REGULATORY IMPACT ANALYSIS (RIA)

SAFETY, HEALTH AND WELFARE AT WORK

(Prevention of sharps injuries in the hospital and healthcare sector) REGULATIONS 2012

(S.I. No. … of 2012)

11th January 2012

Contents

1. Foreword

The Health and Safety Authority, herein after referred to as 'the Authority', has prepared this Regulatory Impact Analysis (RIA) in line with the Revised RIA Guidelines, (Department of the Taoiseach, 2009).

This RIA considers the options and assesses the impacts of the requirement to transpose the Directive 2010/32/EU which implements the Framework Agreement on prevention of sharps injuries in the hospital and healthcare sector reached by the European Hospital and Healthcare Employers' Association (HOSPEEM) and the European Federation of Public Services Union (EPSU). The deadline for Member States to comply with the Directive is 11 May 2013.

The impact of transposing the Directive through the proposed new Regulations is expected to be minimal given that many of the obligations already exist in principles expounded in the Safety Health and Welfare at Work Act2005 and the Safety Health and Welfare at Work (Biological Agents) Regulations 1994 and amended Regulations. The proposed new Regulations apply the same principles specifically to the issue of sharps injuries but are more explicit with regard to certain obligations such as the preparation of a risk assessment for sharps, switching to safety engineered devices, information and training on new devices and a ban on the practice of recapping sharps. The analysis concludes as many of the obligations are already in existence most healthcare employers will only need to extend existing practices to those areas where changes have not yet been implemented. Where costs are involved they are not considered to be disproportionate when balanced against the savings to be made by a reduction in the testing, treatment and follow up that is required when a sharps incident occurs.

2. Policy context

This RIA assesses the legislative proposal to transpose Council Directive 2010/32/EU of the 10 May 2010. The Directive implements the Framework Agreement on prevention of sharps injuries in the hospital and healthcare sector which was concluded by the European Hospital and Healthcare Employers' Association (HOSPEEM) and the European Federation of Public Services Union (EPSU).

Member states are required to bring into force the laws, regulations and administrative provisions necessary to comply with the Directive by 11 May 2013.

The Health and Safety Authority is the agency with responsibility for enforcing the new legislation in Ireland. In current Irish legislation the main provisions relating to the risk of exposure to injury from sharps at work are contained in the Safety, Health and Welfare at Work Act, 2005 and the Safety, Health and Welfare at Work (Biological Agents) Regulations, 1994 and amendment Regulations, 1998. The proposed new Regulations compile existing and new requirements specifically related to the prevention of sharps injuries in the healthcare context.

The issue of potentially harmful exposures to biological agents is addressed in the Safety Health and Welfare at Work (Biological Agents) Regulations 1994 and 1998. In 2011, the Authority produced an information sheet on the prevention of sharps injuries in healthcare. Guidance related to the prevention of blood borne diseases in the healthcare setting and on handling healthcare waste is provided by the Department of Health.

Information from the European Biosafety Network (2011) indicates over one million needlestick injuries in Europe annually. It is not known how many needlestick injuries occur in Ireland in the healthcare setting each year as there is no national system for collating this information.

The Commission did not prepare an impact assessment for the Directive 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. Objectives

The primary objective of the proposed legislation is to increase the level of protection for workers in the healthcare sector from injury or infection caused by use of sharps in the course of their work.

A secondary objective is to ensure that Ireland complies with Directive by the deadline of 11 May 2013 and thereby avoids any penalties imposed by the European Commission for non-compliance.

4. Options

The options for addressing the transposition of Directive 2010/32/EU are as follows:

Option 1 **Do nothing**

Option 2 **Introduce new Regulations**

Option 1, to do nothing, would leave Ireland in breach of the requirement for member states to transpose the Directive by 11 May 2013. The Commission could proceed to take legal action with potentially significant financial penalties arising for the state. It could further create a situation where workers in the Irish healthcare sector are afforded a lower level of protection from injuries from sharps than workers in other Member States. On this basis it is recommended to proceed with option 2, to transpose Directive 2010/32/EU into Irish law by way of the proposed Regulations. The impact of this option is assessed in detail in the following section.

