Response to the Consultation: Options for the future regulation of 'low risk' products
March 2017

SANOFI CONSUMER HEALTHCARE

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About Sanofi Consumer Healthcare

Sanofi Consumer Healthcare Australia is part of Sanofi, a global healthcare company committed to preventing diseases and treating every person across the globe. Sanofi's global portfolio includes diabetes and cardiovascular, vaccines, rare diseases, oncology, immunology and consumer healthcare businesses.

In Australia, Sanofi Consumer Healthcare is one of the country's largest vitamin, mineral and supplement manufacturers and distributers. We are also a large supplier of trusted over the counter medicine brands.

With a brand portfolio that includes Nature's Own, Cenovis, Ostelin, Betadine, Mersyndol, Bisolvon, Dulcolax and Telfast, our products are found in more than 8800 pharmacies and grocery outlets across Australia and New Zealand.

Sanofi Consumer Healthcare is based in Brisbane's northern suburbs, where our $80 million, 35,000 square, TGA licensed and GMP standard vitamin, mineral and supplement manufacturing facility is located. Sanofi Consumer Healthcare is the only large-scale vitamin, mineral and supplements business in Australia to be vertically integrated with full research, development, quality testing, manufacturing and packing capability. In recent years, we have invested in excess of $30 million in this site to grow our Australian manufacturing presence. This investment ensures we remain at the forefront of high quality research, development and manufacturing.

We employ approximately 400 people across Australia including scientists, allied health professionals, regulatory affairs specialists, quality control experts, manufacturing technicians, engineers and warehouse staff.

Overview

Sanofi Consumer Healthcare (Sanofi) welcomes the opportunity to provide feedback on the Department of Health's Therapeutic Goods Administration (TGA) consultation on Options for the future regulation of 'low risk' products, dated March 2017. Sanofi has not provided any comments on options proposed for product categories that are not within our business portfolio.

Summary

Sanofi has concerns on many of the proposed options for down regulation of selected categories and believes the TGA and current regulatory environment provides the appropriate level of protection for consumers and safeguards to consumers. Whilst we encourage the TGA to explore the opportunities presented to further reduce regulatory burden for Sponsors, it is important for consumer and industry that any regulatory changes do not impact the internationally recognised quality and safety standards under which Australian products are regulated by the TGA.

In summary, Sanofi considers that:

- Low risk registered OTC products should remain as registered OTC medicinal products under the current Therapeutic Goods classification, however, reduction in regulatory burden would be safely achieved by expanding the OTC monograph route for these product categories.
- Sunscreen regulatory classification and requirements should be simplified; however, primary sunscreens should remain under the control of the TGA within listed medicines as a safeguard to consumer protection.
- Medical Device classification in Australia should retain the current regulatory system to ensure Australia remains harmonised with other jurisdictions such as the European Union (EU). An Australian specific regulatory environment would restrict the range of medical devices available to the Australian market as well as those exported from Australia.
- All vitamin and mineral complementary medicines should retain the current regulatory regime as Listed or Registered Medicines, including medicinal Good Manufacturing Practice (GMP) standards, and requirements to list these products on the ARTG. The current medicinal GMP standards and application of PIC/S requirements provides an important protection for Australian consumers and the industry. There are opportunities for minor alterations of these standards; however the proposed options to exempt some vitamin and mineral products are not supported.
- Reducing GMP standards will allow lower quality products onto the Australian market which will reduce consumer confidence, damage future export opportunities, prevent investment in local manufacturing facilities and negatively impact the local Australian workforce
- In the context of being competitive in a global environment, quality and safety concerns resulting from non-compliant or counterfeit medicines is a key factor driving export demand for complementary medicine products, including low risk level vitamins and minerals, made in Australia. The regulatory framework must therefore maintain the status of the TGA as a trusted global regulator, to realise the economic benefits from growth in export markets.

Sanofi welcomes the opportunity to further engage and collaborate with the TGA to create an optimum framework that delivers the appropriate level of protection for consumers and reduces regulatory burden for Sponsors.

1. Other low risk registered non-prescription (OTC) medicines

Sanofi has products in some of the categories included under low risk registered OTC medicines:

- antiseptics for first aid treatment of minor cuts and abrasions
- lozenges for relief of sore throats
- rubefacient preparations for minor aches and pains of muscles
- laxatives
- anti-dandruff and antifungal shampoos.

The Company view is that the status quo should remain and the products listed above should continue to be regulated as registered OTC products. However, reduction in regulatory burden should be achieved by expanding the OTC monograph route for these product categories.

