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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.10.2009
COM(2009) 577 final

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Grounds for and objectives of this proposal

The aim of the proposal is to give legal effect to the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector, signed on 17 July 2009 by HOSPEEM (European Hospital and Healthcare Employers' Association) and EPSU (European Federation of Public Services Unions). These two bodies were recognised as European social partners in the hospital and healthcare sector by the Commission in 2006 in accordance with Article 138 of the EC Treaty.

The Framework Agreement (hereinafter 'the Agreement') aims to protect workers at risk of injury from all medical 'sharps' (including needle-sticks) and to prevent the risk of injuries and infections caused by medical sharps. It provides for an integrated approach to risk assessment, risk prevention, training, information, awareness-raising and monitoring and for response and follow-up procedures. The Agreement and this proposal will contribute to achieving the safest possible working environment in the hospital and healthcare sector.

1.2. General context

Injuries caused by needles and other sharp instruments are one of the most common and serious risks to healthcare workers in Europe and represent a high cost for health systems and society in general.

It is recognised that hospital and healthcare workers (nurses, doctors, surgeons, etc.), particularly in certain departments and activities (emergencies, intensive care, surgical operations, etc.), frequently risk infection due to injuries caused by needles or other sharp instruments (scalpels, suture equipment, etc.). The consequences may be very serious, possibly leading to serious diseases such as viral hepatitis or AIDS.

Some studies estimate the number of needle-stick injuries at approximately 1 200 000 per year in Europe.

In the Community strategy 2007-2012 on health and safety at work¹, the Commission announced its intention of continuing its work, through consultation of the European social partners as provided for in Article 139 of the EC Treaty, on ways of improving risk prevention with regard to needle-stick infections, among others.

On several occasions, the European Parliament has expressed concern at the life-threatening risks faced by healthcare workers from contaminated needles.

¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions 'Improving quality and productivity at work: Community strategy 2007-2012 on health and safety at work' (COM(2007) 62 final, 21 February 2007), point 4.3.

In its resolution of 24 February 2005 on promoting health and safety at the workplace², Parliament called for revision of Directive 2000/54/EC specifically to address the risk of working with needles and medical sharps.

On 6 July 2006 the European Parliament adopted a resolution³ on protecting European healthcare workers from blood-borne infections due to needle-stick injuries. The resolution called on the Commission to submit a legislative proposal on the basis of Articles 137 and 251 of the EC Treaty for a directive amending Directive 2000/54/EC⁴ on biological agents at work.

Under Article 138(1) of the EC Treaty, the Commission has the task of promoting the consultation of management and labour at Community level and is to take any relevant measure to facilitate their dialogue by ensuring balanced support for the parties. To this end, before submitting proposals in the social policy field, the Commission has to consult management and labour (i.e. the European social partners) on the possible direction of EU action and the content of the envisaged proposal. Furthermore, Article 138(4) of the EC Treaty provides that management and labour may inform the Commission of their wish to initiate the process provided for in Article 139 of the EC Treaty, i.e. dialogue between them at Community level, which may lead to contractual relations, including agreements.

On 21 December 2006 the Commission launched the first stage in the consultation of the European social partners. The second stage was launched on 20 December 2007.

The consultation documents called on the European social partners to: (1) forward an opinion on the objectives and content of the legislative and non-legislative initiatives envisaged; (2) notify the Commission if they intend to initiate negotiations, in accordance with Article 138(4) and Article 139 of the EC Treaty.

By joint letter of 17 November 2008, EPSU and HOSPEEM informed the Commission of their intention of negotiating a framework agreement on the prevention from sharp injuries in the hospital and healthcare sector.

As the Commission fully recognises the negotiating autonomy of the European social partners on topics falling within their competence, the preparation of the legislative proposal for a directive amending Directive 2000/54/EC on biological agents at work was consequently suspended pending the outcome of the negotiations between the social partners.

On 2 June 2009, the European social partners agreed on the Agreement.

