

Health and Safety Executive Board		HSE/12/51	
Meeting Date:	27th June 2012	FOI Status:	Open with Closed Annex C
Type of Paper:	Above the line	Exemptions:	Section 22 – Intended for future publication
TRIM Reference:	2012/ 0243395		
Keywords:	Sharps, Healthcare, Consultation,		

Consultation on proposals to implement the 2010 Sharps in Healthcare Directive

1. To update the Board on the approach being taken to transposition of Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention of sharp injuries in the hospital and healthcare sector (the Sharps Directive) and seek approval to publish a Consultative Document (CD) on our proposals for new Health and Safety (Sharps in Healthcare) Regulations.

Background

2. The Sharps Directive implements a social partner Agreement (the Agreement), between the European Hospital and Healthcare Employer's association (HOSPEEM) and the European Federation of Public Services Unions (EPSU). In 2008, the Commission was preparing a proposal to amend the Biological Agents Directive to improve measures to prevent sharps injuries. The healthcare sector social partners took up their option to negotiate their own agreement instead. The process means that during the negotiation HSE did not have the usual opportunities to influence; nor was the draft Agreement subject to scrutiny procedures in either the European or UK parliaments. Previous social partner agreements on health and safety issues have remained binding only on the signatories to the agreement¹. In this case, the social partners were successful in petitioning the Council to turn it into a Directive. The UK must now ensure that we have transposed the Directive by the 11 May 2013.
3. The Sharps Directive aims to protect workers in the healthcare sector from the risks that arise from work with medical sharps (including needles and scalpels). The most significant risks arise from potential exposure to blood borne viruses (e.g. hepatitis C), but are not limited to risks of infection. The anxiety and effects of post-exposure prophylaxis² have a significant personal impact on an injured worker. There is no reliable source of data on the number of sharps injuries to healthcare workers. Studies estimate that annually there may be as many as 100,000 injuries in the UK, and a 2010 Care Quality Commission survey of NHS

¹ For example, the 2006 cross-sectorial silica dust agreement.

² Post-exposure prophylaxis assists the person's immune system to fight the virus. They are usually very strong antibiotics taken for months and have unpleasant side-effects.

staff found that 2% reported that they had suffered a needlestick injury in the previous 12 month period³.

4. The substantive requirements are contained within the social partners Agreement, which the Directive implements. The social partners intended to set out in one document an integrated approach to all the relevant requirements. These cover a) Risk Assessment, b) Elimination, Prevention and Protection c) Information and Awareness Raising d) Training e) Reporting of accidents/incidents f) Response and Follow Up.
5. The existing health and safety legislative requirements in GB and supporting guidance from HSE and health departments provide a good standard of protection for healthcare workers from exposure to blood-borne viruses, including injuries where sharps are involved⁴. As with other risks in the healthcare sector most sharps injuries arise from a lack of knowledge of widely recognised minimum standards, or failure to implement them rather than from gaps in the law (see February 2012 Board paper on the proposed strategy for health and social care). Annex A contains more detail on the existing position.
6. The Sharps Directive mostly covers the same ground as the existing legislation. In addition, it introduces new duties on employers:
 - a small number of specific control measures,
 - provides detail on the content of information and training; and
 - new requirements for measures to be taken following a sharps injury.And new duties on injured workers:
 - to report all sharps injuries
 - to provide information about the circumstances of the accidentThese additional measures are already currently taken in the UK where good practice guidance is being followed (e.g. provision of post-exposure prophylaxis).
7. The social partners are not able give the necessary legally binding status to the Agreement in the UK. Therefore, the Government needs to ensure that the aspects of the Sharps Directive that go beyond existing legislative requirements are implemented by new legislation. In devising and analysing implementation options we have been mindful of the Government's guidance on implementing European legislation, including the Guiding Principles for Transposition (see Annex B). We sought to achieve:
 - Regulations which address real health and safety risk and require measures which are proportionate to that risk.
 - Effective implementation of the Directive (such that the risks are minimised of a) a Commission opinion that we have under-implemented and b) Regulations that will pass scrutiny in Parliament).
 - Regulations which provide clarity for the relevant duty holders as to what they are required to do.
 - Regulations which are streamlined with the existing regulatory framework in this area.
 - That any administrative burdens on the relevant duty holders are minimised.

