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Feasibility of a new-to-market risk communication scheme for therapeutic goods May 2013

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI appreciates the opportunity to comment on the TGA Consultation "Feasibility of a new-to-market risk communication scheme for therapeutic goods".

Summary

ASMI supports reforms aimed at enhancing Quality Use of Medicines (QUM) and encouraging consumers to understand the benefits of medicines as well as uncertainties associated with their use.

In principle, ASMI does not object to the concept of a new-to-market risk communication scheme that provides a signal to prescribers and consumers that a particular medicine or medical device is relatively new, has only been available for a short period of time, or may require caution due to its limited clinical experience. However, the way that the scheme is implemented, the selection of products and communications about the scheme will be critical to its success.

The UK Black Triangle Scheme, upon which this proposal is broadly based, has been in operation for many years in the UK however its success in meeting any of the stated public safety objectives has never been properly evaluated. ASMI therefore believes that some caution is required in adopting any new scheme; that it should be appropriately targeted and that effective communication of the scheme should take place to educate health professionals as well as consumers.

ASMI believes that adoption of any new-to-market risk communication scheme should meet the following criteria:

- It should be in response to a documented need for such a scheme
- It should be considered in the context of the ANZTPA harmonisation initiatives and the impact should be considered for both markets
- The objectives of any scheme should be clear in terms of what outcomes it should achieve
- It should be clearly targeted to medicines and/or medical devices that hold the greatest inherent risks

- Non-prescription medicines and complementary medicines should be excluded

Objectives of the scheme

The TGA Consultation document on the feasibility of a new-to-market risk communication scheme has not provided any overall objectives for the scheme, other than as a way of addressing a recommendation from the TGA's Transparency Review and the need to provide a signal that some medicines are new and have not had a long duration of clinical experience.

ASMI believes that any new to market risk communication scheme should be adopted if there is evidence of need and if existing programmes and initiatives are considered to be insufficient.

The TGA currently has some initiatives in place that encourage reporting of adverse events and promote safety of medicines. These include:

- Sponsor requirements for reporting of adverse events that applies to all medicines, including OTC medicines
- Sponsors of certain prescription medicines submit Periodic Safety Update Reports (PSURs) for the first 3 years following registration
- Submission of risk management plans by sponsors of prescription medicines
- More transparent reporting systems and adverse event databases (DAENS and JAENS)
- Recent consultations on a Trans-Tasman early warning system
- Publication of the Medicines Safety Update

Publications from bodies such as the National Prescribing Service (NPS), which regularly write updates for health professionals as well as consumers also assist in providing information and encouraging reporting.

The TGA should clearly define the objectives of any proposed new-to-market risk communication scheme, and consider whether the objectives can be met by enhancing or amending any of its existing initiatives. Objectives should be clear and measurable. Consideration should also be given to how any new system "fits" with the other schemes, so that there is clarity on the objectives, processes and desired outcomes.

Once the objectives have been set, a review should occur post-implementation to measure success and determine whether the scheme should continue.

Selection of products for inclusion in the scheme

ASMI believes that it is appropriate to include new chemical entities and new biological medicinal products in a new-to-market risk communication scheme were it to be adopted. This would be consistent with the proposed new EU pharmacovigilance requirements. New combinations of existing active ingredients, new indications or new dosage forms should be included only for prescription medicines and on a case by case basis following submission of the sponsor's risk management plan.

ASMI believes that any new-to-market risk communication scheme should exclude non-prescription medicines; namely those medicines in that are complementary, unscheduled, or in Schedules 2 or 3 of the Poisons Standard.

Non-prescription medicines (also referred to as OTC medicines) generally have a favourable safety profile and a long history of use in self-limiting conditions or minor conditions which are able to be managed by the consumer. Schedule 3 medicines, which are not available for self-selection, generally have a history of use as a prescription medicine prior to being rescheduled to Schedule 3. Applications for rescheduling are required to provide data on benefits and risks associated with the medicine, the extent of use, safety data, and must demonstrate a low potential for toxicity or misuse. Applications undergo evaluation and consideration by the Advisory Committee on Medicines Scheduling (ACMS) in order to be rescheduled from prescription only medicine (Schedule 4) to OTC status.

