



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 24 February 2010**

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ADD 1**

**SOC 133  
DEVGEN 56  
PHARM 9  
SAN 34**

**ADDENDUM TO THE REPORT**

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from: Permanent Representatives Committee (Part I)  
to: COUNCIL (EPSCO)

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No. Cion prop.: 15305/09 SOC 643 DEVGEN 302 PHARM 20 SAN 292 - COM(2009) 577 final

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Subject: Proposal for a Council Directive implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU  
- Political agreement

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Delegations will find attached the text of the proposal as it stands following the meeting of the Committee of the Permanent Representatives on 17 February 2010.

Proposal for a  
**COUNCIL DIRECTIVE**  
**implementing the Framework Agreement on prevention from sharp injuries in the hospital  
and healthcare sector concluded by HOSPEEM and EPSU**  
**(text with EEA relevance)**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 155(2) thereof,

Having regard to the proposal from the Commission<sup>1</sup>,

Whereas:

- (1) The social partners may, in accordance with Article 155(2) of the Treaty on the Functioning of the European Union (TFEU), jointly request that agreements concluded by them at Union level in matters covered by Article 153 (TFEU) be implemented by a Council decision on a proposal from the Commission.
- (2) By letter of 17 November 2008, the European social partner organisations HOSPEEM (European Hospital and Healthcare Employers' Association, a sectoral organisation representing employers) and EPSU (European Federation of Public Services Unions, a European trade union organisation) informed the Commission of their wish to enter into negotiations in accordance with Article 138(4) and Article 139 of the Treaty establishing the European Community (the "EC Treaty")<sup>2</sup> with a view to concluding a Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector.
- (3) On 17 July 2009 the European social partners signed the text of a Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector.

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<sup>1</sup> OJ C, p.

<sup>2</sup> Renumbered: Articles 154(4) and 155 of the TFUE.

- (4) Since the objectives of the action to be taken, namely to achieve the safest possible working environment by preventing injuries to workers caused by all medical sharps (including needle-sticks) and protecting workers at risk in the hospital and healthcare sector, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.
- (5) When drafting its proposal for a Directive, the Commission took account of the representativeness of the signatory parties, having regard to the scope of the Agreement, for the hospital and healthcare sector, their mandate and the legality of the clauses in the Framework Agreement and its compliance with the relevant provisions concerning small and medium-sized undertakings.
- (6) The Commission informed the European Parliament and the European Economic and Social Committee of its proposal.
- (6a) The European Parliament adopted on 11 February 2010 a resolution on the proposal.
- (7) The purpose of the Framework Agreement as set out in Clause 1 thereof is to further the achievement of one of the objectives of social policy, namely the improvement of working conditions.
- (8) Clause 11 allows the Member States and the Community (since 1 December 2009 replaced by the Union) to maintain and introduce provisions which are more favourable to workers' protection from injuries caused by medical sharps.

- (9) The Member States should provide for effective, proportionate and dissuasive penalties in the event of any breach of the obligations under this Directive.
- (10) The Member States may entrust the social partners, at their joint request, with the implementation of this Directive, as long as they take all the steps necessary to ensure that they can at all times guarantee the results imposed by this Directive.
- (11) In accordance with point 34 of the Interinstitutional Agreement on better law-making, Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables which will, as far as possible, illustrate the correlation between this Directive and the transposition measures, and to make them public.

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

This Directive implements the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector signed by the European social partners HOSPEEM and EPSU on 17 July 2009, as set out in the Annex.

*Article 2*

Member States shall determine what penalties are applicable when national provisions enacted pursuant to this Directive are infringed. The penalties shall be effective, proportionate and dissuasive.

*Article 3*

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive or shall ensure that the social partners have introduced the necessary measures by agreement by [three years after adoption] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When the Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The Member States shall determine how such reference is to be made.

2. [deleted]
3. The Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 4*

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

*Article 5*

This Directive is addressed to the Member States.

Done at ....., [...]

*For the Council*

*The President*

[...]

