EU law is now being finalised requiring all healthcare organisations to implement mandatory healthcare worker safety standards. EU Employment and Social Affairs Ministers have adopted a Directive to prevent injuries and infections to healthcare workers from sharp objects such as needles, along with the risk of subsequent infection with blood-borne pathogens such as Hepatitis or HIV. Needlestick injuries are described by the EU as “one of the most serious health and safety threats in European workplaces…estimated to cause one million injuries each year.”

The new law will legally oblige healthcare organisations to take measures to prevent needlestick injuries to their staff, making the use of safety-engineered medical devices, both needles and intravenous catheters, a very important element of ensuring compliance. The specific clause in the Directive refers to “…providing medical devices incorporating safety-engineered protection mechanisms.”

A number of public and private healthcare organisations across Europe — recognising the need to improve healthcare worker safety, reduce the cost of treating injured workers, and avoid expensive legal actions — have already converted to the use of safety-engineered medical devices well in advance of the impending legislation. Yet many others have not yet done so.

This Management Guide aims to provide healthcare executives with a brief factual summary of the new legislation, along with a more detailed analysis of the scope and implications of the new law.

In the UK, access to safety-engineered medical devices in NHS hospitals is limited, and so this guide is designed to provide non-converted hospitals with a head start in understanding the implications of the new EU legislation, and initial support in planning a path towards compliance.

Management Summary

• In March 2010, European Union Ministers adopted an EU Directive to prevent injuries to healthcare workers caused by sharps objects (e.g., needlestick injuries) and potentially leading to an infection.
• This Directive came into legal force in June 2010, and must be transposed into national law in all EU countries, at the latest by May 2013.
• The legislation is the result of a joint request from employer and employee organisations in the sector.
• There is likely to be little or no delay in transposing the new Directive, with the Declaration recommending that “the measures defined in the proposed directive be urgently adopted and implemented.”

• Both the public and private healthcare sectors are affected by the legislation, which is designed to “ensure the highest possible level of safety in the working environment in hospitals and wherever healthcare activities are undertaken.”
• The Directive declaration specifically defines better training, better working conditions and the general use of safer medical instruments incorporating sharps protection mechanisms.
• Safety-engineered medical devices have already been adopted in parts of Europe, ahead of the Directive becoming law.
In the UK, the public healthcare system has only partially converted to the exclusive use of safety-engineered medical devices, although existing UK best practice guidance already specifically points to their use. Usage of infusion safety devices is 23%, though that of safety injection systems is only 4%. In total, access to safer needle devices remains low with safety devices only making up 6% of the total market of medical devices with needles in the UK.

The Royal College of Nursing (RCN) points out that the majority of needlestick injuries could be prevented by the use of safety-engineered medical devices and compliance with guidelines. The RCN report highlights figures from the Health and Safety Executive that show that devices with safety mechanisms constitute only 5% of all instruments sold to the NHS.

Under the Health Act (2006), the Government has published a specific Code of Practice for the Prevention and Control of Healthcare-Associated Infection, which requires NHS bodies to implement policies that encompass "the provision of medical devices incorporating sharps protection mechanisms."

This code of practice has already been acknowledged by a number of leading trusts that have converted to safety-engineered medical devices in order to provide a safer staff environment, as well as avoiding reputationally and financially-damaging legal cases.

For most healthcare organisations that have chosen to convert to safety-engineered medical devices, the case for general conversion to safety devices has been based on:
1. Enhancing reputation for a safe treatment and working environment, resulting in greater staff loyalty;
2. Reducing the cost of treatment following a needlestick injury and possible infection;
3. Avoiding the cost of possible legal action;
4. Reducing the cost of staff absence from work and possible deflection;
5. Improving staff recruitment and motivation;
6. Reducing the personal trauma and long-term effect of needle-stick injury.

In light of this new legislation from the European Union, some leading healthcare organisations have already begun the process of informing and preparing their management and colleagues about the Directive and its implications. Initial next steps typically include:

- Inform management of the key points of the upcoming European legislation.
- Inform all healthcare workers about the legislation and announce that management are already formulating a strategy for compliance.
- Conduct a revised internal audit of needle-stick injury incidence and risk, in light of the forthcoming Directive.
- Begin initial work on compliance strategies.
- Contact suppliers to research transition strategies and support.

If you would like to receive help, guidance or advice on how to implement a safety conversion strategy, BD would be happy to work with you. Please contact us at:

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