On 17 July 2009, EPSU and HOSPEEM signed the Agreement and informed the Commission of their request to submit the Agreement to the Council for a Council decision, in accordance with Article 139(2) of the EC Treaty.

² European Parliament resolution of 24 February 2005 on promoting health and safety at the workplace (2004/2205(INI)), OJ C 304 E, 1.12.2005, p. 400.

³ European Parliament resolution of 6 July 2006 with recommendations to the Commission on protecting European healthcare workers from blood-borne infections due to needle-stick injuries (2006/2015(INI)), OJ C 303 E, 13.12.2006, p. 754.

⁴ 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 (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L 262, 17.10.2000, p. 21.

1.3. Existing provisions on issues relating to the proposal

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 work⁵ lays down general preventive measures to protect the health and safety of workers. It sets out minimum requirements concerning, among other things, risk assessment and the informing, training and consulting of workers. In particular, Article 6 of the Directive sets out general principles of prevention, namely ‘avoiding risks’, ‘combating risks at source’ and ‘replacing what is dangerous with what is not dangerous or with what is less dangerous’. In addition to Directive 89/391/EEC, some of its individual directives also apply to the prevention of infection risks among staff in the healthcare sector:

(a) 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 (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)⁶ contains provisions aimed at preventing these risks and lays down specific minimum requirements in this area. It establishes employers’ obligations concerning risk prevention. In particular, for any activity likely to present a risk of exposure to biological agents, the nature, degree and duration of exposure for workers must be determined in order to assess any risk to the health and safety of workers and to determine the measures to be taken.

(b) The aim of 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 (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)⁷ (as amended by Directives 95/63/EC⁸ and 2001/45/EC⁹) is to improve safety for workers using work equipment, such as medical equipment used in hospitals. Employers must choose work equipment in accordance with working conditions and the risks to workers so as to eliminate or minimise these risks.

(c) Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)¹⁰ states that the use of personal protective equipment is required where risks cannot be avoided or sufficiently limited by technical means of collective protection or by work organisation methods or procedures. All personal protective equipment must be appropriate to the risks involved, without itself leading to any increased risk. It must correspond to prevailing conditions at the workplace and be adapted to the person wearing it.

⁵ OJ L 183, 29.6.1989, p. 1.

⁶ OJ L 262, 17.10.2000, p. 21.

⁷ OJ L 393, 30.12.1989, p. 13.

⁸ Council Directive 95/63/EC of 5 December 1995 amending 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), OJ L 335, 30.12.1995, p. 28.

⁹ Directive 2001/45/EC of the European Parliament and of the Council of 27 June 2001 amending 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), OJ L 195, 19.7.2001, p. 46.

¹⁰ OJ L 393, 30.12.1989, p. 18.

It should also be noted that Annex I, Part II, to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices¹¹ stipulates that ‘the devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use’ (point 8.1). Any device placed on the market must also have received the CE mark, attesting its conformity with the essential requirements of that Directive.

1.4. Consistency with other policies and objectives of the Union

The aim of this proposal is consistent with EU policies and objectives.

Promoting a safe and healthy working environment and accordingly reducing the economic costs of health and safety problems at work contributes to achieving the overall goals of the Lisbon Strategy for Growth and Jobs, namely economic growth and employment.

Further, the Renewed Social Agenda ‘Opportunities, access and solidarity in 21st century Europe’¹² states that the EU health workforce is a vital component in delivering high-quality health services.

The envisaged action is in line with EU public health policy. The White Paper ‘Together for Health: A Strategic Approach for the EU 2008-2013’¹³ stresses that patient safety is a key area of concern. Any measure to protect the health and safety of workers in the healthcare sector contributes to the quality of services delivered to patients and reduces the possibility of patients experiencing adverse effects from their healthcare.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

2.1. Consultation

Following the resolution of the European Parliament of 6 July 2006 calling on the Commission to submit a legislative proposal on the basis of Articles 137 and 251 of the EC Treaty for a directive amending Directive 2000/54/EC on biological agents at work, the Commission launched a two-stage consultation of the European social partners in accordance with Article 138 of the EC Treaty¹⁴.

