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Cover story : EU notified bodies numbers still yet to bottom out

By A Wenzel adapted from an article in scrip regulatory

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, by two, to three this year, in the wake a new ordinance (MedDO) that authorizes unannounced visits to manufacturers, among other new responsibilities[1]. 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 *Scrip Regulatory Affairs'* sister publication *Clinica* that notified bodies 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) notified bodies 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 notified bodies. Its membership, now 25, has also declined somewhat, notably after it made signature to its recent code of conduct mandatory[2]. But its membership has seen the loss of some names to consolidation, while some others have withdrawn their services. "The fall in [notified body] numbers generally is down to greater competencies needed and the increased regulation of the sector," Schlemmer said.

Notifed body 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 notified bodies.

The bottom has not been reached, she added, pointing to possible duplications in the European Commission's database on New Approach Notified and Designated Organisations (NANDO), further consolidation expected and more withdrawal from the sector up ahead. Some EU members states have a preponderance of notified bodies (Germany has 13, for instance) prompting the notion of more mergers, and some EU notified bodies are likely to have their scope reduced. "Specialisation might be a solution for some, but the smaller notified bodies 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 said that the five Swiss CABs that had recently become three could soon become just two. 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 notified bodies that is less open to unfounded criticism.

A positive development for notified bodies 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[3], 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 notified bodies will soon be back on the agenda, come September/October[4]. Schlemmer is not in favor of special notified bodies, an EU Parliament proposal that would siphon off certain high-risk files to certain notified bodies. 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 notified bodies presents no problems for her.

In spite of the topline fall in numbers, TEAM-NB views the outlook for EU notified bodies with a modicum of optimism. 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."

This story has also been published in Clinica Medtech Intelligence*. Scrip Regulatory Affairs brings selected complementary coverage from our sister publications to our subscribers*.

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2. Europe's notified bodies take up cudgels to meet regulatory challenge, *Scrip Regulatory Affairs*, 17 October 2012

3. French court clears notified body in PIP breast implant case, *Scrip Regulatory Affairs*, 7 July 2015

4. EU medtech reform makes landmark move, *Scrip Regulatory Affairs*, 19 June 2015

1) IMDRF consults on common data elements to help identify a device throughout its lifecycle

By A Wenzel adapted from an article in scrip regulatory

The International Medical Device Regulators Forum is inviting feedback on proposed common data elements that may be used to identify a medical device throughout its lifespan[1].

The proposed data elements, when finalized, may be used through various pre- and post-market regulatory activities, including for possible electronic regulatory submission of device identification information in the future.

The IMDRF explains that at present no common data elements are in place for device identification, which has resulted in inconsistent nomenclature, definitions and structure for the submission of identification information. As a result, each type of submission may reference the same product differently. For example, a pre-market submission could refer to a "product trade name", while the data attributes associated with UDI (unique device identification) for the same device may contain the "brand name" and a recall for the same device may refer to the "proprietary name".

The combination of different ways to identify a product and the unstructured way in which product information is submitted make it difficult over time to reconcile the references to the same product, the IMDRF says. This is because the same device may be described one way in a pre-market submission and in another way in a post-marketing surveillance report. The lack of consistency on these front results in multiple submissions of data, potential conflicts or inconsistencies in submitted information, and ultimately problems regarding compiling effective post-market surveillance information about a product, the IMDRF adds.

The IMDRF believes that it would be useful to establish common data elements, for which values can be provided in the pre-market processes. This could be used throughout the lifecycle. "[The] consistent use of a standardized common set of structured data elements for submission of regulated product identification information will aid in long-term regulatory convergence by providing a common way for regulators to refer to what is regulated and as a result to track and report unambiguously on the national regulatory status of a product around the world," it says.

Stakeholders have until September 15 to comment on the IMDRF document, which identifies preferable data elements that may be used to identify a medical device through its life span. The IMDRF clarifies that the data elements presented in the consultation document do not imply a "requirement" for the exchange and/or use of the data, but only refers to potential data to identify a medical device at each lifecycle phase based on the regulatory requirements in each of the IMDRF jurisdictions.

