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PGEU Comments

PUBLIC CONSULTATION ON THE RECAST OF THE MEDICAL DEVICES DIRECTIVES

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1. Introduction

The Pharmaceutical Group of the European Union (PGEU) is the European association representing community pharmacists in 30 European countries including EU Member States, EEA countries and EU applicant countries. Within the enlarged EU, over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.

PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.

PGEU welcomes the opportunity to respond to the Commission's proposal for a recast of the Medical Devices directives.

2. General comment

The definition of medical devices included in Directive 93/42/EEC of 14 June 1993 concerning medical devices can include an enormous amount of things ranging from a simple bandage to highly sophisticated XR equipment.

From a community pharmacists point of view, and for the purposes of contributing to the current consultation, we shall focus on those medical devices that are intrinsically linked to the safe and correct administration/use of medicines (inhaler, insulin pen, ear drop devices, etc) and also with medical devices used for periodic health checks performed at pharmacy level (e.g. glucose and cholesterol measurements). We shall also give our opinion on highest risk category medical devices.

3. Medical Devices and Community Pharmacists

The safe and correct use of medical devices as well as the monitoring of possible safety problems with marketed medical devices are indeed areas where community pharmacists have a view and a role to play[1,2].

As PGEU has pointed out in its publication "Maximizing Patient Safety in Europe through the safe use of medicines"[3] (February 2007), the pharmacist is the most likely person, outside hospital care, to learn about adverse drug events (ADE) a patient has experienced. The documentation of ADE has therefore been progressively integrated in the systematic process of patient care in the pharmacy, including the use of reporting and learning systems. These comprise the identification of administration errors which can lead to failure of the treatment due to non-effectiveness of drug therapy (e.g. incorrect technique when using inhaler devices) or harm the patient due to safety problems (e.g. insulin devices or even inhaler devices).

[1] Schulz M, Verheyen F, Mühlig Stephan, Müller JM, Mühlbauer K, Knop-Schneickert E, Petermann F, Bergmann KC. *Pharmaceutical Care Services for Asthma Patient: a controlled intervention study*. J Clin Pharmacol 2001;41:668-676

[2] Müller U, Hämmerlein A, Casper A, Schulz M. *Community pharmacy-based intervention to improve self-monitoring of blood glucose in type 2 diabetic patients*. Pharmacy Practice 2006;4(4):195-203

[3] http://www.pgeu.eu/Portals/6/documents/2007/Publications/PR/07.03.05E%20Patient%20Safety.pdf

As we have also explored in our publication "Targeting Adherence: Improving patient outcomes in Europe through Community Pharmacists' Interventions"[4] (May 2008), it is vital that patients fully trust on the medicines (and medical devices) they use and are skilled to use them in the safest and most effective way, in order to improve adherence to therapies. Moreover, pharmacists provide an important contribution to improving patients' knowledge on available options, most indicated for their individual needs.

Considering the above, PGEU will therefore comment on the aspects of the Commission's consultation which are most relevant to ensuring patient safety and healthcare professionals' protection when using medical devices. We will also focus on the measures that would assist healthcare professionals, and particularly, pharmacists, in providing better care to patients using medical devices.

4. Comments to the Commission's Proposal

Scope

Item 1: Legal simplification – Do you see any positive or negative impacts of merging the nine texts into one legal text?

We have no objections to consolidating all existing harmonisation measures on medical devices into a single text.

Item 2: Risk-based classification – In your opinion is such a risk-based classification system more desirable than the current European List system? Are you aware of any consequences for the protection of public health?

We believe that efforts to approach the current legislation to the Global Harmonisation Task Force for medical devices should be welcomed, provided that these will increment, rather than lower, the general quality and safety standards that need to be in place for medical devices available within the EU.

Although the risk-based classification system is proposed for *in vitro* medical devices, from a healthcare professional perspective, and bearing in mind patient and healthcare professionals' safety issues, it could be helpful to introduce the notion of 'associated risk' into the current classification of medical devices. This would provide additional information both to patients and health professionals.

Item 3: To your knowledge, are these the only medical devices currently not regulated at an EU level? Can you indicate others?