## ANNEX

### FRAMEWORK AGREEMENT ON PREVENTION FROM SHARP INJURIES IN THE HOSPITAL AND HEALTHCARE SECTOR

#### **Preamble:**

1. Health and safety at work is an issue, which should be important to everyone in the hospital and healthcare sector. Taking action to prevent and protect against unnecessary injuries if properly carried out, will have a positive effect on resources;
2. Health and safety of workers is paramount and is closely linked to the health of patients. This underpins the quality of care;
3. The process of policy making and implementation in relation to medical sharps should be the result of social dialogue;
4. HOSPEEM (*European Hospital and Healthcare Employers' Association*) and EPSU (*European Public Services Union*), the recognized European Social partners in the hospital and healthcare sector, have agreed the following:

#### **General Considerations:**

1. Having regard to the Treaty establishing the European Community and in particular Articles 138 and 139 (2) thereof<sup>3</sup>;
2. 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>4</sup>;

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<sup>3</sup> Renumbered: Articles 154 and 155(2) of the TFUE.

<sup>4</sup> OJ L 183, 29.6.1989. p. 1.

3. 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>5</sup>;
4. 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>6</sup>;
5. Having regard to the Community strategy 2007-2012 on health and safety at work<sup>7</sup>;
6. Having regard to the Directive 2002/14/EC of the European Parliament and of the Council of 11 March 2002 establishing a general framework for informing and consulting employees in the European Community<sup>8</sup>;
7. Having regard to the resolution of the European Parliament of 6 July 2006 on protecting European healthcare workers from blood-borne infections due to needlestick injuries (2006/2015(INI));
8. Having regard to the first and second stage consultation of the European Commission on protecting European healthcare workers from blood-borne infections due to needlestick injuries;
9. Having regard to the outcomes of the EPSU-HOSPEEM technical seminar on needlestick injuries of 7 February 2008;
10. Having regard to the hierarchy of general principles of prevention laid down in Article 6 of Council Directive 89/391/EEC as well as to the preventative measures defined in articles 3, 5 and 6 of Directive 2000/54/EC;

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<sup>5</sup> OJ L 393, 30.12.1990, p. 13. Subsequently the Directive has been codified into Directive 2009/104/EC, OJ L 260 of 3.10.2009, p. 5–19.

<sup>6</sup> OJ L 262, 17.10.2000, p. 21.

<sup>7</sup> COM(2007) 62 final, 21.2.2007.

<sup>8</sup> OJ L 80, 23.3.2002, pp. 29–34.

11. Having regard to the joint ILO/WHO guidelines on health services and HIV/AIDS and to the joint ILO/WHO guidelines on post-exposure prophylaxis to prevent HIV infection;
12. With full respect to existing national legislation and collective agreements;
13. Whereas action needs to be taken to assess the extent of the incidence of sharp injuries in the hospital and healthcare sector, scientific evidence shows that preventive and protection measures can significantly reduce the occurrence of accidents and infections;
14. Whereas a full risk assessment process is a precondition to take appropriate action to prevent injuries and infections;
15. Whereas the employers, and workers' health and safety representatives need to cooperate to prevent and protect workers against injuries and infections from medical sharps;
16. Whereas healthcare workers are primarily but not exclusively concerned by sharp injuries;
17. Whereas students undertaking clinical training, as part of their education, are not considered as workers under this agreement, they should be covered by the prevention and protection measures outlined in this agreement, with liabilities being regulated according to national legislation and practice;

### **Clause 1: Purpose**

The purpose of this framework agreement is:

- To achieve the safest possible working environment;
- To prevent workers' injuries caused by all medical sharps (including needlesticks);
- To protect workers at risk;
- To set up an integrated approach establishing policies in risk assessment, risk prevention, training, information, awareness raising and monitoring;
- To put in place response and follow-up procedures;



## Clause 2: Scope

This agreement applies to all workers in the hospital and healthcare sector, and all who are under the managerial authority and supervision of the employers. Employers should deploy efforts to ensure that subcontractors follow the provisions laid down in this agreement.

## Clause 3: Definitions

Within the meaning of this agreement:

1. Workers: any persons employed by an employer including trainees and apprentices in the hospital and healthcare sector-directly related services and activities. Workers who are employed by temporary employment business within the meaning of Council Directive 91/383/EC supplementing the measures to encourage improvements in the safety and health at work of workers with fixed-duration employment relationship or a temporary employment relationship<sup>9</sup> fall within the scope of the agreement.
2. Workplaces covered: healthcare organisations/services in public and private sectors, and every other place where health services/activities are undertaken and delivered, under the managerial authority and supervision of the employer.
3. Employers: natural/legal persons/organisations having an employment relationship with workers. They are responsible for managing, organising and providing healthcare and directly related services/activities delivered by workers.
4. Sharps: objects or instruments necessary for the exercise of specific healthcare activities, which are able to cut, prick, cause injury and/or infection. Sharps are considered as work equipment within the meaning of Directive 89/655/EEC on work equipment.

