
Health and Safety Executive**Consultation on proposed regulations to implement Council Directive
2010/32/EU on preventing sharps injuries in the hospital and healthcare sector.****Reply Form****Completing this Questionnaire**

You can move between questions by pressing the 'Tab' / 'Shift-Tab' or 'Page Up' / 'Page Down' keys or by clicking on the grey boxes with a mouse. Please type your replies within the rectangular grey boxes, or click on the square grey boxes to select an answer (e.g. 'Yes' or 'No').

Respondent's details:

Name:	<input type="text" value="Ruth Wakeman"/>
Email:	<input type="text" value="ruth.wakeman@rpharms.com"/>
Town / City:	<input type="text" value="London"/>
Telephone:	<input type="text" value="020 7572 2615"/>
Job Title:	<input type="text" value="Head of Professional Support"/>
Postcode:	<input type="text" value="SE1 7JN"/>
Street address:	<input type="text" value="1 Lambeth High Street"/>
Organisation:	<input type="text" value="Royal Pharmaceutical Society"/>
Fax:	<input type="text"/>

Size of organisation:

Choose one option:

Not applicable	<input checked="" type="checkbox"/>
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1 to 9 employees	<input type="checkbox"/>
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10 to 49 employees	<input type="checkbox"/>
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50 to 249 employees	<input type="checkbox"/>
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250 to 1000 employees	<input type="checkbox"/>
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1000+ employees	<input type="checkbox"/>
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Self-employed	<input type="checkbox"/>
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Type of organisation:

Choose one option:

Academic	<input type="checkbox"/>
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Charity	<input type="checkbox"/>
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Consultancy	<input type="checkbox"/>
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Industry	<input type="checkbox"/>
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Local government	<input type="checkbox"/>
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Member of the public	<input type="checkbox"/>
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National government	<input type="checkbox"/>
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Non-departmental public body	<input type="checkbox"/>
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Non-governmental organisation	<input type="checkbox"/>
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Pressure group	<input type="checkbox"/>
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Trade association	<input type="checkbox"/>
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Trade union	<input type="checkbox"/>
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Other - please specify:

Is your response being made in your capacity as:

Choose one option:

An employer <input type="checkbox"/>	An employee <input type="checkbox"/>
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Health and safety professional <input type="checkbox"/>	Trade union official <input type="checkbox"/>
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Training provider <input type="checkbox"/>	Self-employed person <input type="checkbox"/>
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Other - please specify:

Confidentiality

Please indicate below if you do not wish details of your comments to be available to the public. (NB if you do not put a cross in the box they will be made available to the public. This takes precedence over any automatic notes on e-mails that indicate that the contents are confidential.)

Q1. Is the use of 'medical sharps' in the regulations (see page 5) consistent with how it is commonly used by employers and workers in the healthcare sector?

Yes	<input type="checkbox"/>
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No	X <input type="checkbox"/>
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If you have answered 'No', please provide details to support your answer.

We welcome the Directive as an important contribution to reducing the risk of sharps injury and consequential infection risks to healthcare staff in patient care areas. However it is also important to consider the use of sharps in a pharmacy context, this directive has implications for them and we urge that the views of pharmacy teams working in these areas are considered as part of this consultation. Sharps are used in pharmacy aseptic compounding services to prepare doses of injectable medicines for patient use which would otherwise be made in clinical areas with much increased risk of calculation and measurement errors as well as of microbial contamination. During complex manipulations needles may be removed and replaced more than once and resheathing is integral to practice. The critical difference between this and use of sharps in clinical areas is that in the pharmacy context, there is no risk that any sharps will be contaminated with body fluids or pathogens.

Q2. In addition to the examples provided (see page 10 and paragraphs 17-22), are there other common circumstances under which people carry out healthcare activities using medical sharps where the application of the proposed regulations could usefully be clarified in guidance?

Yes	<input type="checkbox"/>
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No	<input checked="" type="checkbox"/>
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If you have answered 'Yes', please provide details to support your answer.

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Q3. Is it clear what actions employers and employees will need to take under the proposed regulations (see paragraphs 27-29)?

Yes	<input type="checkbox"/>
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No	<input checked="" type="checkbox"/>
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Please provide comments to support your answer.

There may be implications for pharmacy for sourcing and procuring safer devices and providing training in their use.

Expert pharmacy groups have advised us that a total ban on re-sheathing would require re-design of aseptic compounding processes. It is as yet unclear what “safer” devices are available to address this, how they could be used and what the cost and other implications would be.

Q4a. Do you agree that HSE’s guidance on the new Regulations should be built into its existing relevant guidance (see page 15)?

Yes	<input checked="" type="checkbox"/>
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No	<input type="checkbox"/>
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Q4b. In addition to the organisations that produced the guidance listed at paragraphs 31 and 32 are there other organisations that HSE should seek to work with to ensure that relevant non-HSE guidance aligns with the requirements of the new regulations?

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Q5. Does the proposed implementation date have any unintended consequences for the UK healthcare sector?

Yes	<input type="checkbox"/>
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No	<input checked="" type="checkbox"/>
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Please provide comments to support your answer.

