Team NB Perspective on the Medical Devices Regulation in Europe

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Team NB is the European Association of Medical Devices Notified Bodies formed on 2001. It is a not for profit association. The 30 members are Notified Bodies under any or all of the three medical device new approach directives: 90/385/EEC; 93/42/EEC; 98/79/EC. Our aims are: to improve communications with the EC Commission, Industry, Competent Authorities and User Groups by acting as a focal point and the single voice of Notified Bodies, to promote high technical and ethical standards in the functioning of Notified Bodies, to protect the legal and commercial interests of Notified Bodies in their vital role in the functioning of the of the three medical device directives. Team-NB members wrote a position paper under the supervision of their president, Gert Bos (BSI), about the new draft regulations about Medical devices and In vitro diagnostic medical devices, which essentially expresses the following elements.

It is commonly agreed that the current European regulatory framework on medical devices has represented an improvement in the products control before their utilization over the last two decades. The ingenuity of the system is evidenced by the fact that it has served as a basis for global harmonization. It results in safe innovative products reaching European patients in a timely manner. This combination of safety and early availability to patients, is a unique and important feature.

Team NB welcomes the interim measures made by the European Commission, without waiting for the approbation of the two new regulations, to review the designation of Notified Bodies, to precise the context of implementation of unannounced visits and to enhance the 'hands on product' focus that is resulting from assessing the PIP case.

The current system combines short assessment times with a safety that equals the American FDA premarket approval system. Can we make it even better? Yes.

In the vision of Team NB, 3 key elements are needed:

1. More strict and uniform supervision on Notified Bodies. Team NB welcomes joint Member States audits, centrally coordinated and rotating. Member States should decide together on designation and details of the scope assigned to each Notified Body. This scope should be based on objective, demonstrated technical and medical expertise. Qualification requirements should at least meet the specifications in Team NB Code of Conduct, which is publicly available. Notified Bodies should focus on compliance, impartiality and high quality delivery. Approximately 20% of the Notified Bodies review 80% of the products and the expertise of these Notified Bodies is well established. However, not all Notified Bodies are fully resourced with competent personnel matching their scope of designation. This can be changed, not by focusing on the number or the nature of Notified Bodies in itself, but on their quality and on restricting their scope to proven competence and available expertise. A clear window in which Notified Bodies are to operate, will be key to provide safe medical devices to European citizens in an affordable and timely manner in the years to come.

2. Secondly, all stakeholders should coordinate their market surveillance activities. It would be much more effective if all competent authorities were to investigate specific groups of products simultaneously. At the same time, Notified Bodies should focus their unannounced visits on this same product group. Other stakeholders could then follow with their assessments and trend analyses. This way, input from all stakeholders, including medical practitioners and patients, can lead to more detailed product related safety and performance guidance.

3. Thirdly, the best way to enhance scrutiny is for Member States to do unannounced reviews of selected high risk design dossiers after CE marking. This forces Notified Bodies to excel in all their assessments. In addition, this will result in a more harmonized interpretation of the regulation. The Member States should focus on supervision and enforcement. To do so, they must have suitably competent resources. An added layer of review does not improve safety and will significantly delay the arrival of beneficial new treatments to patients.

In addition, TEAM-NB supports the concept of a 'qualified person' that has been introduced into the draft legislation and considers that this will help to support regulatory compliance and consistently high standards across the industry. It is also likely to support notified bodies' interactions with manufacturers and authorised representatives. Also, the regulations must clarify the roles and responsibilities of importers, authorised representatives and manufactures so that they each understand fully their obligations. The "qualified person" should be as equally well qualified as their counterparts in competent authorities and notified bodies.

All stakeholders need to cooperate in building and maintaining a fully transparent system that delivers safe, innovative devices to the patient and healthcare provider as efficiently as possible.