The European Association Medical Devices - Notified Bodies

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Position paper : Notified Bodies workload today and in the future	

Today, the workload of Notified Bodies carrying out conformity assessment of Medical Devices has increased significantly. In the future, with the proposed new Medical Devices Regulation and In Vitro Diagnostics Regulation in place, there will be a further substantial increase of work to be done by a decreasing number of Notified Bodies.

The trends in the previous years since the publication of the amending Directive 2007/42/EC were to see an increase if the conformity assessment process concerning additional requirements on elements such as risks analysis and clinical data

Presently, the impact of the PIP scandal resulted in the generation of an "Action Plan for Immediate Actions under Existing Medical Devices Legislation". Some key actions were published in the form of two recommendation documents which came into force at the end of 2013, the Commission Implementing Regulation No 920/2013 and Commission Recommendation 2013/473/EU. Those Commission documents have also generated an increase in the Notified Bodies workload, concerning further training and qualification requirements, hosting extensive joint audits which may cover up to 60 auditor man days, and specifically in conducting unannounced visits in a minimum frequency (one per cycle) on top of regular assessment cycles. It generally represents a minimum of a third more audits each year.

The regulation on the designation and the supervision of Notified Bodies implies joint assessments of medical device Notified Bodies by Member States and Commission Experts. These joint assessments identified weaknesses in many Notified Bodies and in some cases led to restrictions of scope, inability to take on new clients and even some de-designations. Moreover some Notified Bodies took the voluntary decision to stop their activities in the medical field. These reductions in availabilities led to an increase of work for the remaining Notified Bodies.

TEAM-NB, as association representing the majority of Notified Bodies active in the field of Medical Devices, has always supported an improvement of the quality of Notified Bodies and a stronger regulatory framework. These changes to our work are necessary and are a step in the right direction. but they also create internal challenges which have to be addressed.

The above elements imply that presently

- the quotation process itself is longer than before (2 to 3 months instead of a week up to 1 month)
- the time line from contract signature, either for a new client or a scope extension with an existing client, to audit planning is now around 6 months although it was usually around 3 months in the past; the same delay might occur for the start of dossier reviews.

However, most Notified Bodies have already started hiring new auditors but this is a challenging task. There is a lack of available qualified people on the market, and a training period of 6 to 9 months before the new auditor is able to take over some audits (for dossier reviewers it might be much longer).

In the future with the requirements set in the draft regulations, all the Notified Bodies will need to be assessed to these new regulation requirements before they will be able to audit Manufacturers against them.
The re-notification of Notified Bodies will require Member States to review all the existing notifications in the light of the new requirements. This will mean an increased workload for notifying authorities during the transitional period. It is probably unlikely that notifying authorities would be able to assess the 40 to 50 applications forecast in the initial 6 month period. The question of the planning of the notifying audits and the publication of the notifications has also to be addressed. If this is done as soon as an individual Notified Bodies is designated, that will lead to unfair competition and an additional burden of Notified Bodies firstly notified with a risk of transfer requests.

Moreover, these new regulations have forecast additional requirements which will lead to an increased workload on Notified Bodies mainly I respect of the In Vitro Diagnostics Regulation.

Beside the new regulations, the trends show clearly an increase in terms of applications of new manufacturers and/or in term of applications for new products, also applications for innovative products such as nanomaterials, mobile health applications, robot, genetics testing,… These innovative medical devices are usually time-consuming reviews.

The workload of the Notified Bodies has gradually increased in the past 5 years. The 2013 regulatory documents issued in response to the “Action Plan for Immediate Actions” following the PIP case further intensified the increase of the Notified Bodies workload through both additional requirements (unannounced audits,…etc) and reduction of Notified Bodies availabilities (scope reduction, de-designation). This growth will still intensify after the new regulations are going to enter into the transition period. Moreover knowing the recruitment difficulties of competent auditors and technical reviewers and the time needed to train them, it will be crucial to take into consideration the time period in the applications of the new regulations in order to avoid some certification discontinuance.

TEAM NB calls on the legislators to ensure a transition period of at least five years before the requirements relating to Notified Bodies comes into force.

TEAM-NB asks the European institutions to assess the feasibility of a EU-funding scheme for the training and qualification of auditors in the field of Medical Devices, both for national authorities and Notified Bodies.