This approach would overcome over-regulation by application of the full OTC registration requirements to these low risk products. The benefits would be shorter evaluation timelines, faster speed to market and reduced costs, while maintaining the higher expectations of consumers for OTC medicines with regard to quality and safety. We would like the TGA to consider aligning with other countries that already have an expanded OTC monograph list for over-the-counter medicines. (http://webprod.hc-sc.gc.ca/nhpid-bdipsn/monosReq.do?lang=eng&monotype=product)

We are additionally concerned that the down-regulation of some of these products to listed medicines has the potential to contribute to confusion on ranges of products with an existing brand name if currently used by consumers and healthcare professionals. Such an example could occur for antiseptics which have high level indications registered to support use in the hospital setting, such as pre and post-surgery, as well as a lower regulatory listed classification when sold in retail packs for consumers for treatment of minor cuts and abrasions.

Some products within these broad categories are indicated for conditions that could not be considered as low level and would not be available for consumer use without maintaining the higher level registration classification for these products. Sanofi Consumer Healthcare recommends ensuring alignment with other jurisdictions such as Canada with an expanded OTC monograph list. (http://webprod.hc-sc.gc.ca/nhpid-bdipsn/monosReq.do?lang=eng&monotype=product)

2. Sunscreens

Sanofi believes Option 2 in the consultation document should be adopted, to streamline the regulatory pathways for sunscreen regulation, for the two categories of Listed Sunscreens

(Primary sunscreen for SPF greater than 4 to 50+) and for the Excluded Sunscreens (all secondary sunscreen and primary sunscreens of below SPF 4).

The reason for our preference is the serious public health impact of poor quality sunscreens, both from the immediate risk of harm of sunburn and the long-term risk of developing skin cancers. These risks outweigh any reasons to down-regulate this category of products.

In addition, Sanofi believes the proposals contained within Option 3 – Prevent all secondary sunscreens from making SPF claims; Option 4 – Creation of a GMP standard for primary sunscreens; Option 4B – New ingredient approval process and Option 5 – Alternative ingredient standards for excipients all have merit in being progressed to reduce the regulatory burden on primary sunscreens whilst still maintain the high quality and efficacy requirements for sunscreens with a higher SPF rating to maintain consumer protection in Australia.

3. Low risk products that are currently considered medical devices

Sanofi agrees, as per the consultation document, that the current Australian classification system for medical devices should be maintained to ensure harmonisation with international regulatory environments.

Regarding the proposed actions within the consultation, Sanofi Consumer Healthcare has concerns these actions will significantly increase the burden on existing TGA staff resources and potentially prolong evaluation timelines for new device applications. We believe sufficient additional resources would need to be provided to ensure the current expectations of approvals are maintained if these proposed actions are undertaken.

Any change to the current regulatory classification for devices will also put Australia out of step with other jurisdictions such as the European Union (EU) and this could create an Australian specific regulatory environment, potentially impacting the range of medical devices available to the Australian market as well as the medical devices that are exported. We prefer status quo of registering medical devices on par and in harmonisation with other regulatory environments such as in the EU.

4. Rehydration or formulated sports products

Sanofi agrees that rehydration products with food claims or those that appear as sports drinks are removed from the ARTG and clear requirements for oral rehydration products with a therapeutic purpose are maintained within current Listed Medicines regulatory framework.

5. Vitamin and minerals

Option 1 – Maintain the status quo regulation of vitamins and minerals

Sanofi strongly believes Option 1 – Maintain the status quo regulations of vitamins and minerals is the best option for consumers, industry and the regulator.

The current regulatory framework for complementary medicines was originally designed to ensure industry was able to market what are generally considered to be low risk medicines while ensuring appropriate safety and quality controls were applied to maintain consumer protection.

The current regulatory regime for complementary medicines in Australia is appropriate and commensurate with the risk posed by these products; however there are opportunities to create a more efficient regulatory system. This is currently being addressed in the complementary medicine regulatory reforms including the implementation of a permitted indications list and new evidence requirements for low level listed medicines and intermediate level listed medicines via the new pre-evaluated pathway.

Option 1 also enhances alignment with the New Zealand approach in development. Retaining the current regulatory regime will assist harmonisation between Australia and New Zealand, particularly for complementary medicines businesses that operate in both countries, as Sanofi does.

