injuries
<b>Procedure number</b>	2006/2015(INI)
<b>Committee responsible</b>	EMPL
<b>Date authorisation announced in plenary</b> <b>Rule 45</b> Rule 39	19.1.2006 19.1.2006
<b>Committee(s) asked for opinion(s)</b> Date announced in plenary	ENVI 19.1.2006
<b>Not delivering opinion(s)</b> Date of decision	ENVI 28.3.2006
<b>Enhanced cooperation</b> Date announced in plenary	
<b>Rapporteur(s)</b> Date appointed	Stephen Hughes 27.10.2005
<b>Previous rapporteur(s)</b>	
<b>Discussed in committee</b>	21.3.2006, 19.4.2006
<b>Date adopted</b>	20.4.2006
<b>Result of final vote</b>	+ 27 - 4 0 0
<b>Members present for the final vote</b>	Jan Andersson, Roselyne Bachelot-Narquin, Jean-Luc Bennahmias, Milan Cabrnach, Alejandro Cercas, Ole Christensen, Derek Roland Clark, Jean Louis Cottigny, Proinsias De Rossa, Harald Ettl, Carlo Fatuzzo, Joel Hasse Ferreira, Stephen Hughes, Karin Jöns, Jan Jerzy Kułakowski, Sepp Kusstatscher, Bernard Lehideux, Elizabeth Lynne, Thomas Mann, Mario Mantovani, Ana Mato Adrover, Maria Matsouka, Marie Panayotopoulos-Cassiotou, Pier Antonio Panzeri, Jacek Protasiewicz, José Albino Silva Peneda, Kathy Sinnott, Jean Spautz
<b>Substitute(s) present for the final vote</b>	Edit Bauer, Françoise Castex, Marian Harkin, Anne E. Jensen, Jamila Madeira, Leopold Józef Rutowicz, Elisabeth Schroedter, Evangelia Tzampazi, Yannick Vaugrenard, Anja Weisgerber
<b>Substitute(s) under Rule 178(2) present for the final vote</b>	
<b>Date tabled</b>	25.4.2006
<b>Comments (available in one language only)</b>	...