An example of a medical device which is not regulated is the "alternative cigarette", also known as "electronic cigarette" or "e-cigarette".

Item 4: In your opinion, is it necessary to ensure full protection of public health to regulate these products as "quasi medical devices"? (…)

It is important to clarify what the classification as "quasi medical devices" means. Is this a sub-category of medical devices? Are the requirements (including safety rules) for this category the same as for medical devices?

We see that more and more products that answer to the definition of medicinal products are considered in some countries as medical devices. Some examples include:

[4] http://www.pgeu.eu/Portals/6/documents/2008/Publications/08.05.13E%20Targeting%20adherence.pdf

- products for the irrigation of the bladder
- intra-uterine devices
- hyaluronic acid injections for the knee
- products for artificial tears (e.g. Lacrinorm tube is in Belgium a medicinal product but Lacrinorm unit-dose is a medical device)
- menopause products
- products for the prevention of allergies
- …

Such confusion may have an interest as medical claims are allowed for medical devices and can be advertised.

We also see that there is confusion between medical devices and cosmetics. As an example we can mention products to make bleach the teeth. It is interesting to notice that in some cases legislation on cosmetics is more rigorous than legislation on medical devices.

Finally, there is also confusion between medical devices and food supplements. Examples of this are slimming products (natural polymer with a high lipid absorptive capacity - effect on cholesterol) and products made with oyster extracts against coughing.

It is therefore important that such confusions are eliminated.

Evaluation Procedures

Item 6: New essential requirements – In your opinion what changes are needed to the essential requirements?

PGEU welcomes the addition made to the essential requirements in section one of Annex I of Directive 93/42/EEC, as amended by Directive 2007/47/EC, of 5 September 2007, referring to 'design for patient safety' and 'design for lay, professional, disabled or other users' as indeed reinforces a users' perspective in the legal text which, in our view, can only add value.

With regards to the possibility of including new essential requirements in order, for example, to fight against counterfeiting, we believe it would be advisable to cross-link the results of this consultation with the ones resulting from the Commission's consultation on "Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use". We believe there are some communalities which could possibly be explored.

In this regard, we also feel it would be relevant to raise awareness about the extension of the counterfeiting problem which affects medical devices. For example, a website (possibly through the EU Health Portal and national Medicines Agencies) which would inform health professionals and the general public on defective and counterfeited medical devices would help people to detect and avoid the use of such devices. To this end names and references of devices are not enough. Visual information, i.e. pictures of the devices, is essential.

Whilst recognising the importance of identifying and implementing anti-counterfeiting measures, we are of the opinion that a proper impact assessment has to be carried out in order to ensure that any EU proposal is proportional and equally effective across all Member States.

Item 8: The Commission intends to make some proposals concerning the functioning and the activities of the Notified Bodies, some of which could be cumulative. Furthermore two options could be put forward to strengthen the system. What is your opinion on each proposal and option and what would be an estimate of the impacts and costs involved?

We agree with Proposal 1: increase transparency into the activities of Notified Bodies. E.g.: on the website: http://www.mdss.com it is not possible to find the notified bodies for Belgium. To notify their products, some companies choose a country where requirements are not so rigorous.

Item 9: Highest risk category medical devices - What are the social and economic advantages and disadvantages of extending the role of EMEA in the medical devices legislative framework?

With regards to the possible extension of EMEA's competence in the evaluation process of medical devices we believe it is important to go back to the medical devices definition. It seems unfeasible that EMEA could possibly, within its current structure and budget, incorporate an evaluation competence of medical devices in general. However, and considering the experience EMEA has gained in the past ten years as well as its most recent involvement in the implementation of the paediatric medicines and advanced therapies legislations, we would welcome its involvement in order to include a pre-marketing evaluation component to the highest risk category devices such as coronary stents, pacemakers, HIV test kits or diagnostics to accompanying advanced therapy medicinal products. We would suggest that the post-marketing surveillance component of these products should also be part of EMEA's competence in order to ensure that the entire product cycle is taken into account. Nonetheless, it seems obvious, that if expanded competences are requested, an appropriate revision of EMEA's budget should also need consideration in order to ensure sufficient expertise in this area.