Sanofi advocated for the development of evidence monographs by the TGA with the assistance of industry members for common ingredients in our response to the Expert Panel review of regulation for complementary medicines. We remain of the view that developing evidence monographs is in line with international approaches to regulation of common ingredients found in listed medicines and will assist reduction of regulatory burden by eliminating the need for duplication of evidence assessment by all Sponsors for the same ingredient. Specific evidence monograph use for common ingredients could further reduce compliance issues for claims and labelling whilst maintaining appropriate safeguards for consumers. The final content of each monograph will influence sponsors interest in use of the monographs and we suggest industry participation in the development of these monograph would likely assist in an increased level of interest for use by sponsors.

Option 2 – Exemption from listing in the ARTG and/or GMP, and

Option 3 – Declare vitamins and mineral not to be therapeutic goods

Sanofi does not support Option 2 or Option 3 for vitamin and mineral products.

We believe the retention of medicinal Good Manufacturing Practice (GMP) standards and application of PIC/S requirements provides an important protection for Australian consumers and the industry. While there are opportunities for minor alterations of the application of the PIS/C requirements that would not impact the quality of Australian Complementary Medicines Products, the proposals in Option 2 or Option 3 would likely result in lower quality products available on the Australian market and significantly impact the complementary medicines manufacturing sector in Australia and the local workforce employed within these manufacturing facilities. The complementary medicines manufacturing sector in Australia is currently adding to new jobs to the sector due to the increased demand from China for high quality Australian products, any option that damages the reputation and high regard for the regulatory environment under which these products are manufactured will have a major impact to industry as a whole in Australia.

In the context of being competitive in a global environment, quality and safety concerns resulting from non-compliant or counterfeit medicines is a key factor driving export demand for complementary medicine products, including low level vitamins and minerals, made in Australia. The regulatory framework must therefore maintain the status of the TGA as a trusted global regulator, to realise the economic benefits from growth in export markets.

Maintaining PIC/S Guide for GMP Manufacture to protect export potential

In reviewing Australia's complementary medicines regulatory regime for low level vitamin and mineral supplements, it's imperative that the Government consider an appropriate balance between the needs of Australian consumers and industry, while also considering export opportunities now opening to Australian sponsors.

Using China as an example, the Chinese Cross Border e-commerce business has been a huge success story for the Australian vitamin, mineral and supplements industry. Chinese demand for high quality, Australian made and regulated VMS products has seen the VMS market in Australia grow from $1,397m in 2014 to $1,848m at the end of 20162016 (this is according to Aztec domestic scan data – the total market figure would be much higher when taking into account direct export products). In 2016, the cross border e-commerce VMS industry was worth $2.4B in China and of this, Australian brands contributed approximately $420m value.

The high regulatory and quality standards that Australian vitamin, mineral and supplements are required to meet is one significant reason why Australian brands and products are becoming such large exporters.

Additionally, vitamin and mineral products presented in the format of medicines, such as tablets or capsules, are generally perceived by consumers as medicinal and not as food products. This creates an expectation of the level of quality and regulatory oversight by regulatory agencies. The proposal within Option 3 would require experienced staff and resources at state and territory level to take on the regulatory oversight, which could lead to irregular enforcement of compliance, dependent on the state or territories resource and commitment. Given Option 3's alignment with the US approach, this provides little consumer protection support given reported product failures and level of recall of dietary supplements in the US, such as 2015 example of New York State Attorney General office finding 4 out of 5 products in 4 major retailers did not include any of the claimed ingredients (https://ag.ny.gov/press-release/ag-schneiderman-asks-major-retailers-halt-sales-certain-herbal-supplements-dna-tests)

We remain of the belief that, while low level vitamins and minerals are considered low risk compared to prescription medicines, they are not without risk and regulatory settings in relation to their manufacture and advertising must remain at a standard that protects consumer health and safety. Examples provided in the consultation document as low risk include ingredients if consumed in large quantities or inappropriately, such as Vitamin C above 2g per day potentially causing diarrhea, Calcium at the current market average dose of 1200mg can pose potential concerns with consumers with underlying cardiovascular conditions. The regulations placed on these medicines under the current requirements for listed medicines permits control of recommended doses to be advised, additional cautions to be placed on labels and when sold in pharmacy, the advice of pharmacist or pharmacy assistants to determine the appropriateness of the medicine. As complementary medicines make therapeutic claims, it is also appropriate that these products are regulated in a similar manner to other therapeutic products, but with some specific flexibility due to the nature of the ingredients.

Sanofi believes all vitamin and mineral products should remain regulated under the Therapeutic Goods Act and under the jurisdiction of the medicines regulator, the Therapeutic Goods Administration (TGA), and supports the continued GMP regulation of these goods, along with the requirement to list these products on the ARTG for therapeutic indications.