The European Association Medical Devices - Notified Bodies

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Position paper on the future negotiations on the new legislations for Medical Devices.	

Team-NB, the European Association for Medical Devices of Notified Bodies, welcomes the agreement reached by the Council on the 5th of October 2015 on the two draft pieces of legislation on Medical Devices and In Vitro Diagnostic Medical Devices. As the two proposals have been tabled by the Commission almost three years ago, TEAM-NB hopes that the negotiations between the Council and the Parliament will be concluded quickly. TEAM-NB especially expresses its satisfaction to see the two files being considered by the Luxemburgish Presidency of the Council as priority.

TEAM-NB has always advocated a regulatory framework which strengthens the conformity assessment and market surveillance. It is necessary to learn from the problems of the past and to improve the control system. In this context, TEAM-NB wishes to highlight three issues which still need to be solved during the future negotiations and where it is necessary to find a well-balanced compromise, raising the standards and keeping a reasonable burden on the actors.

TEAM-NB and its members are willing, ready and prepared to support legislators in this crucial phase of the legislative process and to provide their expertise on future wordings of the regulations in order to assess its potential impact on the medical landscape.

1. Draft Regulation on Medical Devices

1.1 Authorised Representatives

Today, a lot of Notified Bodies and market surveillance authorities are facing problems with "ghost" Authorised Representatives developing bad practices, disappearing after a short existence (mostly some months) and reappearing shortly afterwards. This problem must be addressed in an efficient way. Giving Authorised Representatives of non EU-manufactures the full liability for defective devices, as the Council is suggesting it in the new paragraph 4a of article 9 will not contribute to solve the problem but will make things even worse. It will make it unattractive for a lot of small and medium economic players to remain or become Authorised Representatives and will increase the number of "ghost" representatives.

TEAM-NB calls on the institution to delete the wording of the Council in the new paragraph 4a of article 9.

1.2 Distinction between the Notified Bodies

The proposals of the Parliament and the Council differ in their wordings but have in common the idea of distinguishing between Notified Bodies and to provide different Notifications or extra Notifications according to the classification of the devices.

TEAM-NB fully supports the idea of improving requirements towards Notified Bodies. This has also been done at our level, by developing and enforcing our code of conduct. Since several years, notification requirements have been increased by national authorities. Joint audits make sense and it is necessary to require mare from our work.
However, any extra-notification should focus on sectors rather than on classes. It is frequent for manufacturer to have framework contracts with Notified Bodies for the conformity assessment of several devices of several classes. An extra notification only for class III would not make things easier.

1.3 Scrutiny

TEAM-NB agrees that there is a need to review and strengthen the scrutiny, especially on class III devices. In this context, it is important to reinforce already existing mechanisms of pre-market authorisations (conformity assessment carried out by Notified Bodies) rather than destroying a whole system.
Any pre-market scrutiny by national authorities must be harmonised between the two legislations and complementary to the work of Notified Bodies. TEAM-NB is willing and ready to provide expertise to the institutions in order to define such a procedure.

2. Draft Regulation on In Vitro Diagnostic Medical Devices

2.1 Nomenclature code

The new classification rules suggested by the Council are a step in the right direction. It will align the classification with Medical Devices and bring clarity. However, the legislator should go further. An update of the GMDN nomenclature is needed in order to have the classifications aligned in the everyday praxis.

TEAM NB calls on the legislators to clearly mandate the GMDN agency to update its codes and to define a transition period (ideally 3 years) in order to adapt easily.

2.2 Annexes XII and XIII (studies)

The text adopted by the Council remains too vague regarding the classification of studies. It is necessary to clarify the definition of interventional studies in order to have legal certainty (at which point is an approval from the ethic committee needed?).

This is particularly crucial for the right to use old samples from patients (which allow a better diagnostic of certain orphan diseases), which have been used in the past rather than taking the time to find new ones.

The whole industry and Notified Bodies need legal certainty and clarity.

2.3 Companion Diagnostics (Article 40)

Article 40 lays down a new procedure for the Conformity Assessment of such devices. The involvement of national authorities in charge of Medicinal product makes sense. However, such a provision cannot remain vague as it is now.

TEAM NB ask for a clarification of the requirements for a file submission for companion diagnostics and a clear separation of tasks between Notified Bodies and Competent authorities. Otherwise, this new conformity assessment procedure will not increase the safety of patients and create only unnecessary burdens, such as duplication of work.