MTAA's comments on TGA's consultation paper: Evaluating the feasibility if a new-to-market risk communication scheme for therapeutic goods
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1. Executive Summary

The Medical Technology Association of Australia (MTAA) appreciates the opportunity to comment on the Therapeutic Goods Administration's (TGA) consultation paper on evaluating the feasibility if a new-to-market risk communication scheme for therapeutic goods.

MTAA's comments are focused on the application of a new-to-market risk communication scheme for medical devices. MTAA recommends that the TGA review the need and feasibility of the scheme with respect to devices and medicines separately.

MTAA notes that the feasibility evaluation for the new-to-market risk evaluation scheme was a recommendation by a panel with a focus on medicines, not medical devices.

MTAA questions if a new-to-market risk communication scheme is an appropriate way of encouraging end users to report problems with medical devices. MTAA support TGA initiatives to encourage adverse event reporting in all situations, not just when a device is newly introduced to market.

If a new-to-market risk communication scheme was to be implemented for medical devices, robust and transparent selection and a removal criteria from the scheme are required. TGA would need to undertake activities to raise awareness of a new-to-market scheme and explain its meaning for the scheme to be of value to healthcare professionals and end users of medical devices.

MTAA believes that TGA efforts would be better utilised promoting the use of current postmarket systems. Simplified and enhanced online reporting systems would encourage healthcare professionals and consumers to report problems with medical devices.

MTAA also notes that there are currently no risk communication schemes for new medical devices operated by other regulators. As no current international model exists for medical devices, MTAA recommends that Australia does not implement a scheme for medical devices ahead of other regions.

2. About the Medical Technology Association of Australia

MTAA represents the manufacturers, exporters and suppliers of medical technology products in Australia. MTAA represents companies which account for the majority of products listed on the Australian Register of Therapeutic Goods (ARTG) and approximately 75% of the higher risk implantable medical devices products listed on the Prostheses List and used in the Australian marketplace. The member companies cover the spectrum of the industry in Australia, from subsidiaries of major multinational medical technology companies to independent distributors and small to medium sized Australian innovator companies.

3. General Comments

MTAA's comments are focused on the application of a new-to-market risk communication scheme for medical devices. MTAA recommends that the TGA review the need and feasibility of the scheme with respect to medical devices and medicines separately.

MTAA notes that the feasibility evaluation for the new-to-market risk evaluation scheme was a recommendation by a panel with a focus on medicines not medical devices:

'The panel who conducted the review noted that there appeared to be a lack of public awareness of the uncertainties about the safety profiles of medicines early in their life cycles and felt that a risk communication scheme for new products could help to encourage public understandings of safety profiles.'[1]

MTAA recommends that if the new-to-market risk communication scheme is to be further advanced, need of such a scheme for medical devices should first be clearly defined.

MTAA support strategies to enhance postmarket surveillance for medical devices, however questions the relevance of a new-to-market risk communication scheme for medical devices if current postmarket schemes are fully utilised. These schemes include:

- Mandatory medical device adverse event reporting for sponsors/manufacturers
- Voluntary adverse event reporting for end users
- Annual reports for higher risk medical devices - It is a condition of inclusion in the ARTG of Class III, AIMD and implantable Class IIb devices that sponsors provide TGA with three consecutive year annual reports following inclusion.

[1] Background, Page 5 - TGA's consultation paper: Evaluating the feasibility of a new-to-market risk communication scheme.

- International vigilance exchange - Through participation in Global Harmonisation Task Force (GHTF) and now International Medical Device Regulators Forum (IMDRF), the regulators of member nations (including TGA) have an obligation to exchange vigilance information on events that have led to corrective action, including recalls, being taken or where there is a serious risk to the safety of patients and other users. This system gives participating countries knowledge of problems experienced in other nations so that actions can be taken to avoid similar events.

  Most medical devices supplied in Australia are included on the Australian Register of Therapeutic Goods (ARTG) based on European conformity assessment procedures. The Australian market release for AIMD and Class III medical devices usually lags the introduction of these devices in the EU and USA. Medical device sponsors are required to submit the early postmarket information gained from these regions to the TGA as part of the market approval process for AIMD and Class III devices.