Q6. To assist us with the impact assessment please answer the following:

a) Numbers of employers in the healthcare sector

IA1. Please provide any information you have which will help us to fill in the gaps in Table 1 with appropriate references to the source of information.

Hospitals

GPs

Dental Surgeries

Ambulance Services

Care Homes and Hospices

b) Review of Risk Assessments

IA2. Do you agree with the following assumptions made by HSE in the impact assessment:

All risk assessments relevant to sharps injuries will have to reviewed.

Yes	<input type="checkbox"/>
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No	<input type="checkbox"/>
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Please provide comments to support your answer.

It will take each hospital and ambulance trust between 2 and 3 hours to review the relevant risk assessments.

Yes	<input type="checkbox"/>
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No	<input type="checkbox"/>
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Please provide comments to support your answer.

It will take GPs, dental practices and care homes between 0.5 hours and 1 hour to review the relevant risk assessments.

Yes	<input type="checkbox"/>
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No	<input type="checkbox"/>
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Please provide comments to support your answer.

IA4. Can you estimate how many risk assessments your organisation may need to amend as a

result of the proposed regulations?

**IA5. How long will it take your organisation to make amendments to a risk assessment?
Please provide your answer in hours/minutes.**

c) Safer sharps

IA6. Does your organisation use any 'safer sharps' in its activities now?

Yes	<input type="checkbox"/>
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No	<input type="checkbox"/>
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IA7. Will your organisation use an increased number of 'safer sharps' as a result of the proposed regulations?

Yes	<input type="checkbox"/>
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No	<input type="checkbox"/>
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IA8. If you can, please provide an estimate of the % increase in the use of safer sharps by your organisation as a result of the proposed regulations, where 100% is that all possible traditional devices have been replaced by safer sharps.

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d) Familiarisation

IA9. Do you agree or disagree with the following assumptions made by HSE in the impact assessment about familiarisation cost (in other words the time it will take to read and understand the new regulations) :

a) For each hospital and ambulance service between 5 and 10 people will have to spend time familiarising themselves with the proposed regulations.

Agree	<input type="checkbox"/>
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Disagree	<input type="checkbox"/>
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Not within my knowledge	<input type="checkbox"/>
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If you have answered 'Disagree', please can you suggest an alternative figure:

b) For each GP practice, Dental surgery and care home one person will spend time familiarising themselves with the proposed regulations.

Agree	<input type="checkbox"/>
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Disagree	<input type="checkbox"/>
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Not within my knowledge	<input type="checkbox"/>
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If you have answered 'Disagree', please can you suggest an alternative figure:

c) Each person will spend between 1 and 3 hours reading and understanding the proposed regulations

Agree	<input type="checkbox"/>
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Disagree	<input type="checkbox"/>
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Not within my knowledge	<input type="checkbox"/>
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If you have answered 'Disagree', please can you suggest an alternative figure:

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e) Other impacts

IA10. Please provide information about the cost impacts arising from other requirements in the regulations, specifically in relation to the following areas:

a) Placing of secure containers and instructions for safe disposal of medical sharps close to the work area

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Published cost data, please provide the appropriate reference.

Summary of cost data already collated by your organisation – please set out below or provide a summary of what it covers:

Please provide contact details for obtaining a copy of this data:

b) Not recapping needles where there is a risk of injury

Published cost data, please provide the appropriate reference.

Summary of cost data already collated by your organisation – please set out below or provide a summary of what it covers:

Please provide contact details for obtaining a copy of this data:

c) Procedures to be reviewed regularly

Published cost data, please provide the appropriate reference.

Summary of cost data already collated by your organisation – please set out below or provide a summary of what it covers:

Please provide contact details for obtaining a copy of this data:

d) Information and training

Published cost data, please provide the appropriate reference.

Summary of cost data already collated by your organisation – please set out below or provide a summary of what it covers:

Please provide contact details for obtaining a copy of this data:

e) Reporting of sharps injuries by workers and investigation of the circumstances and causes by employers

Published cost data, please provide the appropriate reference.

Summary of cost data already collated by your organisation – please set out below or provide a summary of what it covers:

Please provide contact details for obtaining a copy of this data:

f) Follow up of a sharps injury

Published cost data, please provide the appropriate reference.

Summary of cost data already collated by your organisation – please set out below or provide a summary of what it covers:

Please provide contact details for obtaining a copy of this data:

IA11. Benefits

If you are able to identify any anticipated benefits to you (eg reduced costs of injuries) from implementation of the changes required by the proposed Regulations, please provide a description.

Is there anything you particularly like or dislike about this consultation? Please provide comments.

Do you have any other comments on the proposals that have not been covered by this questionnaire?

We have concerns regarding the implications for safe practice in pharmacy aseptic preparation services and we urge that the views of pharmacy teams working in these areas are considered as part of this consultation. We are also concerned that there is no acknowledgement of the role of pharmacy in providing safe, ready to use injectable medicines.

Please send your response by 8 November 2012 to:

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Thank you for taking the time to complete this questionnaire

