SUBMISSION

In Response to

Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods

JUNE 2013

Submission

Introduction

Medicines Australia welcomes the opportunity to comment on the consultation document "Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods". This submission considers aspects relevant to prescription medicines and does not include considerations for OTC, complementary medicines or devices which would be addressed by the relevant industry bodies.

A risk communication scheme that will enhance the Quality use of Medicines by increasing health care professional and public awareness of the mechanisms to monitor and assess medicine safety, particularly for new to market or new uses of medicines, is fully supported by Medicines Australia.

The information provided in the consultation document around the relationships that the proposed new-to-market risk communication scheme will have with the existing safety management framework for therapeutic goods is noted. The examples provided from the UK and EU also provides valuable insight into international mechanisms for implementing a new-to-market risk communication scheme. However, the lack of any formal evaluation of the UK scheme to support a critical assessment of its effectiveness in achieving its objectives is identified as a significant knowledge gap.

Based on the current consultation being a 'feasibility assessment' rather than providing detailed proposals for the implementation of a scheme in Australia, general commentary and recommendations are provided on the key areas outlined below, taking into account the specific needs of the Australian healthcare system. Additional consultation will be required on any formal proposals for a scheme following completion of the feasibility evaluation. Medicines Australia will be pleased to work in partnership with the TGA to ensure an optimal approach is achieved to meet the desired objectives:

- Whether or not the Medicines Australia supports the idea of a new-to-market risk communication scheme
- The potential value and uses of a new-to-market risk communication scheme
- How a new-to-market risk communication scheme might be best designed, promoted and evaluated
- How a new-to-market communication scheme will impact the pharmaceutical industry

Consultation Comments

WHETHER OR NOT THE MEDICINE AUSTRALIA SUPPORTS THE IDEA OF A NEW-TO-MARKET RISK COMMUNICATION SCHEME

In principle Medicines Australia supports the intent of the scheme as outlined in the consultation document. Better awareness of the importance of adverse event reporting in assessing the overall benefit/risk of 'new' medicines, including new indications or presentations for existing medicines, is seen as a valuable tool to complement the existing framework for risk management plans, the early warning system and therapeutic product vigilance. This is of particular relevance for new to market medicines, considering the well recognized limitations of fully defining a products safety profile under the closely monitored conditions of use within clinical trials compared to routine clinical practice.

However, the scheme in itself should not deter reporting for other medicines due to a misconception that only new medicines require monitoring or result in confusion when unexpected safety issues for existing

medicines arise. To this end support for the scheme is based on it being implemented under a framework that delivers the necessary education and communication to all key stakeholders (healthcare professionals, members of the public, TGA or industry) required for the scheme to operate successfully and meet its objective. Failure to implement appropriately will risk the scheme becoming a redundant process driven exercise that does not add value to any stakeholder in enhancing the safety of medicines. Furthermore, the scheme must be considered in the context of the future joint agency with New Zealand to ensure a harmonized approach that is acceptable to both markets.

THE POTENTIAL VALUE AND USES OF A NEW-TO-MARKET RISK COMMUNICATION SCHEME

As outlined above Medicines Australia supports the idea of the risk communication scheme based on recognizing the potential value in raising awareness of the safety of medicines that are new to market. Increased knowledge and understanding of how the benefit and risks of a medicine contribute to its overall safety profile and how the safety profile may evolve over time as more experience is gained in clinical practice, will assist health care practitioners achieve the best health outcomes for their patients and enable patients to more effectively manage their own health needs.

As previously stated the implementation phase and impact of the new-to-market scheme is likely to rely heavily on the effectiveness of education and awareness measures and a clear understanding of the criteria for inclusion or exclusion of medicines from the scheme.

HOW A NEW-TO-MARKET RISK COMMUNICATION SCHEME MIGHT BE BEST DESIGNED, PROMOTED AND EVALUATED

The close alignment of the TGA regulatory framework to that of the European Union supports similar alignment of the proposed new-to-market scheme with that of the EU. On this basis an important design consideration for the scheme will be to develop clear inclusion and exclusion criteria in order to manage the impact of a product being included in the EU scheme, to determine under what circumstances this may mean automatic inclusion in the Australian new-to-market scheme. A clear and consistent decision making process would need to be evoked to ensure understanding and transparency for all key stakeholders such that any divergent decisions to those of the EU are fully understood in the context of the Australian health care environment.

Clear guidance is also required to define the decision point within the Streamlined Submission Process process at which a product is determined to be included in the new-to-market communication scheme. An early decision is important to avoid any risk of delays in finalizing an evaluation and obtaining registration. One option could be to include this as part of the pre-submission planning process requiring a Sponsor to justify on the presubmission planning form (PPF) its intended approach, aligned with the current process for risk management plans. Similarly, where relevant a Sponsor should be able to present a justification for why a product shouldn't be included as part of the new-to-market scheme to obtain a waiver.

