Introduction

The global medical innovation and technology industry brings thousands of market proposals for medical devices every year, including ophthalmic devices. However, there have been concerns about the safety and performance of high-risk devices. Although thousands of drugs obtain approval only after randomised controlled trials, relatively few new medical devices are subject to comparable studies. The Therapeutic Goods Administration (TGA) is the Australian regulatory body in charge of evaluating these applications.

Australia’s regulatory framework

The TGA safeguards and enhances the health of the Australian community through effective and timely regulation of therapeutic goods. A robust legislative basis is in place to support these objectives such as the Therapeutic Goods Act 1989.

Medical devices are classified using a set of rules based on manufacturer’s intended use of the device, level of risk to patients, users and other persons (the probability of occurrence of harm and the severity of that harm), degree of invasiveness in the human body and duration of use (Table 1).

<table>
<thead>
<tr>
<th>Medical device classification</th>
<th>Level of risk</th>
<th>Examples</th>
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</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Low to low-medium</td>
<td>Bandages, non-sterile dressings, occluders</td>
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<tr>
<td>Class IIa</td>
<td>Low-medium</td>
<td>X-ray films, intravenous tubing, contact lenses, lubricating eyedrops</td>
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<td>Class IIb</td>
<td>Medium-high</td>
<td>Dressings for severe wounds, femtosecond laser systems</td>
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<tr>
<td>Class III</td>
<td>High</td>
<td>Intraocular lenses, glaucoma implants, medical devices that contain medicines</td>
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<tr>
<td>Active implantable medical devices (AMD)</td>
<td>High</td>
<td>Retinal implant</td>
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Note: In-Vitro Diagnostics (IVDs) are regulated as a subset of medical devices - there are several points of difference between the regulation of IVDs and medical devices including classification.

Specific provisions are given for the evaluation of ophthalmic devices. The TGA requires manufacturers of high-risk ophthalmic devices such as intraocular lens implants to demonstrate safety and effectiveness before the devices can be marketed.

The current Medical Device Standards Order determines the matters in the relevant standards or parts of those standards published by the International Organization for Standardization, specifically intraocular lenses. Another example of specific standards used corresponds to Implantable Glaucoma Devices.

Assessment of ophthalmic device applications

The level of assessment of a particular ophthalmic device depends on the intended use of device and/or risk classification and/or other questions/concerns TGA may have. Clinical evidence has to be provided by the manufacturer to demonstrate that it is designed and produced to be safe, fit for purpose and perform as intended.

5758 applications for medical devices were received by the TGA during the period analysed, most of them were classed as low risk devices (Figure 1).

From the applications that underwent a review of clinical evidence, less than 3% were related to ophthalmic devices (Figure 2).

Conclusion

The role of the TGA is to regulate therapeutic goods. The TGA does this by applying scientific and clinical expertise to an assessment of the evidence of the risks compared to the benefits of use of therapeutic goods. The role of supporting clinical evidence in the evaluation of medical devices in general, and ophthalmic medical devices in particular, is fundamental.

References

3. Medical Device Standards Order (Standards for Clinical Evidence) 2008
5. ANSI (American National Standards Institute) standard Z80.27 on Implantable Glaucoma Devices