The first stage of the consultation process was launched on 21 December 2006 on the possible direction of Community action to strengthen the protection of European healthcare workers from blood-borne infections due to needle-stick injuries. The social partners were also asked whether they would consider a joint voluntary initiative under Article 139 of the EC Treaty.

¹¹ OJ L 169, 12.7.1993, p. 1.

¹² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions ‘Renewed social agenda: Opportunities, access and solidarity in 21st century Europe’ (COM(2008) 412 final of 2 July 2008), p. 12.

¹³ COM(2007) 630 final of 23 October 2007, pp. 8–9.

¹⁴ <http://ec.europa.eu/social/keyDocuments.jsp?type=50&policyArea=0&subCategory=0&country=0&year=2006&advSearchKey=&mode=advancedSubmit&langId=en> and <http://ec.europa.eu/social/keyDocuments.jsp?pager.offset=10&langId=en&mode=advancedSubmit&policyArea=0&subCategory=0&year=2007&country=0&type=50>.

On 20 December 2007, the second stage of the consultation process was launched on the substance of the envisaged Community action.

On the whole, the workers' organisations considered that while the existing legislation covered the risks in general terms, more specific legislation would reinforce worker protection, so were in favour of a Community initiative in the form of legislation.

The employers' organisations, however, considered that the existing legislation already afforded appropriate protection and were unanimously opposed to any Community initiative in the form of legislation.

As regards the possible negotiation of an agreement between the European social partners under Article 139 of the EC Treaty, most of the employers' and workers' organisations did not rule out the possibility of negotiating a sectoral agreement (in the hospital sector in particular). Further to the consultation, EPSU and HOSPEEM, the main umbrella organisations representing employers' and workers' organisations, informed the Commission that they could consider the possibility of starting negotiations on the issue with a view to a possible agreement.

2.2. Collection and use of expertise

External expertise on the problem of needle-stick injuries in the EU and the likely impact of possible policy options was gathered through a study carried out by an external consultant selected by the Commission after an open call for tenders. The purpose of the study was to conduct an in-depth analysis of the socio-economic, health and environmental impact of a possible Community initiative on the protection of EU healthcare workers from blood-borne infections due to needle-stick injuries and other sharp objects and instruments.

On 7 February 2008, the European social partners held a technical seminar with scholars, healthcare workers and employers (professors, surgeons, doctors and nurses), who presented a wide range of case studies and statistics. The seminar provided an opportunity for the exchange of good practice and data on healthcare injuries. It addressed the various types of exposures (cutaneous, mucous and non-intact skin) and the related occupational infections (bacterial, viral, protozoan, fungal and tumoral). It also reviewed all the causes of injuries (syringes, butterflies, lancets and catheters) and the prevalence of each. This clearly confirmed that the remit for occupational risks to be tackled in the hospital sector should cover all types of injuries caused by medical sharps, including needle-sticks. The European social partners accordingly informed the Commission of their intention to launch negotiations.

2.3. Impact assessment

The Commission has not prepared a specific impact assessment on this proposal, as it is not required to do so when it proposes to give legal effect to an agreement between social partners in accordance with Article 139(2) of the EC Treaty.

3. LEGAL ASPECTS OF THE PROPOSAL

3.1. Legal basis

The proposal is based on Article 139(2) of the EC Treaty.

Article 139(2) of the EC Treaty provides that agreements concluded by the European social partners at Community level in matters covered by Article 137 of the EC Treaty are to be implemented ‘at the joint request of the signatory parties, by a Council decision on a proposal from the Commission’. It goes on to say that ‘The Council shall act by qualified majority, except where the agreement in question contains one or more provisions relating to one of the areas for which unanimity is required pursuant to Article 137(2). In that case it shall act unanimously.’

