



**RCN Policy and International Department
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Revision of European Legislation on Medical Devices

RCN Position Statement

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Summary

The RCN supports the updating of rules relating to medical devices regulation in the EU and specifically supports

- **the extension of the scope to include invasive and implantable devices without a medical purpose**
- **the explicit clarification that devices for diagnostic or therapeutic purposes sold over the internet must comply with both regulations**
- **improvements in the traceability of medical devices**
- **the reference to seeking advice from an ‘appropriate healthcare professional which updates the reference to a ‘medical practitioner’ in the previous Directive**
- **the role of health professionals in reporting adverse incidents**

and seeks further clarification on;

- **signposting of users of self testing devices**
- **classification of self testing devices**

About the RCN

With a membership of over 410,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nursing cadets, the RCN is the voice of nursing across the UK and the largest professional union of nursing staff in the world. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European institutions, trade unions, professional bodies and voluntary organisations. The RCN is a member of the European Federation of Nurses Associations (EFN), the European Federation of Public Service Unions (EPSU) and the European Public Health Alliance (EPHA)

Background

The new draft EU regulations on medical devices¹ and *in vitro* diagnostic medical devices² were published on 26th September 2012 with a stated aim to ‘achieve a suitable, robust, transparent and sustainable regulatory framework’ for medical devices and *in vitro* devices. These seek to replace three existing directives dealing with medical devices and *in vitro* diagnostic devices, which were agreed in the 1990’s. The rationale for these draft proposals was a recognition at EU level that the current legislation is no longer responsive to the considerable development in healthcare and associated developments in medical device technology in the last twenty years. Equally, concern

¹ http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf

² http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf

has been raised about the lack of consistency in the application of the Directives across an EU that has more than doubled in size since the legislation was first adopted.

The context of the proposals is also important. The initial proposals were drawn up during the PIP breast implant scandal and therefore the Commission has sought to address concern about the lack of regulation of aesthetic products by extending the scope of the regulation to include such products. Equally, safety concerns around metal on metal hip replacements have also arisen during the drawing up of the draft regulations.

The new legislation is proposed as a regulation rather than a directive. This will mean that the new regulation will have general application in every member state rather than being transposed through individual member state legislation. The effect of this will be to ensure a more consistent approach to the regulation of medical devices across the EU, something that has been a cause for concern for member states (including the UK).

The new regulations update and extend legislation to a number of areas. Those areas that are of particular interest to the RCN include:

- Extending the scope of the legislation to include invasive and implantable devices without a medical purpose (within proposed medical devices legislation)
- Extending the definition of an in vitro device to include genetic tests
- Clarifying that a device sold over the internet for diagnostic or therapeutic purposes must comply with both of the proposed regulations
- Clarifying existing rules on self testing and signposting to healthcare professionals
- Requiring all manufacturers of implantable devices to provide an 'implant card' for users.
- Establish a system of unique device identification (UDI), a central database to underpin the reporting system and a requirement on manufacturers of certain products to produce a summary of safety and clinical performance of the device.
- Requiring competent authorities to encourage healthcare professional to report nationally and to develop a standard form for healthcare professionals when they report.

This position statement focuses on those areas that are of particular importance to the RCN and its members. The position statement will feed into the RCN's response to the consultation on the UK position on the regulations which is currently being conducted by the Medical and Healthcare products Agency (MHRA) which closes on 21st January.

Proposals and RCN position

Extending scope of regulation and clarifying definitions

In response to both the PIP breast implant scandal and wider calls for regulation of non medical aesthetic products in healthcare settings, the new regulation extends the scope of the regulation of medical devices to include implantable or invasive products without a medical purpose, with a positive list which can be updated through delegated powers. The list is as follows:

- contact lenses
- implants for modification or fixation of body parts
- facial or other dermal or mucous membrane fillers
- equipment for liposuction
- invasive laser equipment intended to be used on the human body; and
- intense pulsed light equipment

The new proposals ensure that manufacturers of these products will *need to ensure that such products present either no or minimal acceptable risk, which is consistent with a high level of protection for the safety and health of persons.*

The RCN has already identified that the Health and Safety at Work Act and General Product Safety Directive are insufficient to provide assurances of safety and adequate levels of quality and opportunity for recourse in the event of harm for patients. More than two thirds (69%) of respondents to our survey did not believe that existing regulations covering aesthetic practice are sufficient to protect public and patient safety.