MTAA questions if a new-to-market risk communication scheme is an appropriate way of encouraging end users to report problems with medical devices. MTAA support TGA initiatives to encourage adverse event reporting in all situations, not just when a device is newly introduced to market.

MTAA also questions the relevance of the scheme, given that sponsors are heavily engaged with healthcare professionals when a new device is introduced. Sponsors usually conduct face to face training with healthcare professionals and for more complex devices animal laboratory training or international training is conducted. The risks and benefits of using the device are iterated to healthcare professionals during training. Sponsor representatives are usually present to support healthcare professionals if they are using a device for the first time.

MTAA disagrees with the statement that a new-to-market risk identification scheme "*alerts public to uncertainty about the overall safety profile of a product*"[2] as the term 'safety profile' is not defined for medical devices. The statement encourages the perception that new-to-market devices have more risks associated with their use than currently available medical devices. The risks of a medical device are evaluated by the manufacturer at all stages of design, development, and manufacture through various risk evaluation techniques described in ISO 14971 Medical devices – Application of risk management to medical devices. Through the application of ISO 14971 a manufacturer can demonstrate that the risks associated with the intended use of a device have been appropriately mitigated and the clinical benefits of use outweigh the risks. These risks and benefits are made clear to users through the device labeling and instructions for use provided with the device. Hence, there should be no 'uncertainty' about the benefits and risks of used of a medical device for its intended purpose prior to market release..

[2] Box 1, Page 11 - TGA's consultation paper: Evaluating the feasibility of a new-to-market risk communication scheme.

4. Benefits and Risks of a new-to-market risk communication scheme

Benefits

Transparency - MTAA questions the benefit of indicating to users that a device is subject to monitoring activities such as annual reporting. TGA should be actively promoting awareness of these schemes as part of postmarket vigilance, not just for new-to-market products.

Supporting the quality use of medical devices- In order for a new-to-market scheme to support the quality use of medical devices, guidance on the level of quality needs to be provided to end users. An indication that a device is new-to-market does not indicate if it is better or worse than a currently marketed device. Discussions about therapeutic product choices should be the responsibility of healthcare professionals for all products regardless of stage of device life cycle.

Better targeting of adverse event reporting – As previously discussed, MTAA believes that proactive promotion of current system will encourage healthcare professionals and end users to report adverse events with all devices, not just new-to-market.

Risks

MTAA agrees with the risks identified with respect to the introduction of a new-to-market risk communication scheme:

- The scheme may encourage the perception that a new product should be avoided – Medical devices are generally iterative. A new medical device is often an enhanced/improved version based on feedback of a currently available device, hence this scheme could prevent progression to new improved technologies in the medical sector and delay patient access to state of the art technologies.

- The scheme may encourage the perception that TGA is only interested in reports relating to new devices. – MTAA encourages TGA to promote the reporting of adverse events under all situations.

5. International examples

MTAA notes that no published evaluation of the UK's Black Triangle Scheme for medicines is currently available. MTAA suggests that consultation with the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) on the effectiveness of the Black Triangle Scheme is required as part of a feasibility study for an Australian new-to-market risk communication scheme.

MTAA also notes that there are currently no risk communication schemes for new medical devices operated by other regulators and that a Black Triangle or equivalent scheme was recommended for implantable medical devices that had been approved using equivalence data[3]. As no current international model exists for medical devices, MTAA recommends that Australia does not implement a scheme ahead of other regions

6. Practicality of a new-to-market scheme for medical devices.

Inclusion criteria

MTAA notes that the scope for inclusion in the new-to-market risk communication scheme is much broader than the similar scheme recommended in the UK. The medical devices proposed to be included for example are:

- *"the product is a new class IIa or above home use medical device, or an implantable class IIb, class III or active implantable medical device, AND*
- *a TGA evaluator considers that it has a sufficiently different or uncertain benefit–risk profile to warrant inclusion in the scheme, OR*
- *one of the TGA's expert advisory committees has advised the TGA to include a product, OR*
- *the product has previously been included in the ARTG and inclusion is now sought for a new intended purpose."*[4]

MTAA recommends that if a new-to-market risk communication scheme is implemented, TGA should have a robust and transparent decision process in place for including devices in the scheme. Terminology used in the selection criteria needs to be clearly defined. For example the term "new" with respect to a medical device may be interpreted as a novel device, hence iterative devices would not be subject to the scheme. The decision to include a device in the scheme should be based on a clearly identified need.

[3] House of Commons Science and Technology Committee. 'Regulation of medical implants in the EU and UK. Fifth Report of Session 2012-13. London: The Stationery Office Limited, 1 November 2012.

[4] Page 15, TGA's consultation paper: Evaluating the feasibility of a new-to-market risk communication scheme.

MTAA is concerned that the inclusion of a device in the scheme could be perceived as detrimental and discourage use of the device.

MTAA notes that the inclusion criteria in bullet points 2-3 do not differ from current annual reporting arrangements for implantable medical devices.

Communication to healthcare professionals and consumers

It has been suggested that the fact a particular product is included in the scheme is communicated to health professionals and consumers using a symbol next to the name of the product whenever it appears in certain sources. It is noted for medicines the Black Triangle symbol appears on the Consumer Medicine Information (CMI) or Product Information (PI). MTAA questions the practicality of the use of a symbol for medical devices as there is currently no equivalent documentation as the PI or CMI to add the symbol to. It is also noted that the Black Triangle symbol does not appear on medicine packaging or information supplied with a medicine. MTAA supports the notion any symbol used should not be identified on medical device labeling or packaging. As Australia is a small market, any symbols that are not internationally recognised should not be used on a medical device's labeling.

The success of a new-to-market risk communication scheme is dependent on the understanding of healthcare professionals and consumers on the meaning of the symbol. If this method is to be used to alert users that a device is new-to-market extensive promotion and training on the scheme is required to meet the aims of the scheme.

Removal of products from the scheme

MTAA recommends that if a scheme is implemented the removal criteria from the scheme is robust and transparent. The TGA assessment process for removal of a device from the scheme should be subject to statutory timeframes.

Communication about a scheme

MTAA agrees that activities would need to be undertaken to raise awareness of the scheme and explain its meaning. MTAA believe that these efforts would be better utilised promoting the use of current postmarket systems. Simplified and enhanced online reporting systems would encourage healthcare professionals and consumers to report problems with medical devices regardless of the stage of the device in its lifecycle.

Evaluation of a scheme

MTAA agrees with the evaluation of any scheme implemented. MTAA also suggests that current postmarket systems are properly evaluated to identify if a new-to-market scheme is required.

7. Conclusion

MTAA recommends that the TGA review the need and feasibility of a new-to-market risk communication scheme with respect to medical devices and medicines separately.

MTAA recommends that if the new-to-market risk communication scheme is to be further advanced, need of such a scheme for medical devices should first be clearly defined.

MTAA support strategies to enhance postmarket surveillance for medical devices, however questions the relevance and value of a new-to-market scheme for medical devices if current postmarket schemes are fully utilised.

MTAA suggests that current postmarket systems are properly evaluated to identify if a new-to-market scheme is required.

If a scheme was to be implemented, robust and transparent selection and removal criteria from the scheme are required.

MTAA agrees that activities would need to be undertaken to raise awareness of a new-to-market scheme and explain its meaning for the scheme to be of value to healthcare professionals and end users of medical devices.

MTAA believes that TGA efforts would be better utilised promoting the use of current postmarket systems. Simplified and enhanced online reporting systems would encourage healthcare professionals and consumers to report problems with medical devices.

MTAA also notes that there are currently no risk communication schemes for new medical devices operated by other regulators. As no current international model exists for medical devices, MTAA recommends that Australia does not implement a scheme for medical devices ahead of other regions.