The objective of the Agreement concluded by HOSPEEM and EPSU is 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. It thus aims to ensure ‘improvement in particular of the working environment to protect workers’ health and safety’, an area governed by Article 137 of the EC Treaty, in which the Council can decide by qualified majority. Article 139(2) of the EC Treaty is hence the appropriate legal basis for the Commission proposal.

Article 139(2) of the EC Treaty does not provide for Parliament’s involvement in the legislative procedure. However, in line with previous commitments, the Commission will inform Parliament of its proposal so that it can, where it so desires, send an opinion to the Commission and the Council. The same applies to the European Economic and Social Committee.

3.2. Analysis of the Agreement

According to the Commission Communication¹⁵ laying down the rules for implementing agreements under Article 139 of the EC Treaty, ‘the Commission will prepare proposals for decisions to the Council following consideration of the representative status of the contracting parties, their mandate and the “legality” of each clause in the collective agreement in relation to Community law, and the provisions regarding small and medium-sized undertakings set out in Article [137(2)(b) of the EC Treaty].’ This *ex-ante* assessment is set out below.

3.2.1. Representativeness of the signatory parties and their mandate

The European social partners’ ability to be consulted and to negotiate agreements depends on their representativeness. One of the criteria defining that ability in Commission Decision 98/500/EC of 20 May 1998 on the establishment of Sectoral Dialogue Committees promoting the Dialogue between the social partners at European level¹⁶ states that they ‘shall consist of organisations which are themselves an integral and recognised part of Member States’ social partner structures and have the capacity to negotiate agreements, and which are representative of several Member States.’

3.2.1.1 Representativeness of EPSU and HOSPEEM in the public and private parts of the hospital and healthcare sector

In 2008 the Commission launched a study (published on 29 May 2009) on the representativeness of the EU social partners in the hospital sector¹⁷. It states that ‘the vast majority of the sector’s employees work in public hospitals’. Nonetheless, HOSPEEM and

¹⁵ Commission Communication concerning the application of the Agreement on social policy (COM(93) 600 final of 14 December 1993).

¹⁶ OJ L 225, 12.8.1998, p. 27.

¹⁷ <http://www.eurofound.europa.eu/docs/eiro/tn0802017s/tn0802017s.pdf>.

EPSU represent both parts of the hospital and healthcare sector. Indeed, when the hospital social dialogue committee was being set up in 2006, the Commission ensured that the private part of the sector was also represented on the employers' side through the signing of a cooperation agreement between HOSPEEM and HOPE (*European Hospital and Healthcare Federation*). HOPE represents national public and private hospital associations and hospital owners, comprising federations of local and regional authorities and national health services with 10 affiliations in seven countries. Through this cooperation agreement, HOPE has given a specific mandate to HOSPEEM in European social dialogue activities.

On the workers' side, EPSU covers all the Member States and its membership is open to all trade unions, whether they operate in the private, public or non-profit areas. Most unions affiliated with EPSU organise workers throughout the whole of the healthcare sector: these may be general services unions (such as Unison, Ver.di and Abvakabo FNV) or general healthcare/social services unions (such as CGT Santé-Sociaux and EDDSZ). EPSU also includes a large number of professional unions (such as DNO, RCM and Marburger Bund) among its members. These unions all organise both privately and publicly employed workers in the healthcare sector. In countries where public-sector and private-sector healthcare workers come under different trade unions, EPSU in general represents both the public-sector and the private-sector unions (e.g. Belgium and Austria). Lastly, EPSU also includes organisations that act solely in the private sector.

3.2.1.2 Representativeness of HOSPEEM and EPSU in the hospital and healthcare sector

At the time the European social dialogue committee for hospitals was set up in 2006, the Commission assessed the representativeness of EPSU and HOSPEEM, which clearly stated that they represented public, private and non-profit hospitals and hospital associations, which form an integral part of healthcare delivery and provide such services as accommodation, meals, nursing care, medical treatment and rehabilitation of patients, while medical therapy is administered by professional physicians. The designations of most of their national affiliate members also demonstrate that the European social partners are representative of the healthcare sector. Lastly, the representativeness study highlighted the multi-sectoral dimensions of HOSPEEM and EPSU (with HOSPEEM stemming from CEEP, recognised as a cross-industry European social partner representing public employers).

