The European Association Medical devices - Notified Bodies

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Team-NB Reflections on European Parliament today votes

The European Association for Medical devices of Notified Bodies (TEAM-NB) welcomes today's debate and vote in the European Parliament. It is good to see the interest is high to move the regulatory revision that started in 2008 forward without losing much more time. The topics of debate are not surprising. TEAM-NB agrees we need more transparency in the system, clearly prioritising as key point the safety of patients and restoring the trust they can have in the healthcare system.

We very much appreciate the improvements various groups have prepared in the last few days. Ensuring a high level of patients' safety and confidence and promotion of innovation in the medical device industry are key concerns of Team-NB. Our association has been very much involved in the debates which took place in the Parliament in the last months.

In line with our positions, we were quite pleased to hear Ms. McGuinness stress the achievements of joint audits from member states and commission today, that have resulted in serious improvements in the supervision on medical device notified bodies. As such we believe the concept of further supervision by EMA on a select group of notified bodies will not further enhance the safety of patients, but will increase the bureaucratic elements of the process and above all will lead to increased costs for manufacturers, which will ultimately be paid by patients.

We were also interested in the comments of Mr. Seeber, stressing the innovative advantage EU has over FDA, resulting in an average of 43 months earlier market access in EU as compared to USA. That is significantly different from the 130 days process described by Ms. Roth-Behrendt in her closing remarks on today's debate. Looking at the effective time needed to review a centralised procedure on pharmaceuticals, a description of 130 days delay seems far from realistic. And if we compare to the success of the new regulation on ATMP combination products including medical devices, it is clear that in over 5 years no such products have seen market approval. TEAM-NB stays of the opinion that any form of scrutiny should be done in parallel to notified body assessment, or even better as joint effort in market surveillance.

We are encouraged by the message of Commissioner Mimiça that he is convinced there will be a short term solution and that he will personally work on early closure of the new regulation in spring 2014. The good news he brought that the European presidency of Lithuania agreed to start negotiations before the end of the year.

As to the votes, the European parliament should be applauded for their focussed endorsement of many last minute amendments prepared in the last week. TEAM-NB is very pleased to see that the improvements proposed by Ms. McGuinness and Mr. Liese for EPP and ALDE on special notified bodies, restricted EMA involvement, ACMD and MDCG have been endorsed, including those that were altered in the split votes on specific articles. This shows great progress towards keeping the system flexible with timely product approvals, whilst increasing transparency, coordination and clinical oversight. Also good to see the default position of clinical trials being randomised and performed against a comparator did not make it, as it

would lead to cost explosion on clinical trials, and subsequently on affordability of healthcare. On the other hand the clinical investigation as per annex XIV, part I, point 2.1 will need to include efficacy of the device in the future, so a serious increase on clinical evaluation is included in the Parliament endorsed text.

So great improvements were reached today, but clearly more work is needed on the proposals to get the legislation where it needs to be.
Of great concern to TEAM-NB members are still some detailed aspects relating to the operation of notified bodies.
- A key concern relates to the direct suspension mode of notified bodies when a member state so requests (art. 33.8). TEAM-NB believes that prior to suspension there should be a critical objective review of the notified body and its work, given the extreme consequences that would result for a large number of manufacturers certified by the notified body. In certain cases de- designation leading to invalidation of large numbers of certificates and wholesale removal of products from the market could negatively impact the continuity of patient care.
- Notified bodies may hire external experts on an "ad hoc and temporary" basis provided they make publicly available the list of these experts, as well as their declarations of interest and the specific tasks for which they are responsible. Many experts will not make themselves available to serve notified bodies in questions related to specific technical or new developmental issues when names have to be made fully public. This would lead to a lack of sufficient high level expertise to the reviewing side of the CE approval process in EU.
- The amendments of the ENVI regarding standard fees for notified aim that the competition between the notified bodies should not be at the expense of the depth of the conformity assessment. This objective cannot be achieved through uniform fees for conformity assessment activities in Europe. Especially as it doesn't exist a consistent wage level in Europe (and in the single member states), standard fees would result in distortions of competition. For a European wide uniform depth of conformity assessment, standardized test programs are an effective means.
- We continue to be concerned on the reprocessing of single use devices, although improvements to the text have been accomplished today. Patient safety remains with the push of reprocessing as default option, as this is in direct conflict with key established risk management principles currently applied in the sector.
- A further concern is raised on the new definition of incident to now relate to "any product malfunction or deterioration in the characteristics or performance of a device..."; whilst the intend of improving reporting is understood and agreed to, the proposed wording might result in such over-reporting that the essential safety information will be hard to find in the "noise", thus leading to a potentially less effective signalling system.

In addition for the IVD good improvements have been made. Still concerns of members include at this stage:
- Article 41a.4 indicates a selection of applicant notified bodies by EMA, rather than an evaluation of competence of notified bodies applying for a scope including class D products.
- A transition of 3 years will put extreme stress on all operators. The reduction of transition period from 5 to 3 years for application of IVD Regulation after entry into force will produce tremendous problems, due to the huge impact of the change in the classification system for IVD Devices on the amount of products to be assessed. As Article 78 on EU Reference Laboratories shall apply 24 month after entry into force of the IVD Regulation – this will result in the need to assess all class D products according to the new Regulation within one year, which will be extremely challenging to Notified Bodies as well as other organisations involved.