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Source: *Vibha Sharma* , Scrip Regulatory

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2) UK ABHI suggests linking medtech fee to product registration in EUDAMED

By A Wenzel adapted from an article in scrip regulatory

As various EU member states make plans to launch - or have already launched - new fees to cover the cost of regulating medical devices in their respective jurisdictions, the UK's medtech industry association ABHI is suggesting that a pan-EU approach be adopted by making a registration charge in connection with the EUDAMED medical device database[1].

The ABHI suggests that the registration charge can be levied when the updated database (ie, EUDAMED III) is launched. This would be a possible way forward "particularly as work to set this up is now starting in earnest," the trade group says.

The ABHI's comment was made in response to a consultation by Ireland's Health Products Regulatory Authority on proposals by the agency to introduce a new annual fee for medical device manufacturers and distributors[2].The ABHI said that while it did not have a direct interest in the regulation of devices in the Republic of Ireland, the UK authorities are also considering introducing a fee-based system for regulating medical devices and its response to the HPRA consultation was "limited to general points of principle".

Ireland issued a detailed proposal for a new annual fee for all manufacturers and other economic operators supplying or manufacturing medical devices last month. The HPRA believes that the most effective fee structure would be an EU-level model with a single fee for each device, with an ongoing single annual maintenance payment to cover all of Europe along with funding distributed to competent authorities in accordance with their activities and responsibilities.

The ABHI says that as the medtech sector is governed by EU law, "any funding system should be pan-European." However, it acknowledges that the development of a pan-EU system "would not be easy to put in place in the short term" and says that "this lends greater urgency to starting work on this without delay".

The European Commission's proposed revision of the EU medical device legislation includes specific provision for full cost recovery through fees levied by national authorities[3]. The UK intends to consult with stakeholders in the second quarter of this year on a new funding model that will contain a mix of a new periodic fee, adjustments to existing fees and minor central funding. Other EU countries that already have fee-based systems include Austria, Belgium, Croatia, Denmark, France, Germany, Italy, Latvia, Lithuania, Portugal and Spain.

Until a pan-EU approach was finalized, the Irish agency said that member states should aim to harmonize their national fee models. The ABHI said it supports the harmonization goal, but is surprised that the HPRA's proposed model is based on company size rather than on value of sales. "This will mean that manufacturers based in Ireland would effectively pay twice when making sales in any member state where a levy is already in place," it said.

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3. Latest EU medtech proposals take a different view on fees, *Scrip Regulatory Affairs*, 25 June 2015

Source: *Vibha Sharma* , Scrip Regulatory

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3) Singapore consults on guidance on device grouping, notifying changes to marketed products

By A Wenzel adapted from an article in scrip regulatory

Singapore's Health Sciences Authority is inviting feedback on proposed changes to its guidelines on grouping of medical devices for product registration, and on notifying changes to marketed devices.

The HSA intends to replace its current guideline on grouping of medical devices with two separate guidance documents. The first document (GN-12-1) deals with general grouping criteria that can be applied to all medical devices using broad-based principles that permit a group of devices to be incorporated into one product registration submission. The second document (GN-12-2) contains information on the grouping of specific device types that have similar technical characteristics that allows them to be grouped into one product registration submission[1-4].In the guideline that deals with general grouping principles, the HSA has offered further clarification on various grouping criteria, and has also expanded the permissible variants in a "family" grouping to include:

- Specific products like “blood bags” and “catheter”.
- Permissible variants like “color” and “(non-) formable”.

A complete list is published in scrip regulatory.

The guideline on grouping of specific device types offers information on:

- dental grouping terms (DGT) – These are Class A and Class B dental medical devices with a common intended purpose;
- hearing aids – This section only applies to Class B hearing aids and excludes implantable hearing devices;
- immunohistochemistry *in vitro* diagnostic reagents – These consist of polyclonal or monoclonal antibodies labeled with directions for use and performance claims, which may be packaged with ancillary reagents in kits;
- fluorescence *in situ* hybridization probes *in vitro* diagnostic reagents – These allow for the detection and localization of the presence or absence of specific DNA sequences on chromosomes, whereby the hybridization of the probes with the DNA site is visible using fluorescence microscopy; and
- *in vitro* fertilization media.