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<sup>9</sup> OJ L 183, 29.6.1989, p. 1.

5. Hierarchy of measures: is defined in order of effectiveness to avoid, eliminate and reduce risks as defined in article 6 of Directive 89/391/EEC and articles 3, 5 and 6 of Directive 2000/54/EC.
6. Specific preventative measures: measures taken to prevent injury and/or transmission of infection in the provision of hospital and healthcare directly related services and activities, including the use of the safest equipment needed, based on the risk assessment and safe methods of handling the disposal of medical sharps.
7. Workers' representatives: any person elected, chosen or designated in accordance with national law and/or practice to represent workers.
8. Worker's health and safety representatives are defined in accordance with Article 3(c) of Directive 89/391/EEC as any person elected, chosen or designated in accordance with national law and/or practices to represent workers where problems arise relating to the safety and health protection of workers at work.
9. Subcontractor: any person who takes action in hospital and healthcare directly related services and activities within the framework of working contractual relations established with the employer.

#### **Clause 4: Principles**

1. A well trained, adequately resourced and secure health service workforce is essential to prevent the risk of injuries and infections from medical sharps. Exposure prevention is the key strategy for eliminating and minimizing the risk of occupationally acquired injuries or infections.
2. The role of health and safety representatives is key in risk prevention and protection.
3. The employer has a duty to ensure the safety and health of workers in every aspect related to the work, including psycho-social factors and work organisation.

4. It shall be the responsibility of each worker to take care - as far as possible - of their own safety and health and that of other persons affected by their actions at work, in accordance with their training and the instructions given by their employer.
5. The employer shall develop an environment where workers and their representatives are participating in the development of health and safety policies and practices.
6. The principle of the following specific preventative measures indicated in clauses 5 - 10 of the present agreement means never assuming that there is no risk. The hierarchy of general principles of prevention according to article 6 of Directive 89/391/EEC and articles 3, 5 and 6 of Directive 2000/54/EC is applicable.
7. Employers and workers' representatives shall work together at the appropriate level to eliminate and prevent risks, protect workers' health and safety, and create a safe working environment, including consultation on the choice and use of safe equipment, identifying how best to carry out training, information and awareness-raising processes.
8. Action needs to be taken through a process of information and consultation, in accordance with national laws and/or collective agreements.
9. The effectiveness of awareness-raising measures entails shared obligations of the employers, the workers and their representatives.
10. In achieving the safest possible workplace a combination of planning, awareness-raising, information, training, prevention and monitoring measures is essential.
11. Promote a "no blame" culture. Incident reporting procedure should focus on systemic factors rather than individual mistakes. Systematic reporting must be considered as accepted procedure.

## **Clause 5: Risk Assessment**

1. Risk assessment procedures shall be conducted in compliance with articles 3 and 6 of Directive 2000/54/EC, and Articles 6 and 9 of Directive 89/391/EEC.
2. Risk assessment shall include an exposure determination, understanding the importance of a well resourced and organised working environment and shall cover all situations where there is injury, blood or other potentially infectious material.
3. Risk assessments shall take into account technology, organisation of work, working conditions, level of qualifications, work related psycho-social factors and the influence of factors related to the working environment. This will:
  - Identify how exposure could be eliminated;
  - Consider possible alternative systems;

## **Clause 6: Elimination, prevention and protection**

1. Where the results of the risk assessment reveal a risk of injuries with a sharp and/or infection, workers' exposure must be eliminated by taking the following measures, without prejudice to their order:
  - Specifying and implementing safe procedures for using and disposing of sharp medical instruments and contaminated waste. These procedures shall be regularly reassessed and shall form an integral part of the measures for the information and training of workers referred in clause 8;
  - Eliminating the unnecessary use of sharps by implementing changes in practice and on the basis of the results of the risk assessment, providing medical devices incorporating safety-engineered protection mechanisms;
  - The practice of recapping shall be banned with immediate effect;