Both EPSU and HOSPEEM cover countries outside the EU.

EPSU covers all of the 27 Member States. EPSU brings together the largest national trade unions in the sector and represents the majority of its unionised employees. All national affiliates of EPSU are involved in bargaining or 'quasi-bargaining', i.e. de facto negotiations or consultation.

HOSPEEM (including HOPE) covers a total of 16 Member States (AT, BE, CZ, DE, DK, EE, FR, IE, IT, LU, LV, NL, PL, SE, SK and UK) (no employers' association exists in six of the 11 Member States not covered). According to the study, HOSPEEM covers far more countries than any other European association.

3.2.1.3 Activities covered by the European social partners

According to the information provided by EPSU and HOSPEEM, the European social partners cover activities in the range Q86 to Q88 (NACE codes), which include *Human health activities, Hospital activities, Medical and dental practice activities, General medical practice*

activities, Specialist medical practice activities, Residential care activities, Residential nursing care activities, Residential care activities for mental retardation, mental health and substance abuse, Residential care activities for the elderly and disabled, Other residential care activities, Social work activities without accommodation for the elderly and disabled, Other social work activities without accommodation, Child day-care activities, Other social work activities without accommodation.

3.2.1.4 Capacity to negotiate

One of the criteria for representativeness at European level is the capacity of European social partners to negotiate on behalf of their members. The Commission assessed this negotiating capacity in 2006 when social dialogue was set up in the hospital sector. The representativeness study states that EPSU has a mandate to negotiate on matters concerning European social dialogue in accordance with its constitution. HOSPEEM also has a mandate to negotiate on behalf of its members in matters concerning European social dialogue.

In conclusion, the signatories to the Agreement have sufficient representative status with regard to the hospital and healthcare sector in general and the workers who may be covered by it. Therefore all the conditions for representativeness of the signatories are met.

3.2.2. Legality of the clauses in the Agreement

The Commission has scrutinised all the clauses in the Agreement and has found none to contravene Community law.

The substance of the Agreement falls within the scope of Article 137(1)(a) of the EC Treaty (improvement of the working environment to protect workers' health and safety).

The Agreement contains a 'minimum standards' clause, which states that the Agreement is without prejudice to existing or future national and Community provisions that are more favourable to workers' protection from injuries caused by medical sharps (Clause 11).

The Commission therefore considers that the Agreement meets the condition of legality.

3.2.3. Provisions regarding small and medium-sized enterprises

Under Article 137(2) of the EC Treaty, legislation in the social field must 'avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings'.

Although there are no specific clauses in the Agreement setting out specific arrangements for SMEs, no clause appears to impose inappropriate burdens on SMEs.

3.3. Subsidiarity and proportionality

The aim of this proposal is 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 at European level. Thus, action taken by the Member States alone cannot suffice to achieve an EU-wide minimum level of protection against medical sharps, which can therefore be better achieved by action at Community level. Both the European social partners and the Commission are convinced of the need for Community action in this area.

The fact that the substantive provisions of the Agreement incorporated in the proposal were drafted by the legitimate representatives of workers and employers acting at EU level (i.e. those most concerned by the various measures on the ground) is another guarantee of respect for the principle of subsidiarity.

As for proportionality, the proposal goes no further than necessary in ensuring that the objectives are met. The Member States and the Community have a degree of latitude in maintaining or adopting provisions that are more favourable to workers' protection from injuries caused by medical sharps (Clause 11). It should also be noted that the Agreement is termed a 'framework' Agreement.

The proposal, which is taken at the right level and does not go further than absolutely necessary to achieve the objectives at EU level, therefore complies with the principles of subsidiarity and proportionality.