³ The survey of NHS staff reported work-related illnesses: 29% work-related stress, 10% manual handling, 3% slips, trips and falls, 2% needlesticks and 1% exposure to a dangerous substance.

⁴ The general Health and Safety at Work Act 1974 duties, COSHH, PUWER and Management of H&S Regulations are all relevant. The Regulations are themselves based on European Directives.

Argument - Implementation Options

8. In analysing the options we have been helped by the joint clarification of intent by the social partners which will be used by the Commission in assessing implementation of the Directive. An impact assessment has been prepared of the following options (See Annex B of the consultation document).

Option 1 Amending the existing legislation to add in the additional requirements of the Agreement – this would involve inserting new requirements or additions/qualifications to existing requirements within various existing statutory instruments.

9. This option builds on the established legislation and proportionate risk regulation. Though superficially an attractive way to streamline, this would complicate existing legislation, as the new requirements would only apply to certain activities and protect a different category of workers than other requirements in COSHH and MHSWR. This would open each of these Regulations to further scrutiny as to the burdens they may place on business. A wide range of employers would therefore be required to take some action (if only to familiarise themselves and realise it is not relevant to them). This seems disproportionate for a Directive addressing only the healthcare sector.

Option 2 Create new Regulations to transpose the substantive requirements, following the wording of the Agreement, where possible.

10. The new Regulations will be clearly applicable only to employers and workers in the healthcare sector, including contractors. The wording of the Directive would be used except under two circumstances. Firstly, where doing so would duplicate existing legislation. Secondly, where it would not provide the necessary legal certainty about what is required. To avoid both these problems we will use an alternative to provide effective drafting. HSE's existing guidance would be amended where appropriate to explain to duty holders how the new requirements build on their existing legal obligations.

Option 3 Copying out the Agreement entirely as a new set of Regulations.

11. The requirements on healthcare employers relating to sharps risks would be in one set of regulations. However, these new Regulations would contain unclear requirements and while they would overlap with duties in existing legislation, they would also differ significantly from COSHH/MHSWR. This would create uncertainty and confusion. Measures to reduce the duplication, for example removing healthcare employers from the relevant requirements of COSHH and MHSWR, would introduce further complexity, similar to option 1.
12. We believe Option 2 to be the only credible option. The others fail the test of clarity, would place unnecessary administrative burdens on employers and/or fail to meet the drafting standards required by Parliament's Joint Committee on Statutory Instruments. These are the main reasons in favour of this option but, in addition, the impact assessment concluded that the administrative costs of Option 2 were lowest (see the consultation document).
13. On this basis we have prepared a proposed set of draft Regulations (Annex A of the consultation document) and a Consultation Document (Annex C) which seeks views on the proposed approach, some of the specific difficulties we have identified and in general seeks to improve our evidence base, especially in

regard to costs and benefits. We are also seeking ideas on how best to work with our stakeholders to promote the required changes.

14. The consultation will run from July to October 2012. We plan to return to the Board with proposals for Regulations, guidance and promotional activities in December, ready to lay the Regulations early in 2013, to come into force on 11 May 2013.

Action

15. The board is asked to:

- Agree the proposed approach to transposition of Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention of sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU (the Sharps Directive), and
- Approve the publication in July 2012 of the enclosed Consultative Document (CD).