2. Having regard to the activity and the risk assessment, the risk of exposure must be reduced to as low a level as necessary in order to protect adequately the safety and health of the workers concerned. The following measures are to be applied in the light of the results of the risk assessment:
  - Place effective disposal procedures and clearly marked and technically safe containers for the handling of disposable sharps and injection equipment as close as possible to the assessed areas where sharps are being used or to be found;
  - Prevent the risk of infections by implementing safe systems of work, by:
    - a. Developing a coherent overall prevention policy, which covers technology, organisation of work, working conditions, work related psycho-social factors and the influence of factors related to the working environment;
    - b. Training;
    - c. Conducting health surveillance procedures, in compliance with article 14 of Directive 2000/54/EC;
  - Use of personal protective equipment;
3. If the assessment referred to in clause 5 reveals that there is a risk to the safety and health of workers due to their exposure to biological agents for which effective vaccines exist, workers shall be offered vaccination.
4. Vaccination and, if necessary, revaccination shall be carried out in accordance with national law and/or practice, including the determination of the type of vaccines.
  - Workers shall be informed of the benefits and drawbacks of both vaccination and non-vaccination;
  - Vaccination must be offered free of charge to all workers and students delivering healthcare and related activities at the workplace;

## **Clause 7: Information and awareness-raising**

As sharps are considered as work equipment within the meaning of Directive 89/655/EC<sup>10</sup>, in addition to information and written instructions to be provided to workers specified in article 6 of Directive 89/655/EC, the employer shall take the following appropriate measures:

- To highlight the different risks;
- To give guidance on existing legislation;
- To promote good practices regarding the prevention and recording of incidents/accidents;
- To raise awareness by developing activities and promotional materials in partnership with representative trade unions and/or workers' representatives;
- To provide information on support programmes available;

## **Clause 8: Training**

In addition to measures established by article 9 of Directive 2000/54/EC, appropriate training shall be made available on policies and procedures associated with sharps injuries, including:

- The correct use of medical devices incorporating sharps protection mechanisms;
- Induction for all new and temporary staff;
- The risk associated with blood and body fluid exposures;
- Preventive measures including standard precautions, safe systems of work, the correct use and disposal procedures, the importance of immunisation, according to the procedures at the workplace;
- The reporting, response and monitoring procedures and their importance;
- Measures to be taken in case of injuries;

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<sup>10</sup> Subsequently the Directive has been codified into Directive 2009/104/EC.

Employers must organise and provide training which is mandatory for workers. Employers must release workers who are required to attend training. This training shall be made available on a regular basis taking into account results of monitoring, modernisation and improvements.

### **Clause 9: Reporting**

1. This includes the revision of the reporting procedures in place with health and safety representatives and/or appropriate employers/workers representatives. Reporting mechanisms should include local, national and European wide systems.
2. Workers shall immediately report any accident or incident involving sharps to the employers and/or the person in charge, and/or to the person responsible for safety and health at work.

### **Clause 10: Response and Follow-up**

Policies and procedures shall be in place where a sharp injury occurs. All workers must be made aware of these policies and procedures. These should be in accordance with European, national/regional legislation and collective agreements, as appropriate.

In particular the following action shall be taken:

- The employer takes the immediate steps for the care of the injured worker, including the provision of post-exposure prophylaxis and the necessary medical tests where indicated for medical reasons, and appropriate health surveillance in accordance with clause 6 §2,c
- The employer investigates the causes and circumstances and records the accident/incident, taking -where appropriate- the necessary action. The worker must provide the relevant information at the appropriate time to complete the details of the accident or incident;
- The employer shall, in cases of injury, consider the following steps including counselling of workers where appropriate and guaranteed medical treatment. Rehabilitation, continued employment and access to compensation shall be in accordance with national and/or sectoral agreements or legislation;

Confidentiality of injury, diagnosis and treatment is paramount and must be respected;

### **Clause 11: Implementation**

This agreement will be without prejudice to existing, future national and Community<sup>11</sup> provisions which are more favourable to workers' protection from medical sharps' injuries.

The signatory parties request the Commission to submit this framework agreement to the Council for a decision in order to make this agreement binding in the member states of the European Union. If implemented through Council decision, at European level and without prejudice to the respective role of the Commission, national courts and the European Court of Justice, the interpretation of this agreement, could be referred by the Commission to the signatory parties who will give their opinion.

The signatory parties shall review the application of this agreement five years after the date of the Council decision if requested by one of the parties to the agreement.

Brussels, 17 July 2009

For EPSU: Karen Jennings – For HOSPEEM: Godfrey Perera

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<sup>11</sup> "Community" has been replaced since 1 December 2009 by "Union".