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EUROLAB Special Briefing

Latest developments in the Medical Devices field

The revision of the EU Regulation on medical devices (COM 2012/542) and in vitro diagnostic medical devices (COM 2012/541) has entered a critical phase now. The European Parliament has completed its report and must now work together with the European Council and the European Commission towards an agreement on a final text.

On 1st December 2014 coincidently a **Dutch TV programme, RADAR TV**, spotlighted medical products that are currently under investigation in various parts of the world.

The purpose of the programme was to reveal **weaknesses in the CE marking procedure for medical devices**. In order to do so, the reporters created a new “medical product”, more precisely a "vaginal mesh". As a basis for this they took a mesh material which is normally used for keeping oranges together in the supermarket. They took pictures of this mesh and put together a full set of technical documentation needed to get a CE marking from a Notified Body. RADAR then asked three Notified Bodies to study their "new product" and to estimate the chances of getting a CE marking soon. The programme gives the impression that all three Notified Bodies stated that there was a very good chance that the RADAR product would get a CE mark, without mentioning that severe non-conformities had been found by the Notified Bodies. The programme also featured a section on a Medical Devices CE Marking training session (filmed with hidden camera) suggesting that this course provides information on how to get CE marking in an easy and quick way.

The European Parliament member, Glenis Wilmott (S&D) who is currently in charge of the Medical Devices regulation, commented that obviously the rules and regulations, and/or the implementation of this legislation, are not sufficient and should be evaluated. She added that the European Parliament has been struggling with this issue for many years and that Member States should stop “dragging their feet” and contribute to a better solution for a better system. Surely the whole process needs to be carefully investigated.

The broadcasting of the Dutch TV show was followed by statements of TÜV AUSTRIA, BSI, Kiwa, Eurofins, The European medical device industry association (Eucomed) and other medical associations.

TÜV AUSTRIA stated that the interviews with the experts were edited so as to create the impression among the viewers that the conversations recorded with a hidden camera anticipate the results of the complex approval process for medical devices. This, according to TÜV AUSTRIA, is incorrect mainly because:

- The review of the product documentation that has been submitted has been found with serious flaws which have not been mentioned in the TV programme.

- The invoice for the initial review of the technical documentation shown in the TV programme was merely a **partial invoice** for a multi-step process and this was never mentioned in the TV Show. Additionally for the handling **of the complete Conformity Evaluation Process** it was pointed out that the involvement of technical experts is required and would create additional costs, but this as well was never mentioned.

- Both **on-site audits** as well as a **detailed review** of the product documentation were required, involving an **expert in the field**. This as well was not mentioned

- Despite multiple requests, no product sample was provided. The complete risk management dossier was missing and there were no documents available proofing the fulfilment of the Essential Requirements for the CE marking.

- **Several 'non-conformities' had been found** in the documentation, which were mostly – but not exclusively – errors of form. (Examples: The clinical evaluation report is not in line with the requirements of MedDev 2.7.1 Rev3; There is no document available proofing the fulfilment of the Essential Requirements; The complete risk management dossier is missing)

Kiwa and **Eurofins** provide a similar picture in their statement: the **technical documentation** of the product which had been submitted was inadequate and incomplete and deficiencies were noted. **Test results were missing**, additional information had not been provided and the requested **inspection visit** to the production had not taken place. The undercover TV team only agreed to an initial review of the submitted technical documentation for the fake medical product yet the TV programme gives the impression that all three Notified Bodies had granted a CE mark, not mentioning that the majority of the steps necessary for approval had not even taken place yet.

Kiwa also points out that it is the European Union and the national governments that set the rules and that have failed so far to address the apparent weaknesses in the system. **BSI** picked up on Kiwa's point and stated the following: "BSI takes our role as an EU Notified Body extremely seriously and patient safety is paramount to us. We are **confident in our existing approach as a European Union Notified Body** (EU NB), however, we are always **looking for continuous improvement** and work with our competent authority the MHRA to strengthen and develop the EU system in the interest of patient safety. As a result of transfers to BSI from other European Notified Bodies, we are aware of the variable application of the requirements by a few Notified Bodies and have lobbied the MHRA pro-actively for this to be addressed. Allied to this, BSI strongly supports the proposed changes in legislations currently going through the European Parliament."

The European medical device industry association (Eucomed) also issued a statement. Eucomed shared the concern and frustration expressed in the Dutch Television Show and stated that: "[…] this clearly **highlights the known weaknesses in the current approval system**. […] the lack of consistency among Notified Bodies is a known weakness. We fully support measures such as **stricter controls on Notified Bodies** to ensure that only the best are allowed

to evaluate products destined for use by European doctors and patients. We also welcome unannounced manufacturers inspections, improvements in labelling and clinical performance data as well as increased post-market surveillance of products once they are available to European Patients […]."

EUROLAB recognises the **need to modernise and strengthen the current medical devices legislation in Europe** by strengthening the Notified Body system and pushing to an increased EU Member State coordination. The objective is to achieve a clear, safe and effective legislative framework that is consistently implemented across the EU and increases consumer safety. This only can be achieved by increasing dialogue between Notified Bodies, European Institutions and Member States Authorities. Already in 2012 and 2013 did EUROLAB, together with its partners CEOC International and IFIA, publish two position papers with suggestions on how to strengthen and improve the current medical devices approval and Notified Bodies system. EUROLAB and its members will make their expertise available in a constructive way in future legislative procedures in order to achieve an overall regulatory framework which looks towards the future - and which guarantees rapid market access for innovative medical devices to the benefit of patients, whilst at the same time offering the highest possible levels of safety by means of intensified control activities.

For further information please visit:

- TÜV AUSTRIA statement: http://www.tuev.at/start/download/Dokumente/presseaussendungen/richtigstellung_radar_tuv_austria_01122014.pdf (Dutch, German, English)
- Kiwa statement: http://www.kiwa.nl/nieuws/radar-bekkenbodemmatje-geen-ce-verklaring-kiwa/ (Dutch)
- BSI statement: http://www.radartv.nl/uitzending/artikelen/detail/article/reactie-bsi/ (English)
- CEOC – EUROLAB – IFIA position paper on the proposal for a regulation on medical devices (COM 2012/542): http://www.ceoc.com/publications/positionpapers/Position%20on%20the%20proposal%20for%20a%20regulation%20on%20medical%20devices.pdf
- CEOC – EUROLAB – IFIA position paper on Safe Medical Devices for Europe http://www.ceoc.com/publications/positionpapers/POSITION%20PAPER%20-%20Safe%20medical%20devices%20for%20Europe.pdf

Please do not hesitate to contact EUROLAB General Secretariat at info@eurolab.org should you have any questions or comments.