3.4. Choice of instrument

The term 'Council decision' in Article 139(2) of the EC Treaty is to be understood in its general meaning as referring to the legally binding instruments provided for in Article 249 of the EC Treaty. It is for the Commission to decide and propose which of the three binding instruments (directive, regulation or decision) is most suitable. The aim of the Agreement is to establish minimum requirements which, given the type and substance of the Agreement, are best applied indirectly through provisions to be transposed into national law by the Member States and/or the social partners. The appropriate instrument is therefore a Council directive to which the Agreement is annexed.

3.5. Correlation table

The Member States are required to send the Commission the text of national provisions transposing the Directive, together with a correlation table between those provisions and the Directive.

3.6. European Economic Area

As the Agreement is relevant to the European Economic Area, the Directive will be applicable to the non-EU Member States of the European Economic Area, following a decision by the EEA Joint Committee.

4. BUDGETARY IMPLICATIONS

The proposal has no implications for the Community budget.

5. DETAILED EXPLANATION OF THE SPECIFIC PROVISIONS

5.1. Text of the Directive

Article 1

This Article will make the Agreement between the social partners, annexed to the Directive, legally binding across the European Union, which is the purpose of a Council decision adopted under Article 139(2) of the EC Treaty.

Article 2

The proposed Article is the standard Article relating to penalties. It is expected to contribute substantially to the effective implementation of the Agreement.

Articles 3, 4 and 5

These Articles set out the usual provisions on transposition into Member States' law and specific provisions regarding the possibility for transposition by way of collective bargaining.

5.2. Text of the Agreement in the Annex to the Directive

Clause 1: Purpose

This Clause lays down out the overall objective of the Agreement (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). To this end, it provides for an integrated approach, establishing policies in risk assessment, risk prevention, training, information, awareness-raising and monitoring, and for response and follow-up procedures.

Clause 2: Scope

This Clause makes it clear that the Agreement applies to all workers in the hospital and healthcare sector and to all who are under the managerial authority and supervision of the employers.

Clause 3: Definitions

The Agreement employs various terms: workers, workplaces, employers, sharps, hierarchy of measures, specific preventative measures, workers' representatives, workers' health and safety representatives and subcontractors. Clause 3 sets out the meanings of these terms for the purpose of this Agreement.

Clause 4: Principles

This Clause lays down the principles which must be observed when taking action under the Agreement.

Paragraph 1 points to the vital role of a well-trained, adequately resourced and secure health service workforce in preventing risks. It also states that preventing exposure is the key strategy for eliminating and minimising the risk of injuries and infections.

Paragraph 2 concerns the role of health and safety representatives in risk prevention and protection.

Paragraph 3 sets out the duty of the employer to ensure the health and safety of workers in every aspect relating to the work.

Paragraph 4 makes it the responsibility of each worker to take care of his or her own safety and that of other persons affected by their actions at work.

Paragraph 5 deals with the participation of workers and their representatives in the development of health and safety policy and practice.

Paragraph 6 explains that the principle of the specific preventative measures is never assuming that no risk exists. It also points to the hierarchy of measures concerning the safety and health protection of workers as set out in the relevant Community Directive, i.e. to avoid risks, to evaluate remaining risks which cannot be avoided, to combat risks at source and to reduce risks to a minimum, is applicable.

Paragraph 7 concerns collaboration between employers and workers' representatives with a view to eliminating and preventing risks, to protecting workers' health and safety and to creating a safe working environment.

Paragraph 8 recognises the need for action involving information and consultation in accordance with national law and/or collective agreements.

Paragraph 9 deals with the effectiveness of awareness-raising measures.

Paragraph 10 stresses the importance of a combination of several measures for achieving the safest possible workplace environment.

Paragraph 11 states that incident reporting procedures should focus on systemic factors rather than individual mistakes and that systematic reporting must be considered as accepted procedure.

Clause 5: Risk assessment

Paragraph 1 states that risk assessment procedures are to be conducted in compliance with the relevant provisions of Directives 2000/54/EC and 89/391/EEC.

Paragraph 2 stipulates what is to be included in risk assessments and specifies potentially hazardous situations to be covered by them.

