TGA Consultation Submission

Amgen Australia P/L comments on:

Whether or not you support the idea of a new-to-market risk communication scheme & the potential value and uses of a new-to-market risk communication scheme:

Amgen supports the idea of a new-to-market risk communication scheme and see the following potential value and uses of such a scheme:

- Recognise that consumer groups and healthcare professional groups have highlighted the need for improved communication about medicines
- Would signal to healthcare professionals and consumers that a medicine has only been available for a short time and therefore encourage discussion and education about the product
- Would encourage vigilance when prescribing, administering, dispensing or using the medication, therefore promoting quality use of medicines
- Would encourage healthcare professionals to report adverse events associated with new products, thereby improving knowledge of the benefit risk profile
- Provides an opportunity to communicate about the importance of pharmacovigilance to healthcare professionals and consumers

How a new-to-market risk communication scheme might best be designed, promoted and evaluated:

Design – Suggest;

- Harmonise with the EMA additional monitoring scheme, use the same symbol and messaging to minimise confusion
- Have a discretionary model for inclusion/non-inclusion of products in the scheme
    - Sponsor's have the option to include a justification in the Risk Management Plan for non-inclusion in the scheme
    - Align inclusion of products with EMA model
    - Don't automatically apply inclusion for new indication, dosage form or route of administration, should be risk based approach
- Clearly defined criteria for removing a product from the scheme
    - 5 years as per the EMA model is too long and not aligned with the TGA requirement to submit PSURs for 3 years post registration
    - Recommend automatic removal after 3 years
- Requires common language agreed across stakeholder groups and harmonised with EMA scheme if possible
- Communication plans for addition and removal of products from the scheme
- Addition of the symbol and explanatory statement to the Product Information and Consumer Medicine Information only and not to the packaging
- Include a revision date for re-assessing inclusion in the scheme

Promotion – suggests;

- Consumer Group forums
- Healthcare professional groups
- National Prescribing Service
- TGA website
- Sponsor's information services and educational materials
- Learning modules linked to Healthcare professional accreditation
- Healthcare professional press

Evaluation – suggest;

- Summary of experience date when products are removed
- Awareness and customer satisfaction surveys of consumers and healthcare professionals, potentially via National Prescribing Service
- Measure AE reporting and impact on benefit risk profile
- Assess prescribing patterns

How a new-to-market risk communication scheme will impact you:

Sponsors of medicines will be responsible for the operational aspects of a new-to-market risk communication scheme and will bear a financial & resource burden in managing the addition and removal of a product to and from the scheme:

- Updating Product Information and Consumer Medicine Information and replacing these materials when required
- Giving consideration to inclusion in the scheme for any new products, assessing the global marketing status of the product and if necessary including a justification in the Risk Management Plan for an exemption
- Ensuring that any extended usage of the new-to-market risk communication scheme is up to date; eg prescribing software, therapeutic guidelines
- Resource requirements for stimulated adverse event reporting and medical information enquiries

Additional issues for consideration:

Potential risks:

- Possible perception that new products are not safe
- Potential for desensitisation and thereby loss of effect of the scheme if scheme is not correctly targeted
- Possibility of labelled materials being available after the product has been removed from the scheme, eg CMIs, Product Information for injectable products included in packaging
- May influence adverse event reporting of products not included in the scheme, create perception that the TGA is only seeking adverse event reports on products with the symbol, thereby create under-reporting for products without the symbol
- Potential legal ramifications with placement of a symbol adjacent to the Trade name of a product

- Difficult to consistently place the symbol on promotional material because of the diversity and complexity of these materials

Other issues:

- Responsibility for management and oversight of the scheme, TGA can only mandate what Sponsor's have to do and have no jurisdiction over other organisations
- Need flexibility in the scheme, based on risk. For some products exposure data may be a more relevant determining factor for removal of a product from the scheme, rather than a period of time
- A new-to-market risk communication scheme could be applied to medicines but would be difficult to apply to medical devices
- A singular new-to-market risk communication scheme across both prescription medicines and complementary medicines would be difficult to effectively manage
    - Level of risk, evaluation and pharmacovigilance is different for a innovative, first in class, prescription medicine compared with a complementary medicine
- Responsibility, resourcing and funding of initial and follow-up communication of the scheme
- Responsibility, resourcing and funding of evaluation of the scheme