Similarly, the majority of complementary medicines are non-prescription medicines, are low-risk and include vitamins, minerals and some herbal products.

The TGA Consultation paper (pages 7-8) describes the product lifecycle for registered new medicines, outlining that some new medicines are developed and tested in relatively small populations prior to approval and that more comprehensive safety information becomes available only after the a medicine or medical device becomes more widely available in larger populations that include different patient groups.

Medicines are rescheduled to OTC status only after being widely used as prescription medicines and post-marketing safety data have become available. By this stage, more information is known about a product's safety and benefit vs. risk. The recent rescheduling of single dose famciclovir for cold sores (herpes simplex virus) to Schedule 3 is an example. Famciclovir was first registered more than 15 years ago, and rescheduled to Schedule 3 for use as a single dose of 1500mg. This example is one of many that could be provided, illustrative of the duration of post-marketing experience that is typical of most OTC medicines. In addition, OTC medicines are usually used at lower doses and for shorter duration than prescription medicines.

Complementary medicines may be either listed or registered. Listed complementary medicines are composed of ingredients which have a long history of safe use and these ingredients have been assessed by the TGA as low risk. There are a few registered complementary medicines, which also contain ingredients with a long history of use and a well known safety profile. These medicines undergo a more rigorous evaluation by the TGA. Very few complementary medicines are entirely novel and these ought to be considered on a case by case basis before inclusion in any proposed scheme, for example an injectable vitamin product which would be classified as a Schedule 4 medicine.

ASMI believes that OTC and complementary medicines should only be included in general awareness campaigns designed to encourage quality use of medicines and adverse event reporting, but inclusion of these medicines in a new-to-market risk communication scheme as outlined in the consultation paper should not be required. Non-prescription medicines are by definition not "new-to-market" and have been marketed in Australia and/or overseas for many

years. Sponsors of these products already have responsibilities as per the TGA Pharmacovigilance guidelines, for reporting of adverse events and for monitoring safety of these medicines.

Inclusion of these medicines in a new-to-market risk communication scheme would tend to confuse healthcare professionals and consumers, and imply that special caution is needed with these medicines due to insufficient clinical use. This message would also conflict with scheduling principles, as it would carry the implication that the TGA has allowed products with an insufficient history of safe use to be allowed to be marketed as over-the-counter medicines for self-selection by consumers.

Communication to health professionals and consumers

ASMI believes that communication and education in relation to the scheme is very important in order to meet its objectives and minimise confusion.

Communications about the scheme should explain the principles of the scheme, its objectives, the meaning of the symbol, and the actions required from prescribers and consumers. Prescribers, pharmacists and consumers should be educated on what the symbol means, how this scheme differs from existing pharmacovigilance activities, and what actions are required from them in order for the scheme to operate effectively. It should explain why or how these medicines should be treated differently to other medicines; and what separate considerations are needed in any decisions to prescribe or supply a particular medicine or therapeutic good marked with a "symbol".

ASMI believes that the symbol used should be harmonised with the UK / EU "Black Triangle" symbol as there is no compelling reason for Australia to adopt a unique symbol.

If the scheme is adopted, the symbol should be shown on:

- PI and CMI (for medicines)
- Patient Information Leaflets.

There should be in-principle consistency with the way that the scheme operates in the EU. Australia should not adopt unique requirements in this respect.

The symbol should not be required on product labelling. Decisions about benefit and risk and safety are integral in deciding whether to prescribe or dispense a new medicine, therefore the symbol is most useful in determining whether to prescribe or supply a medicine, and it is of limited usefulness when it is actually present on the label.

The symbol will therefore be most useful when it is included in sources of information about new medicines directed to prescribers and pharmacists, such as MIMS, the AMH, NPS information, prescribing and dispensing software.

Removal of products from the scheme

ASMI believes that any new-to-market risk communication scheme adopted by the TGA should be consistent with the European requirements and not adopt unique Australian requirements.

In this context, the proposal for a 5 year inclusion period is reasonable, although ASMI suggests that perhaps a 3 year period (consistent with the need to supply PSURs) ought to be considered. Products should automatically be removed from the scheme unless there are compelling reasons to the contrary.