5. Impact analysis

The impacts of the proposed Regulations are expected to be minimal on the basis that most provisions are already enforced in Irish legislation and that the cost of compliance will be offset by a reduction in the costs associated with the follow up procedures when a sharps incident occurs. New requirements under the Directive are listed below:

(i) The replacement of existing equipment with new equipment, such as safety engineered devices, that can eliminate or reduce the levels of exposure to a minimum. Needle stick injury prevention devices include needles that retract into the syringe after use, those that have a protective shield over the needle and systems that do not use needles.

(ii) A risk assessment specifically for sharps injuries that requires certain specific elements to be considered, for example, the existence of replacement equipment, such as safety engineered devices, that can eliminate or reduce the levels of exposure to a minimum.

(iii) The provision of information and training specifically concerning the prevention of sharp injuries. For example where medical devices are provided which incorporate safety engineered protection mechanisms, workers must be trained in their correct use.

(iv) The practice of recapping, that presents a risk of injury and/or infection, is banned.

5.1 Benefits of introducing proposed Regulations

Health and safety benefits: The introduction of the proposed Regulations should further reduce the risk of sharps injury for workers in the healthcare environment and associated activities. Healthcare

workers will benefit from the reassurance that there is a specific set of requirements to protect against this common occupational hazard.

Business benefits: A lower rate of sharps injuries will result in lower costs for employers. A sharps injury can result in significant costs associated with the injured party being required to leave their workplace and seek medical attention which can involve taking blood samples, treatment, follow up of the injured party and a significant amount of paperwork.

5.2 Costs of introducing proposed Regulations

Business costs: The expected impact of the proposed Regulations in terms of compliance costs is expected to be minimal given the significant work which has already been undertaken in the sector to address the risk of sharps exposure.

Many healthcare practices have already moved to safety engineered devices in line with the requirement to have a safe system of work under the Safety, Health and Welfare at Work Act 2005 particularly for those work practices involving most intensive use of sharps. The proposed Regulations will require employers to consider some areas of less intensive use and purchase new equipment as necessary. Where specific practices such as dental or anaesthetic work have retained the practice of recapping and where there is a risk of injury these employers will be required to adopt safer work practices and procedures. The proposed changes will be advised to healthcare employers in advance of the introduction of the Regulations to facilitate preparation and planning.

The obligation to produce a risk assessment specifically for sharps injuries will have limited impact as many healthcare employers will already include sharps as a topic in their risk assessments given the importance of the hazard in the sector. Healthcare employers have an existing and ongoing process of preparing risk assessments. This includes assessing the risk to employees of harmful exposures to biological agents which includes contaminated sharps. At most, the new obligation will involve the inclusion of this topic in the existing and ongoing process of preparing the risk assessment.

In terms of information and training for new equipment it is usual for training and information to be provided to staff by suppliers as part of the package when purchasing new equipment; the employer will be required to supplement this training as required to ensure employee competency when using devices. This is unlikely to incur additional costs to the employer.

Enforcement costs: The expected impact of the proposed Regulations in terms of enforcement costs is expected to be minimal as inspectors already assess sharps hazards as part of inspections in the healthcare sector. Costs related to the preparation and publication of a guidance document to support the new Regulations will be accommodated in the Authority's annual budget allocation for guidance material.

6. Consultation

The proposed Regulations and this RIA will be made available on the Authority's website for a one month period in accordance with the Authority's standard public consultation policy. Selected stakeholders may be contacted directly by the Authority and invited to make submissions, including the following:

- Department of Jobs, Enterprise and Innovation
- Department of Health
- Health Service Executive
- Health Information Quality Authority
- Irish Congress of Trade Unions

Submissions will be collated and considered by the Authority and relevant additions or amendments may be incorporated in the proposed Regulations and reflected in an updated RIA. The revised Regulations and RIA will be submitted to the Legislation and Guidance Sub-Committee of the Board and the Board of the Authority for consideration and approval. Any resultant proposals for legislative change will be submitted to the Minister for at the Department of Jobs, Enterprise and Innovation for his consideration with a view to formal legal settlement by the Office of the Parliamentary Counsel to the Government.

7. Review

The Authority will review the impact of the proposed Regulations through review of sharps injury reports received and reviewing progress with stakeholders in the sector.

References

European Biosafety Network (2011), *Toolkit for implementation of European Directive on Prevention from Sharps Injuries (Council Directive 2010/32/EU) in Member States*