Consultation: Proposed changes to the medical device Essential Principles for safety and performance

Due 17 October 2019

Mylan in Australia

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INTRODUCTION

The Mylan group of companies, Alphapharm Pty Ltd and Mylan Health Pty Ltd (herein referred to as 'Mylan'), has been supplying medicines in Australia since 1982. We are the leading supplier of medicines by volume to the Pharmaceutical Benefits Scheme (PBS), with about one in six PBS prescriptions dispensed with a Mylan medicine.

Mylan offers locally a broad range of branded, generic and over the counter products - more than 800 individual formulations - and is one of the largest pharmaceutical manufacturers in the country. Last year, our internationally-accredited manufacturing plant at Carole Park, Queensland, produced over 3 billion doses of oral solid dose medicines, more than half of which was exported to about 40 countries.

Mylan also has interests in medical devices.

GENERAL COMMENTS ON THE CONSULTATION

Mylan values this opportunity to provide comment on the *Proposed changes to the medical device Essential Principles for safety and performance.*

Mylan Comments:

The consultation document shows the evolution to date of medical device Essential Principles based on the early work of the Global Harmonization Task Force (GHTF) and more recently the International Medical Device Regulators' Forum (IMDRF). Requirements for safety and performance of medical devices in Australia and Europe, derived from discussions and publications from the GHTF and the IMDRF, are considered similar. Gathering current regulatory considerations broadly from the IMDRF and EU GSPR, the proposal seeks to encourage greater clarity of requirements for safety and performance, and medical device labelling. Closer international harmonization is encouraged by proposing alignment with the IMDRF Essential Principles and Labelling document.

In principle, closer agreement and greater clarity of requirements across jurisdictions can be of substantial benefit to manufacturers, potentially reducing design, production and regulatory costs while assisting to ensure supply of medical devices with improved economies to health care professionals and patients alike. Such harmonization may have other benefits too.

Questions and Responses

Question

1. Do you agree with the proposal to update the Australian Essential Principles to:

   a. Align (considering the Australian regulatory and legal context) with the IMDRF Essential Principles and Labelling documents?

   b. include relevant additional details captured by the General Safety and Performance Requirements in the EU MD and IVD regulations (as compared with the IMDRF documents)?

In your answer, please provide reasons for your position.

Response

1. a. Mylan agrees to the proposal to update the Australian Essential Principles to align with the IMDRF Essential Principles and Labelling documents. With a view to continue the trend towards regulatory harmonization for medical devices and IVD medical devices, the IMDRF documents provide a well-considered framework for manufacturers and national regulatory authorities to follow. However, as the IMDRF is not a regulatory authority its documents provide guidance without legal authority. Alignment of the Australian Essential Principles with the IMDRF documents will require amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002*, effectively bringing the regulations up to date for "state of the-art" devices.

   The Australian Essential Principles provide broad guidance for manufacturers of any and all kinds of medical devices and IVD medical devices. Written as principles, this allows manufacturers the widest scope to decide how they will demonstrate compliance at audit. It is understood that the legislated Essential Principles form the basis for TGA audits and regulatory decisions regarding these therapeutic goods.

1. b. Mylan agrees in principle to the inclusion of relevant additional details captured by the General Safety and Performance Requirements in the EU MD and IVD regulations (as compared with the IMDRF documents) and listed in Appendix 2 of the consultation document at pages 17 and 18.

   These additional requirements, aligning with the EU, will facilitate trade between the jurisdictions.

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Question

2. Do you agree with the proposal to provide additional clarity regarding expectations for compliance as specified under Proposal 2?

In your answer, please provide reasons for your position.

Response

Mylan agrees with the proposal to provide greater clarity regarding expectations for compliance as specified under Proposal 2.

Greater clarity for manufacturers around expectations and requirements to meet compliance in the areas specified will reduce questions and concerns and facilitate planning for medical device compliance from manufacture and throughout the life cycle.

Question

3. Do you agree with the proposal to restructure the Essential Principles and Labelling requirements for clarity and readability?

In your answer, please provide reasons for your position.

Response

Mylan agrees with the proposal to restructure the current presentation of the Essential Principles in the legislation to improve clarity and readability. This will facilitate understanding of the scope and its application in relation to the particular kind of medical device or IVD medical device.

Question

4. Do you agree with the proposal that software medical devices without any physical packaging should include the ARTG number on the electronic label?

   Are there other devices where the ARTG number should be provided?

In your answer, please provide reasons for your position.

Response

Mylan agrees with the proposal that software medical devices without any physical packaging should include the ARTG number on the electronic label only if there is a good reason to do so. Further, if this is seen as advantageous, Mylan considers that software medical devices with physical packaging that is

discarded as the software is installed, or otherwise put to use, should also include the ARTG number on the electronic label.

Understanding that medical device registration in Australia is for "a kind" of medical device, it is certainly possible that there will be multiple versions of the same "kind" which would each rely on the same ARTG number.

Other devices that should carry their ARTG number might be all Class III implantable devices and all active implantable medical devices (AIMD), again, only if there are benefits in doing so.

Question

5. What financial or other effects—including any that are unintended—do you anticipate the changes to the Essential Principles may have for yourself, your business, and other stakeholders (such as consumers, healthcare professionals, health organisations, industry, etc.)?

Response

Mylan welcomes closer alignment of the TGA's Essential Principles with the General Safety and Performance Requirements (GSPR) that come into effect with the European MDR. Differences in any requirements between different territories place additional burdens (in terms of finance, effort and time required to compile the necessary responses to the requirements) on the industry and hence potential longer lead times in making much needed medicines available to the patient population. An alignment of the fundamental intent, structure and format of the TGA Essential Principles with those of the EU MDR GSPRs and IMDRF, with a clear demarcation of regulatory jurisdictional distinctions, would benefit stakeholders through enabling efficient demonstration of regulatory compliance and the reduction of unnecessary duplication of effort.

Question

6. Do you have any comments regarding the transitional arrangements proposed in this paper?

Response

Mylan appreciates the need for a transitional period for the introduction of the new Essential Principles. That those new Essential Principles are suggested to start from November 2020 may be optimistic, depending on the flow of legislation through Parliament, so some flexibility is recommended. The four-year transition proposed for medical device applications submitted to TGA before the date the proposed amendment takes effect should be adequate, particularly considering device lifecycle and requirements for ongoing post-market compliance.

Question

7. Are there any further issues, questions, or requirements we should consider when implementing this change (including areas that can/should be clarified in our guidance)?

Response

No further comments for consideration.

Conclusions

Regulations should change to allow for advancements in all medical device fields. Harmonization across jurisdictions by alignment with such well-considered international guidances as those developed by the IMDRF, and major authorities, can benefit all in the supply chain from source manufacturers through to patients.

Support and Suggestions

Mylan supports the intentions of the TGA's proposals.

Consideration to apply the least burdensome approach to regulation of medical devices will be welcomed. Removal or reduction of unnecessary burdens that may delay the marketing of beneficial new products, while meeting legislative requirements for inclusion on the ARTG, could be achievable for lower-risk medical devices. Such decisions would ensure maintenance of good regulation supporting timely patient access to high quality, safe and efficacious medical devices. This would also parallel trends in other highly regulated jurisdictions.