Stakeholders have until August 31 to comment on the two guidelines, which are expected to apply to all medical device registration applications submitted to the HSA as of October 1.

Change notification guidance

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The guideline on submission of change notification has been updated with a revised checklist to help medical device sponsors determine the types of documents they must provide to the agency to support various changes to their marketed products[5].

The revised guideline clarifies that following the HSA's approval of a change notification application, a company can "concurrently supply" both the original registered medical device and the changed medical device only if both versions of the device conform to the essential requirements for safety and performance as stipulated in the First Schedule of the Health Products Regulations.Stakeholders have until August 14 to comment on the revised guidance on submission of change notifications.

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Source: *Vibha Sharma* , Scrip Regulatory

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4) US medical device submission user fee rates to rise in FY 2016

By David Filmore in scrip regulatory

The US Food and Drug Administration's user fees for individual device submissions will increase by about 4% beginning October 1, and the annual registration fee will rise by 5.5% in FY 2016[1].

This is a switch from last year when rates for individual submission fees actually declined in FY 2015 compared to the prior year.

The agency issued its annual device user-fee rate listing for FY 2016 on July 31 (see Table 1). The fees are based on amounts set in the user fee provisions of the 2012 FDA Safety and Innovation Act, but adjusted for the impact of inflation and estimates of how many of each submission the FDA expects to receive in the coming year. The agency's inflation-adjusted revenue target from device user fees in FY 2015 is $137.7 million, up from the FY 2014 target of $131.2 million.

All of the rates that companies must pay in conjunction with a premarket submission are based off of the full rate for a premarket approval application (PMA) submission, which will be $261,388 in the coming fiscal year. The standard rate for a 510(k) submission will be $5,228. Submissions also have a small business user-fee discount of either 25% or 50% depending on the application type.

Companies also must pay an annual fee linked to PMA annual reports and an annual establishment registration fee, which must be paid by all registered device firms each year. The registration fee will be $3,845 in FY 2016; there is no small-business discount.

The current medical device user fee program (MDUFA III) took effect in FY 2013 and expires at the end of FY 2017. Companies have already started the push to avoid significant hikes in fee rates during the anticipated MDUFA IV program.

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This story has also been published in The Gray Sheet. *Scrip Regulatory Affairs brings selected complementary coverage from our sister publications to our subscribers.*

5) HTA momentum grows in Southern Africa for medical devices

By A Wenzel adapted from an article in scrip regulatory

The Southern African Health Technology Assessment Society, which acts a neutral forum for collaboration and the sharing of HTA information and expertise, has partnered with the city of Johannesburg on its forthcoming inaugural regional conference set for September 10-12, 2015[1]. While SAHTAS's remit covers HTA for healthcare technologies in general, the current focus of its activities is medical devices and procedures.

"This is good progress," SAHTAS interim secretariat Jani Müller told *Scrip Regulatory Affairs*. HTA is a fledgling concept in many parts of Africa, and what activity exists is largely isolated, under-reported, and poorly disseminated. The SAHTAS initiative aims to change that in what is seen as a major awareness-raising initiative that potentially reaches out to all 54 African countries, in spite of SAHTAS' ostensibly regional name.

Recent interest in attending SAHTAS's conference has been shown by Tunisian HTA experts, who are in the throes of setting up their own national HTA agency. Other regional bodies around Africa are also tracking the meeting, in spite of the high cost of intra-Africa travel (which can be more expensive than travelling outside Africa). Müller expects over 100 attendees, including confirmed attendance by representatives from INAHTA, the international network of publicly-funded HTA agencies, and HTAi, the global scientific and professional society.

The meeting will include workshops on the basics of HTA and the pathway of innovation to the market. There will also be plenaries, panels and abstracts. A new SAHTAS board will be elected, including president, vice president, treasurer, secretary and directors, and possibly a date set for a follow-up set. The main aim of the event is to highlight key HTA themes, discuss how HTA is used by different governmental bodies and generally raise awareness of a concept that remains uncommon in Africa.