The RCN welcomes the extension of the scope to include invasive and implantable devices without a medical purpose. Given that future technological advancement may lead to other new devices, **the RCN also welcomes the proposal to allow the list of non medical devices covered by the regulations to be extended through delegated powers**

Both regulations also clarify that a device or service involving a device for diagnostic or therapeutic purposes sold over the Internet must comply with the regulations in their entirety. One of the main concerns that the RCN has is that some tests are available over the internet which are not regulated or licensed; or even illegal (for example HIV home testing kits). **The RCN therefore welcomes the explicit clarification that devices for diagnostic or therapeutic purposes sold over the internet must comply with both regulations.**

The regulation for IVD also amends the definition of an IVD to include genetic testing. **The RCN welcomes this explicit definition in the regulation.**

Implant Cards and unique device identification (UDI)

The new regulations introduce a new system of identification and traceability centred around a unique device identification number linked to a centralised European database. This imposes greater requirements on traceability in the supply chain. **The RCN welcomes improvements in the traceability of medical devices.**

Clarifying existing rules on self testing devices and signposting to healthcare professionals

Signposting of self testing devices

Previous Directives made provision for the regulation of self testing but the new regulations clarifies the position as to the specific safety and performance requirements of self testing kits. This includes a specific reference to instructions for self testing devices needing to provide information *‘with advice to the user on action to be taken (in case of positive, negative or indeterminate result) on the test limitations and on the possibility of false positive or false negative result’*. There is also a reference that *‘for devices intended for self-testing, the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional’*.

The RCN supports self testing but such testing must be safe and effective for patients. The RCN also believes that it is vital that all users of self testing devices should be signposted to an appropriate healthcare professional if the result of the self test indicates such, i.e. a result that implies something is wrong or may be wrong once the result of the self test is known so that they can receive relevant health advice and treatment as necessary. **The RCN supports the reference to seeking advice from an ‘appropriate healthcare professional which updates the reference to a ‘medical practitioner’ in the previous Directive. We will seek clarification as to whether the reference to a ‘decision of medical relevance’ could be clarified to ensure that users are signposted correctly.**

Classification of self testing

All medical devices must undergo a conformity assessment, the depth of which depends on the risk of the device being assessed. In relation to conformity assessment of a self testing device, the new regulation also classifies that self testing devices are within the Class C risk category, except for ‘devices intended for self testing where the result is not determining a medically critical status or is preliminary and requires follow up for the appropriate laboratory test in which case they are categorised as Class B. The extra requirement for class B self testing devices is that the conformity assessment application must include ‘test reports, including results of studies carried out with the intended users and data showing the handling suitability of the device in view of its intended purpose for self testing’. **The RCN would advocate that given the nature of self testing devices, it is difficult to justify why the additional requirement should not apply to all self testing devices rather than those in category B and will be exploring this further with relevant officials.**

Reporting of incidents

Both regulations place a requirement on national authorities (in the case of the UK this will be the MHRA) to encourage healthcare professionals to report concerns and serious incidents connected with medical devices. The regulations will also delegate power to the Commission to develop a standard electronic form for healthcare professionals, users and patients when they report.

The RCN fully supports a system which allows healthcare professionals to report concerns they have with specific devices. Any standard form must be straight forward, simple to use

and clear, with a focus on the national authorities following up should further information be required. Any reporting mechanism should complement manufacturers and national authorities own responsibilities for reporting serious incidents rather than replacing those responsibilities.

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