Paragraph 3 lists the factors to be taken into account in risk assessments with a view to identifying how exposure can be eliminated and considering possible alternative systems.

Clause 6: Elimination, prevention and protection

Paragraphs 1 and 2 list several measures to be taken to eliminate the risk of injuries with a sharp and/or infection and to reduce the risk of exposure.

Paragraph 3 and 4 address situations where there is a risk to the safety and health of workers owing to their exposure to biological agents for which effective vaccines exist. Under these circumstances workers are to be offered vaccination, which is to be carried out in accordance with national law and/or practice. Furthermore, workers are to receive information on the benefits and drawbacks of vaccination and non-vaccination. Vaccination must be free of charge.

Clause 7: Information and awareness-raising

As medical sharps are considered work equipment in accordance with Directive 89/655/EEC, this Clause lays down several information and awareness-raising measures to be taken by the

employer, in addition to the provision of information and written instructions in accordance with Article 6 of that Directive.

Clause 8: Training

This Clause stipulates that workers are to receive training in certain policies and procedures associated with injuries caused by sharps, including those listed. This training is in addition to measures laid down in Article 9 ('Information and training of workers') of Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work.

The Clause also imposes various obligations on employers with regard to training and stipulates that the training is mandatory for workers.

Clause 9: Reporting

Paragraph 1 stipulates that the existing procedures for accident reporting involving injuries are to be adapted and should be revised in conjunction with health and safety representatives and/or appropriate employers and workers' representatives. Reporting procedures should include technical details with a view to improving data collection on this type of hazard (which is underestimated) at local, national and European level.

Paragraph 2 imposes an obligation on workers to report any accident or incident involving medical sharps immediately.

Clause 10: Response and Follow-up

This Clause deals with policies and procedures that are to be in place where an injury involving a sharp occurs. In particular, it specifies several steps that are to be taken, such as the provision of post-exposure prophylaxis and the necessary medical tests, appropriate health surveillance, the investigation of the causes and circumstances of the accident, the recording of the accident and the counselling of the workers.

It states that confidentiality of injury, diagnosis and treatment must be respected.

Clause 11: Implementation

This Clause lays down several provisions regarding the implementation of the Agreement.

It lays down a 'minimum standards' clause, which states that the Agreement is without prejudice to existing or future national and Community provisions which are more favourable to workers' protection from injuries caused by medical sharps.

It states that the Commission could refer the interpretation of the Agreement to the signatory parties, who will give their opinion, without prejudice to the roles of the Commission, the national courts and the European Court of Justice.

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 establishing the European Community, and in particular Article 139(2) thereof,

Having regard to the proposal from the Commission¹⁸,

Whereas:

- (1) The social partners may, in accordance with Article 139(2) of the Treaty, jointly request that agreements concluded by them at Community level in matters covered by Article 137 of the Treaty 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 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.
- (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 Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. 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

¹⁸ OJ C, p.

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.
- (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 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,

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

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive, and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission at the latest by the date specified in Article 3 and shall notify it without delay of any subsequent amendments affecting them.

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 [two years after adoption] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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. The Member States may have a maximum additional period of one year to comply with this Directive, where this is necessary to take account of particular difficulties or in case of implementation by collective agreement. They shall inform the Commission thereof by [deadline for implementation] at the latest, stating the reasons why an additional period is needed.

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 Brussels, [...]

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;
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 work¹⁹;
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 work²⁰;
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 work²¹;
5. Having regard to the Community strategy 2007-2012 on health and safety at work²²;
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 Community²³;

¹⁹ OJ L 183, 29.6.1989, p. 1.

²⁰ OJ L 393, 30.12.1990, p. 13.

²¹ OJ L 262, 17.10.2000, p. 21.

²² COM(2007) 62 final, 21.2.2007.

²³ OJ L 80, 23.3.2002, pp. 29–34.

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;
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 relationship²⁴ 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.
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.

²⁴ OJ L 183, 29.6.1989, p. 1.

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, 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;

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 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