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Source: *Asley Yeo* , Scrip Regulatory

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No. 6

6) Ukraine: 'Two months' to know if new medtech regulatory system is workable

By A Wenzel adapted from an article in scrip regulatory

Ukraine pushed through its new conformity assessment system of medical device regulation on July 1 - a year later than planned, but still too early for those critics who think the infrastructures are not yet in place and that moving away from the established state registration system so rapidly will be detrimental.

The somewhat rapid transition away from the Decree 1497 (the basis for state registration) and towards the three technical regulations/decrees (on devices, IVDs and active implantables) might lead to confusion and market disruption, some observers have said[1].

The situation won't be clear for another two months. A large volume of applications and technical documents is expected in the weeks ahead, testing the system's ability to cope "according to the new national procedures."That is the view of Maxim Bagreev, head of the Kiev-based drug and device regulatory consultancy, Cratia. Speaking to *Scrip Regulatory Affairs,* Bagreev said that the coming two months would provide enough time to gauge the capacity of the national notified bodies and their ability to supply enough experts to assess and handle all the incoming application documents.

Critics have also pointed to the lack of standards. At present, around half of the necessary medical device standards have been approved in Ukraine, said Bagreev. But there is a debate ongoing with the authorities as to whether international standards can be referred to in meeting the essential requirements in declarations of conformity. For exporters of registered devices to the Ukraine, the concerns are less pressing. "Medical devices can be imported into Ukraine without any problems according to their registration certificates, as they have been issued according to the previous legislation," the Cratia chief said. They can be imported for another year, until July 1, 2016.

He reiterated: "We will see within two months how our new national system of conformity works and if our notified bodied will have enough human resources to work with the volume of applications."

What happens then will depend on if there are problems, and how serious they are. One avenue of speculation is that the Ukraine government might accept the two procedures (ie state and conformity assessment) in parallel. Another is that Ukraine may be permitted to recognize CE-marking assessment procedures done in the EU. These are possible short-term solutions.

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Right now Ukraine is at the very beginning of its new system, and the hopes locally are that the notified bodies will be able to cope with the demand. At the present time, there is no shortage of supply of medical devices to Ukraine. Cratia's own experience is of receiving a welter of questions from companies, helping format applications and translating documents.

On the positive side, Cratia thinks procedures have become much more understandable and logical now the system is based on the EU medical devices directives. Companies with CE-marked products can "easily understand the market authorization process, which is now much clearer", said Bagreev.

In addition, for Class I and IVD products that are subject to self-declaration procedures, access to the market has become much easier. For the other risk classes, additional time is needed to get a full picture for applicants.

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1. Ukraine's new medtech regulations in force, transition decision awaited, *Scrip Regulatory Affairs,* 8 July 2015

Source: *Asley Yeo* , Scrip Regulatory

7) Pharma and Medtech Keeping A Close Watch On New Danish Medicines Agency

By A Wenzel adapted from an article of Scrip Regulatory

As of 2016, the Danish Medicines Agency is to be re-established as an independent entity and will resume its responsibility of only overseeing the pharmaceutical and medtech sectors[1].

In March 2012, the DMA was merged with the National Board of Health to form the Danish Health and Medicines Authority, which currently performs a range of activities, including licensing and monitoring of medicines (including pharmacies, medicine prices, side effects etc), registering companies marketing medical devices, and issuing and withdrawing authorizations in relation to 18 different professions - from chiropodists to physiotherapists[2].

When the DMA was combined with the National Board of Health, the government had then expected the merger to result in greater synergy between the two agencies, and to also help cut costs.However, LIF CEO Ida Sofie Jensen told *SRA* that the expected synergies from the merger were never realized and instead it started having a negative impact on the evaluation timelines. While in the first nine months of the merger, 93% of all new drug applications were assessed within the 240-day limit set by the EU for evaluating rug applications, at present, only around 70% of applications are being evaluated within the EU-established timeline, Jensen said.

The Danish government announced that from the turn of the year 2015/2016, the DHMA will be split into four separate agencies:

- the DMA as an independent agency;
- a health agency that will focus on disease prevention, health planning and radiation protection;
- a patient safety agency to supervise and register healthcare professionals and deal with complaints; and
- a new health data agency that will make health data available to researchers and authorities, and strengthen the overall digitization of the healthcare system.