Paper clearance

At SMT meeting of 6 June 2012

Annex A - The current position

1. The evidence on the incidence of sharps injuries, their causes and circumstances and effective measures to control risks is limited. The most useful information has come from Health Protection Agency's 'Eye of the Needle' report, published studies evaluating the introduction of safer sharps and information from NHS suppliers on the volume of safer sharps supplied by them.
 2. In October 2010 HSE prosecuted Worcestershire Acute Hospitals Trust and they were fined £12,500 (+£9000 costs) following an incident where a healthcare worker contracted Hepatitis C following an injury with a needle used to take blood from an infected patient. The investigation highlighted a number of failings by the Trust to manage the risks, which led to the prosecution. In 2010/11 Occupational Health Inspectors carried out an inspection campaign where they looked at how 22 NHS Trusts/Boards were managing the risks of sharps injuries, enforcement action was taken in three Trusts/Boards. A summary report will be published later this year.
 3. HSE's current guidance on this topic is in *Prevention of Blood Borne Viruses* (INDG342), the Health and Social Care webpages and the new ACDP Blood Borne Viruses section of the HSE website. These provide guidance on appropriate precautions, including signposts to the relevant NHS and other guidelines. In practice, most healthcare sector managers/workers seek guidance or work to standards on control of sharps risks issued by other bodies than HSE, along with guidance on wider infection control measures and safe use and disposal of medical instruments in general.
 4. In the last decade 'safer sharps' have become much more available. These are needles and other devices which incorporate some form of cover for the needle, which automatically or manually moves into place once the needle has been used. The evidence is that these are being taken up by many healthcare employers, but others are yet to take a systematic approach to assessing where their use can better control risk.
 5. The evidence about current practice in non-NHS healthcare is especially poor. However, we understand that most private hospitals will adhere to similar standards to the NHS on issues such as safe systems of work for handling sharps.
 6. HSE has sought to improve our evidence base, by the following:
 - a) HSL carried out a systematic review of the published evidence on the efficacy of safer sharps (RR914). The quality and quantity of evidence was limited, mainly due to study designs used by publishing authors. Despite this, there was sufficient published evidence:
 - to consider the use of safer sharps devices to reduce the incidence of sharps injuries amongst UK healthcare workers and
 - that when educational programmes were implemented alongside a safer sharps device, lower rates of sharps injuries were sustained for longer. However, the benefit attributable to education alone could not be isolated from the impact of the introduction of the safer sharps device.
- Insufficient studies have investigated user acceptability of safer sharps devices and patient outcomes to draw any conclusions on this question.

- b) In 2011, HSE sought further evidence from approximately 50 employers and employee representative bodies in the hospital and healthcare sector. The focus was to establish what is already done to comply with existing legislation and to compare this to what they will need to do to comply with the Directive. Only 9 responses were received. Consequently this evidence, while helping to guide our future work, can only be seen as anecdotal.
- c) We have also carried out some informal consultation with targeted representatives of the healthcare sector to gather relevant information where we had been alerted that there may be issues, for example talking to hospital pharmacists and ambulance services.
7. The nature of the evidence means that it is not possible to quantify levels of current compliance or provide robust estimates of the costs or benefits of the anticipated changes. Overall, we found that the UK healthcare sector currently has well-established relevant procedures and guidance designed to control infection risks arising from work with patients and the potential for exposure to blood-borne viruses. However, compliance in some aspects can be improved:
- Reviewing existing risk assessments;
 - Use of 'safer sharps', where they provide protection against risk;
 - Adherence to safe working procedures, especially safe disposal of sharps; and
 - Use of existing accident and near-miss reporting systems.

Annex B – HM Government Guiding Principles for Transposition of EU Directives

Since publication of the Directive the Government has introduced guiding principles for transposition of EU Directives. These are:

- Wherever possible, seek to implement EU policy and legal obligations through the use of alternatives to regulation;
- Endeavour to ensure that UK businesses are not put at a competitive disadvantage compared with their European counterparts (this includes the aligning measures to implement EU Directives with existing GB legislation, avoiding duplication and avoiding adding additional measures or 'gold-plating');
- Always use copy out for transposition where it is available, except where doing so would adversely affect UK interests e.g. by putting UK businesses at a competitive disadvantage compared with their European counterparts ;
- Ensure the necessary implementing measures come into force on (rather than before) the transposition deadline specified in a directive, unless there are compelling reasons for earlier implementation; and
- Include a statutory duty for Ministerial review every five years.