Sponsors should not be required to "apply" to the TGA for removal of the symbol. There should be an understanding that sponsors can remove the symbol after this period of time. Should there be reasons for continuation in the scheme, sponsors should be advised and have the opportunity to provide evidence or discuss the matter with the TGA. There should be solid reasons, on the basis of documented evidence, for sponsors to be required to continue with the symbol following the first 3 or 5 (to be determined) years of inclusion. Sufficient notice should be given to sponsors.

Communications about a scheme

ASMI concurs that if a scheme were to be implemented, it should be accompanied by activities to raise awareness of the scheme and to explain its meaning to healthcare professionals and consumers.

Industry should be further consulted and the appropriate processes of wide consultation should be followed. There should be a regulatory impact statement to determine the impact on industry of any scheme to be implemented.

Communication should not focus purely on the scheme to be implemented, but it should also cover how the proposed scheme fits in with other TGA initiatives and be clear in describing what further actions are required from healthcare professionals and consumers.

Evaluation of a scheme

ASMI believes a scheme should only be adopted if there is clear evidence of it being needed, if its objectives are clear, if it is communicated effectively and evaluation takes place.

The TGA's consultation does not feature details on the objectives of a scheme, other than as an awareness tool and a means of increasing adverse event reporting and consolidating safety information on new medicines.

ASMI believes that should a scheme be implemented, it should be subject to evaluation to determine that it has had the desired impact on knowledge, awareness, prescribing behaviour and patient advice, and adverse event reporting.

General observations

ASMI would like to make some general comments in relation to the consultation.

The TGA should carefully consider the objectives of such a scheme:

- If the scheme is intended to increase adverse event reporting, there may be other ways of doing this, such as more inclusive campaigns and awareness activities
- If it is about "flagging" new therapeutic goods, can this be done differently without the need for an additional scheme?

- Clarity is needed on exactly what healthcare professionals are required to do with this information or how it is meant to influence behaviour. How should it be used in prescribing decisions? How should the information influence their medical practice and communication with patients / consumers?

As with any scheme proposed for implementation, a strong case should be made as to whether the objectives can be met by other means:

- Could the objectives of increased awareness and increased reporting of adverse events be met by other means, such as: providing more education on drug development and benefit-risk considerations for new medicines, in the form of continuing professional development courses for health professionals?

- Would general adverse event reporting awareness campaigns be beneficial in increasing awareness of the need to report adverse events of all therapeutic goods?

- What can be done to make adverse event reporting easier?

Consideration should be given to the possible unwanted impact of such a scheme:

- Would the implementation of such a scheme lead to perceptions that the TGA is not interested in reports of adverse events relating to other medicines or therapeutic goods?

- Would the large number of products included under such a scheme over time result in a gradual "dilution" of the objective of the scheme, as more and more products carry the symbol?

New medicines can have benefits as well as risks:

- Does adoption of a new-to-market risk communication scheme carry an implication that all new medicines are too risky and should be avoided? Will there be a perception that the TGA is trying to diminish access or uptake of new medicines?

- Is there an undue emphasis on risk avoidance rather than risk management and provision of information?

Harmonisation:

- Any proposal to adopt a new scheme should be in the context of the ANZTPA harmonization initiatives currently underway. Input should be sought from Medsafe and New Zealand sponsors, and consideration should be given to how a scheme would work across both markets.

Conclusion

ASMI welcomes the opportunity to provide feedback on the feasibility of a new-to-market risk communication scheme. As a strong advocate of Quality Use of Medicines and increased TGA transparency, ASMI does not object to the principles of a new-to-market risk communication scheme on the provision that the following provisions are met:

- It should only be introduced if there is evidence for need and if it is considered that existing initiatives cannot address the need
- Its objectives should be clear and measurable and consider the impact on healthcare professionals, consumers and sponsors
- Non-prescription medicines (complementary, unscheduled, Schedule 2 and Schedule 3 medicines) are by definition not "new-to-market" and should not be included within such a scheme
- Education and communications are integral to the success of any such scheme
- Any scheme that is introduced should be evaluated after a sufficient time period, for example 3 years