Item 12: Do you see any reason why EMEA Medical Devices Committee should not also have the possibility to have access to all evaluation reports of the Notified Bodies in order to establish and monitor a high level of evaluation and to require corrective action where needed?

See our answer to item 9.

Vigilance

Item 13: One or more proposals to improve the vigilance system could be foreseen to be appropriate. In each case can you give an estimate of the socio-economic impact of the particular proposal?

PGEU strongly supports the need to improve the medical devices' vigilance system and we welcome a possible role of the Commission towards increased vigilance and coordination between Member States in this regard.

Proposal 1 suggests establishing an obligation for the medical institutions and healthcare professionals to report incidents and to invite patients to do the same. Current legislation on Pharmacovigilance and even the expected Commission proposal to revise it do not foresee incidents reporting as an obligation, but rather as a desirable although voluntary measure. As we had the opportunity to mention in our response to the Commission's consultation on "strategy to better protect public health by strengthening and rationalising EU Pharmacovigilance", healthcare professional organisations play a relevant role in improving professional practice and can collaborate with competent authorities in the implementation of policies and measures to enhance healthcare professionals'

contribution to the pharmacovigilance system. The same applies to a medical devices vigilance system. The synergies between the two systems should be explored and the use of existing reporting tools (Eudravigilance and Eudramed) should be streamlined, at least from a patient and healthcare professional angle. In fact, using different reporting systems whether an adverse event has been caused by a medicine or by a medical device may pose difficulties.

Proposal 2 to create an obligation for the Notified Body to periodically review the manufacturer's vigilance system seems to be a reasonable and most immediate measure to put into operation; however this measure alone would not suffice to ensure a strengthened vigilance system throughout the EU. Therefore we believe that a combination with proposal 5, which envisages the exchange of information on incidents and corrective measures at an international level, should be explored. Further to the products already mentioned under item 9, we are unsure of what would be the added value of providing EMEA with a coordination role of vigilance reports and signals detection for ALL medical devices, if a combination of proposal 2 and 5 would be in place.

Still in what concerns the safe use of medical devices, we would like to draw attention to the fact that there are some cases where patients decide to sell their used medical devices (e.g eBay). This is an area that needs further auditing and public awareness to ensure that devices sold keep their original characteristics (e.g. calibration; sterilisation; etc).

Market Surveillance
Item 14: In order to reinforce market surveillance, it could be appropriate:
– to have a central European registration system for devices;
– to redraft and rationalise the rules on market surveillance;
– to strengthen the provisions related to the Commission on coordination; and,
– in cases where the Commission has to take a decision, to have the possibility to ask for a scientific opinion of the Medical Device Committee in EMEA.
Do you see any problems with these measures to increase the integrity of market surveillance?
We agree with the first point: "to have a central European registration system for devices". All national authorities, health professionals and patients must have access to this central European registration system.

In Belgium, for instance, there is a very bad example of non-communication between countries: mesoActive - Cellulyse. This product was notified in France as medical device and was also sold in Belgium. In April 2007, this product was withdrawn in France, but health professionals in Belgium did not know about it.

Borderline cases
Item 15: The Medical Devices Committee in EMEA could provide a joint opinion together with the Committee for medicinal Products for Human Use on the appropriate qualification of a product.
We are in full agreement with this proposal as indeed most borderline cases involve medical devices and medicinal products.

Global Harmonisation Task Force for Medical Devices
Item 16: To what extent should European legislation reflect the GHTF global model?

PGEU welcomes the suggestion to evaluate how the GHTF guidance documents could be further included in the European framework. Manufacturers and Notified Bodies should be involved in such evaluation.

Imports, exports and Counterfeiting
Item 19: Can you suggest appropriate measures within the future legal framework for medical devices that could help battle against the counterfeiting of medical devices?
Please see our response to item 6.

5. Conclusion

Overall, PGEU welcomes the Commission's initiative to examine a possible recast of the medical devices directives to promote a more uniform level of protection of public health in the European Union.

END