SELECTION OF PRODUCTS FOR INCLUSION IN THE SCHEME

All new prescription medicines should be automatically considered for inclusion in the scheme at the point of the product being marketed. The scheme should not apply to compassionate use or special access scheme programs for unapproved medicines or 'off-label' use of existing medicines. Separate consideration needs to be given as to how products such as biosimilars, generics, over the counter, complementary medicines and devices are included in this type of scheme. Whilst generic medicines would be expected to mirror the safety profile of the innovator, the more complex situation for biosimilars may warrant additional vigilance due to potential differences in immunogenicity or unanticipated safety events following expanded use in clinical

practice. In other situations, such as new indications dosage forms etc the Sponsor should justify whether inclusion or exclusion from the scheme is warranted taking into account the individual product safety profile, extent of clinical experience and routine pharmacovigilance and risk management measures already in place. As outlined above it will be important to consider the potential impact if a different approach were taken in Australia compared to the EU. In all cases a clear and transparent decision making process for inclusion/exclusion from the scheme, together with stakeholder education and awareness to ensure understanding of the relevance and purpose of selecting a medicine for inclusion in the scheme would be a critical success factors.

COMMUNICATION TO HEALTHCARE PROFESSIONALS AND CONSUMERS

Medicines Australia recommends that the same symbol as used in the EU (inverted black triangle) is used to identify products in the scheme since it is already established as the symbol for a new-to-market risk communication scheme. Aligning with the EU on the symbol used would reinforce the risk based messages and provide consistency, which would be valuable for Australians traveling overseas and vice versa.

The European risk communication scheme outlined in Table 1, page 14 of the Consultation document, recommends the inclusion of a symbol in the SmPC and pack leaflet (EU equivalent of the Australian PI and CMI). However, the TGA proposal is much broader and additionally seeks to include a symbol in Prescribing and dispensing software; Promotional and educational materials produced by the sponsor; and the Product packaging.

Including the symbol in a broad range of sources for both healthcare professionals and consumers alike, requires consideration of complementary guidelines or codes that will also need to be updated to effectively implement the scheme. For example the regulations around Advertising and the Medicines Australia Code of Conduct would all require amendments to reflect the scheme.

REMOVAL OF PRODUCTS FROM THE SCHEME

Medicines Australia strongly believes that a clear process that defines when a product should be removed from the new-to-market scheme is critical to its success. This will ensure the appropriate focus to identify important safety concerns, rather than all products remaining in a scheme indefinitely due to 'uncertainty' that can be addressed through the standard pharmacovigilance and risk management frameworks. Any decisions should be based on a clear scientific rationale rather than be time bound for a fixed period post approval.

COMMUNICATIONS ABOUT THE SCHEME

Medicines Australia considers a robust training and awareness plan is critical to support launch of any new-to-market scheme risk communication scheme. Options could include utilizing avenues such as CPD modules for healthcare professionals, integrated prescribing software alerts as well as consumer friendly information & Apps that highlight the purpose and value of the scheme. Partnerships across the health care sector between industry, regulators, health care professionals and consumer groups should be utilised to support a standard approach that will ensure the success of the scheme based on a common goal of Quality use of Medicines through improved safety awareness.

EVALUATION OF THE SCHEME

Establishing clear objectives for the new-to-market scheme along with quantitative and qualitative measures to facilitate future tracking and even publication of the impact of this system are important measures to assess its effectiveness. The TGA could consider market research surveys of different groups of

stakeholders as well as monitoring the volume of adverse event reports received. Additionally experience from the EU and any similar schemes around the world, could be utilized to design a method for evaluating the new-to-market scheme. Discussions with other regulators would thus be valuable to inform the approach used in Australia.

HOW A NEW-TO-MARKET RISK COMMUNICATION SCHEME WILL IMPACT THE PHARMACEUTICAL INDUSTRY

Inclusion of an additional symbol on packaging, advertising and many other sources of information utilized by various stakeholders will have a significant impact on the processes Sponsors currently use to develop, review and approve such materials. In particular manufacturing lead times can be lengthy (6-12+ months), particularly in the early stages of introducing a new product when production volumes are often lower whilst regulatory approvals are secured around the world. Thus the decision to include a product in this scheme must be made as early as possible in the evaluation process to prevent any delays in new product availability post approval.

Summary

In summary Medicines Australia is supportive of the idea of the new-to-market communication scheme based on its potential to enhance Quality Use of Medicines, through improved awareness of the mechanisms for monitoring the benefit/risk of new to market or new uses of medicines and the importance of reporting adverse events for new medicines, where clinical practice experience may be limited.

To ensure an optimal approach with implementation of such a scheme the following points need to be addressed:

- Alignment with the EU scheme should be considered where relevant, in particular the same symbol should be used to identify any products in the scheme
- Selection of medicines for inclusion in the scheme should be based on a clear and transparent decision making process early in the evaluation phase
- Clear guidance on the inclusion/exclusion and removal of products from the scheme must be available based on robust scientific criteria rather than a standard time bound approach
- Implementation of the scheme must be supported by a comprehensive stakeholder education and awareness campaign to ensure the purpose of selecting a medicine for inclusion in the scheme is fully understood
- Appropriate measures to assess effectiveness need to be implemented to ensure the scheme is delivering on its objectives