LIF hopes that the DMA, once re-established as an independent agency, would restore its regulatory functions in full earnest to support the pharmaceutical industry and support its further growth. "This is something that we asked for, and we are happy that the government has listened to us," Jensen said.

Medicoindustrien director Peter Huntley told *SRA*: "We are curious to see what the changes in the Danish Health and Medicines Authority will mean [for the medtech sector]. There is still a lot that needs to be clear before we can point to the pros and cons."While Medicoindustrien had not formally lobbied for the DMA to be re-established as an independent agency, it said it had pointed out on several occasions that the DHMA lacked the necessary resources to carry out its tasks.

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"It has been pointed out by the Danish minister of health that the reason behind the split up is to have more focus on vigilance and surveillance by the authorities," Huntley said. In line with this goal, Medicoindustrien said it wants the re-established DMA to improve reporting of adverse events by healthcare practitioners, who currently account for around 15% of all adverse events reported (the industry accounts for around 45% of all adverse events reported). Healthcare practitioners are the ones who have first-hand experience with medical devices, and there is a broad consensus within Denmark that there is a underreporting of adverse events from this group, Medicoindustrien said.

LIF explained that the DMA has historically operated on fees paid by the industry and this fee-based arrangement would continue following the re-establishment of the DMA as an independent agency. "The merger had created problems and it was not transparent to us how the funds [ie, fees collected from industry] were being used… We are ready to pay – not all that they demand for – but at least for the cost of the services," Jensen said.

Loss of specialist staff

Earlier this year, Else Smith was removed from the post of director-general of the DHMA following a series of incidents that had led the government to believe that the DHMA's supervision over certain matters was inadequate[3].

Among other things, Smith's dismissal was also a consequence of the fact that several specialist staff had left the DHMA, with whom the industry had developed individual relations over the last several years, Jensen said. "The loss of so many experienced and competent staff made us worried as we could not get specialist advice… We told the government that we were not happy about the situation as we pay a fee for various services," she added.

The government has assured that the re-established DMA would focus on promoting the growth of the medical products sector, Jensen said.

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Source: *Vibha Sharma* , Scrip Regulatory

No. 8

8) Electronic Medical Device Reporting Is Now Mandatory In US

By A Wenzel adapted from an article of Scrip Regulatory

Mandatory electronic medical device reporting (eMDR) in the US went into effect on midnight, Aug. 14, as noted in a 2014 Food and Drug Administration final rule[1]. But manufacturers will have a grace period of one month wherein they will still be able to send paper adverse events to the agency.

"Since MDR reporting is triggered on the date a manufacturer or importer becomes aware of a reportable event, we will continue to accept reports from manufacturers and importers for a period of 31 days following the mandatory electronic compliance date," or Sept. 15, said Isaac Chang, director of the Division of Postmarket Surveillance in the FDA's Center for Devices and Radiological Health.

After Sept. 15, "the FDA will return to manufacturers and importers any paper submissions received and companies will be required to re-submit these reports in electronic format," Chang told *Scrip Regulatory Affairs* sister publication *The Gray Sheet*.

Operational since 2006, the eMDR system is intended to enhance the device center's ability to analyze adverse event reports and identify troubling patterns. A large majority of adverse event reports already come to the agency electronically, even though e-reporting was voluntary before Aug. 14.

About "75 to 80 percent of MDRs were already being submitted electronically at the time the final rule was published in February 2014," Chang noted.

"The eMDR requirements apply only to device manufacturers and importers. Device user-facilities are encouraged, but not required, to submit MDRs electronically."

Manufacturers that haven't set up a process to send electronic medical device reports to FDA are far behind the 8-ball.

"Electronic Medical Device Reporting – that's where it's at," former longtime CDRH official Cap Uldriks said recently.

"If you haven't started … do it now. FDA has some guidance documents on that. They take you through step by step by step," said Uldriks, who spent 37 years at FDA and now runs consulting firm Encore Insight.

The process to become electronic-compliant takes about two to three weeks and involves establishing an Electronic Submissions Gateway (ESG) account[2].

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9) About us:

By L. Wenzel

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