EU notified body numbers still yet to bottom out

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EU notified body numbers are still sinking and the bottom is not yet in sight. This month Swissmedic announced that conformity assessment bodies (CABs) working in the EU medtech regulatory arena have been cut from five to three this year, in the wake of a new ordinance (MedDO) that authorizes unannounced visits to manufacturers, among other new responsibilities. Switzerland is indicative of the EU trend as it enacts EU medtech law and harmonizes with EU rules in order not to hinder its own trade.

The same is happening within the EU in general. TEAM-NB, the European Association of Notified Bodies for Medical Devices, monitors numbers monthly. Director Françoise Schlemmer told *Clinica* that NBs accredited to work under Directive 93/42 EEC (medical devices) had dropped from 73 to 63 in the past year. There are now 17 (2014, 18) NBs that can work on active implantables, and 23 (26) that can work on in IVDs.

Liège, Belgium-based TEAM-NB does not represent all EU NBs. Its membership, now 25, has also declined somewhat, notably after it made signature to its recent Code of Conduct mandatory. But its membership has seen the loss of some names to consolidation, while some others have withdrawn their services. "The fall in NB numbers generally is down to greater competencies needed and the increased regulation of the sector," Ms Schlemmer said.

NB withdrawals are due to three reasons, she said:

•not being able to conform to new regulations;

•following a joint assessment or competent authority audit; and/or

•mergers of NBs.

The bottom has not been reached, she added, pointing to possible duplications in the Nando website, further consolidation expected and more withdrawal from the sector up ahead. Some EU members states have a preponderance of NBs (Germany has 13, for instance) prompting the notion of more mergers, and some EU NBs are likely to have their scope reduced. "Specialization might be a solution for some, but the smaller NBs will not be able to do all competencies in the future," she said.

Two TEAM-NB members have recently decided that they will not meet the standards set in the association's CoC, and a Swissmedic spokesman told *Clinica* that the five Swiss CABS that had recently become three could soon become just two. Ms Schlemmer advocates a philosophical view in such matters, and believes the restructuring of industry, albeit painful, has quality delivery in its target sights, and will moreover result in a body of NBs that is less open to unfounded criticism.

A positive development for NBs generally was seen this month when the French appeal court cleared notified body TÜV Rheinland of any wrongdoing in the Poly Implant Prothèse company PIP fraud case, the manufacturing scandal that implanted a false picture of an unregulated industry in the minds of those pressing for a system overhaul.

Elsewhere, the proposed EU Medical Device Regulation has reached a critical stage, and the scope of NBs will soon be back on the agenda, come September/October. Ms Schlemmer is not in favor of special NBs, an EU Parliament proposal that would siphon off certain high-risk files to certain NBs. She fears confusion over how such a system would work, and opposes any trend towards a two-tier sector. On the other hand, assessing the scope of NBs presents no problems for her.

In spite of the topline fall in numbers, TEAM-NB views the outlook for EU NBs with a modicum of optimism. Ms Schlemmer said: “We have the processes in place to really deal with matters. And often overlooked as it is, protecting public health is our objective.”