Summary of the EU Directive and Implementation Guidance

What is an EU Directive?
EU Directives lay down certain end results that must be achieved in every Member State. Directives are used to bring different national laws into line with each other. In this instance, the EU Sharps Directive has been drafted to provide protection for healthcare workers across Europe.

What does the EU Sharps Directive aim to do?
The Directive aims to achieve the safest possible working environment for healthcare workers through the prevention of sharps injuries.

What does the Directive provide?
The Directive provides a framework to put in place and implement practical preventative measures before the publication of the required national legislation in each country.

When was this agreed?

- The Council of the European Union adopted this Directive on 10 May 2010
- This Directive was published on 1 June 2010
- The new Directive gives legal effect to an Agreement concluded by the employers and the trade unions of the hospital and healthcare sector (HOSPEEM and EPSU) on 17 July 2009

Why is this important?
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. The everyday work of healthcare staff puts them at risk of serious infections including hepatitis B, hepatitis C and HIV, as a result of needle stick injuries. More than one million needle stick injuries are estimated to occur in the European Union each year.

What is each Member State required to do?
Each Member State is required to implement the Directive within the three years following its publication (The Directive was published on June 1 2010). This means each Member State is required to implement by May 11 2013 at the latest. The Directive sets out minimum requirements and Member States are free to adopt additional measures to protect workers. National implementation negotiations should start immediately so that risks are reduced as soon as possible.

What is the scope of the Directive? Who does it include?
The Directive applies to all workers in the hospital and healthcare sector, and all who are under the managerial authority and supervision of the employers, including trainees and apprentices (full-time, part-time or temporary contract). Sub-contracted or agency staff also fall within the scope of the agreement. Employers should deploy efforts to ensure that subcontractors follow the provisions laid down in this agreement.

What approach does the Directive require?
The Directive lays out an integrated approach. Establishing policies in risk assessment, risk prevention, training, information, awareness raising and monitoring, and for response and follow up procedures.

Independent studies show that an integrated approach is key, showing that a combination of training, safer working practices and the use of safety engineered devices can prevent the majority of needlestick injuries.

What must employers do?
The Directive states that employers must comply with the hierarchy of controls. Where the results of the risk assessment reveal a potential risk of injury or exposure to blood or other potentially infectious material, this must be controlled by:

- Elimination - eliminating the unnecessary use of sharps by changes in practice and on the basis of the results of the risk assessment,
- Safe Procedures - specifying and implementing safe procedures for using and disposing of sharp medical instruments and contaminated waste. The practice of recapping shall be banned with immediate effect;
- Engineering Controls - providing safety engineered devices;
- Protective Equipment - the use of Personal Protective Equipment (gloves, masks, gowns, etc).

The Directive states that where a risk cannot be eliminated the employer must take appropriate measures to minimise the risk.

Where are the risks?
The highest risk procedures include blood collection, IV cannulation and percutaneously placed syringes. Small amounts of blood can result in potentially life threatening infection. Hollow-bore needles contain more blood and therefore carry more risk than solid needles.

The incidence of hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) is significantly higher in the hospital population than in the general population. Additionally, patients will be treated before it is known that they are carrying a serious blood-borne infection, so it is not feasible to reliably segregate patients on the basis of risk and universal sharps injuries prevention measures are therefore, appropriate.

What are appropriate measures?
Appropriate measures include the provision by employers of safer needle devices and sharps containers to their workforce. This must be provided in combination with training and safer working practices.

How should safety-engineered devices be selected?
Managers should consult with workers' representatives on the choice and uses of safety-engineered devices. Identifying the best device for the use, and also how best to carry out training, information and awareness raising.

What selection criteria should be used?

- The device must not compromise patient care;
- The device must perform reliably;
- The safety mechanism must be an integral part of the safety device, not a separate accessory;
- The device must be easy to use and require little change of technique on the part of the health professional;
- The activation of the safety mechanism must be convenient and allow the care-giver to maintain appropriate control over the procedure;
- The device must not create other safety hazards or sources of blood exposure;
- A single-handed or automatic activation is preferable;
- The activation of the safety mechanism must be clear by means of an audible, tactile or visual sign to the health professional;
- The safety mechanisms should not be easily reversible once activated.

What key principles should be observed by employers, employee representatives and employees when taking action?

- The vital role of a well-trained, adequately resourced and secure workforce in preventing risks;
- That 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;
- The responsibility of each worker to take care of his or her own safety and the duty of the employer to ensure the health and safety of workers in every aspect relating to their work;
- To never assume that no risks exist;
- The hierarchy of measures concerning the safety and health protection of workers in the Directive;
- The importance of an integrated approach for achieving the safest possible workplace environment;
- Promoting a 'no blame' culture. Incident reporting should focus on systemic factors rather than individual mistakes and systematic reporting must be considered as accepted procedure.

For further information please refer to the European Biosafety Network's Guidance paper: *Prevention of Sharps Injuries in the Hospital and Healthcare Sector, Implementation Guidance for the EU Framework Agreement, Council Directive and Associated National Legislation*.

This can be found along with other information about the Directive on www.europeanbiosafetynetwork.eu