Increased application audit requirements for some medical devices applications

Increased audit requirements for medical devices using conformity assessment by selected European notified bodies

16 September 2014

In October 2012 the British Medical Journal published an article titled 'How a fake hip showed up failings in the European device regulation' (BMJ 2012; 345: e7126). The article named eight European notified bodies and questioned if they were "likely to be more interested in repeat business than patient safety".

Following consideration of the BMJ article and consultation with other regulators, the TGA has selected for audit all applications for inclusion of medical devices in the Australian Register of Therapeutic Goods (ARTG) that use supporting evidence from the named notified bodies (see Table 1). The TGA has so far received applications for inclusion using supporting evidence from three of these notified bodies. As the TGA receives applications for ARTG inclusion that use supporting evidence from the remaining notified bodies, these applications will also be selected for audit.

The TGA is conducting these application audits to obtain its own evidence of the quality of certificates and reports issued by these notified bodies. Ensuring that therapeutic goods marketed in Australia meet acceptable standards of quality, safety and performance is the TGA's core role, so it is important that the TGA responds appropriately when matters that could impact on public health and safety are raised.

Table 1: Application audit focus[1] - applications for ARTG inclusion using conformity assessment certification from listed European notified bodies selected for audit

NANDO[2] ID	Notified Body Name	EU Member State	European Designation[3]
NB #1008	TÜV Rheinland InterCert Műszaki Felügyeleti és Tanúsító Korlátolt Felelősségű Társaság	Hungary	MDD
NB #1015	Strojirensky Zkusebni Ustav s.p.	Czech Republic	None[4,5]
NB #1023	Institut Pro Testováni A Certificaci, a.s. (ITC)	Czech Republic	MDD, AIMD and IVD
NB #1293	EVPU a.s.	Slovakia	MDD and IVD[6]
NB #1979	SGS Hungária Minoségellenorzo, Kereskedelmi és Szolgáltató Kft.	Hungary	MDD and IVD

NB #2138	Alberk QA Uluslararası Teknik Kontrol ve Belgelendirme Anonim Şirketi	Turkey	MDD[7]
NB #2179	Kalitest Belgelendirme ve Egitim Hizmetleri Ltd Sti.	Turkey	None[8]
NB #2265	3EC International a.s	Slovakia	MDD and IVD

1. These 8 notified bodies were named in a British Medical Journal article in October 2012 and are included in TGA's review.
2. NANDO refers to European Commission *New Approach Notified and Designated Organisations* Information System
3. MDD refers to Medical Devices Directive 93/42/EC, AIMD refers to Active Implantable Medical Devices Directive 90/385/EEC and IVD refers to In-Vitro Diagnostics Directive 98/79/EC.
4. Strojirensky Zkusebni Ustav s.p had MDD designation withdrawn 28 December 2013
5. Please note that this table was updated on 16 September 2014 to include the notified body Strojirensky Zkusebni Ustav s.p (#1015, based in the Czech Republic) and to remove the notified body Szutest Teknik Kontrol ve Belgelendirme Hizmetleri Ticaret Limited Şirketi (#2195, based in Turkey). Szutest Teknik Kontrol ve Belgelendirme Hizmetleri Ticaret Limited Şirketi (#2195) was previously included in error, and the table above has been amended to reflect those notified bodies mentioned in the British Medical Journal article from October 2012.
6. EVPU a.s. had AIMD designation withdrawn 11 June 2013.
7. Alberk QA Uluslararasi Teknik Kontrol ve Belgelendirme Anonim Şirketi has MDD designation valid until 13 January 2015 (source: Europa NANDO website accessed 10 June 2014).
8. Kalitest Belgelendirme ve Egitim Hizmetleri Ltd Sti. had MDD designation withdrawn 26 February 2013.

What will happen?

The TGA will continue to select for audit all applications for ARTG inclusion which are supported by certification from the European notified bodies listed in Table 1 until further notice. Mandatory audit arrangements will continue without change.

For this reason, if a sponsor is supplying certification from these notified bodies to support an application for ARTG inclusion, they are likely to experience delays in obtaining approval to market in Australia.

Regulatory requirements, risk and conformity assessment

Regulatory requirements for medical devices vary depending on the device and its intended use. Risks associated with using medical devices can range from low potential risk to patients and users, through to significant potential risks. These higher risk devices undergo greater premarket scrutiny prior to inclusion in the ARTG and use in Australia.

A manufacturer must be able to demonstrate that both the device and the manufacturing processes used to make the device conform to the requirements of Australian therapeutic goods legislation. Conformity assessment provides objective evidence of compliance with these requirements through a determination that an appropriate Quality Management System (QMS) has been applied in the manufacture of the medical device to ensure the quality, safety and performance of that device.

The TGA is conducting this review of certificates and reports from specified bodies to obtain evidence of whether the notified bodies had sufficient evidence to conclude that:

- the manufacturer had adequately demonstrated the implementation of an appropriate QMS, and

- the kind of device complied with the essential principles.

European authorities have recognised the need for reforms to strengthen controls on medical devices in the European Union particularly the role played by notified bodies. In the context of the possible future adoption of two new EU Regulations on medical devices, the following issues are currently under discussion:

- strengthened **notified body requirements** such as ensuring that notified bodies have permanent "in house" competent personnel. Where subcontracting takes place, notified bodies would include the names of subcontractors and the tasks undertaken in their annual report to the relevant national authority. This will enable the verification of the subcontractors' qualifications.
- introduction of new **special notified bodies** responsible for conformity assessment of high risk medical devices (Class III, implantable devices and devices incorporating medicinal products)
- introduction of an **assessment committee for medical devices** the decisions of which will be adopted by the European Commission and binding on special notified bodies
- increased **rigour of clinical investigations** e.g. authorisation for conducting a clinical investigation will be granted only after examination and approval by an independent ethics committee and manufacturers will be required to collate clinical data to prove that their devices meet performance (encompassing efficacy and benefit to patient) and safety requirements
- strengthened **designating authority requirements** to ensure regulatory personnel have sufficient qualifications, charging fees and establishing penalties for manufacturers that commit fraud
- obligations for manufacturers to take **liability insurance**
- improved **information to patients and healthcare professionals**, including patients supplied with implant cards and the information electronically provided to hospitals and clinics
- improved **electronic systems** to provide key information on medical devices that may pose a risk to public health and safety
- improved **vigilance and market surveillance**
- tighter use of **single-use devices** including changes to labelling, implementation of stricter reprocessing standards with increased transparency and establishing a list of single-use devices that are not suitable for processing.

Further information

Email enquiries to devices@tga.gov.au for further advice.

Tags: medical devices, conformity assessment, audits
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