Response to the TGA Consultation: Business process improvements supporting complementary medicines assessment pathways

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About Sanofi Consumer Healthcare

Sanofi Consumer Healthcare Australia is part of Sanofi, a global life sciences company committed to improving access to healthcare and supporting the people they serve throughout the continuum of care. Sanofi's global portfolio includes diabetes and cardiovascular, vaccines, rare diseases, oncology 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, Gastrolyte and Telfast, our products are found in more than 8500 pharmacies and grocery outlets nationwide.

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 supplement business in Australia to be vertically integrated with full research, development, 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, and 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 the Business process improvements supporting Complementary Medicines assessment pathways, dated September 2017.

Sanofi generally supports the development of clearly defined requirements and business process for the various assessment pathways within this consultation. As the minimum data requirements for the various proposed classifications are yet to be defined, it is assumed the requirements will be subject to further discussions and consultations with relevant industry stakeholders.

1. Risk categorisation for applications and criteria for use of overseas regulatory reports.

Sanofi supports

- The proposed risk categories for new ingredients and medicines and the proposals for enabling use of overseas regulatory reports. As the minimum data requirements are yet to be defined, it is assumed the proposed categories will be further clarified once this information is available.
- The proposals for application categories to enable use of overseas regulatory reports.
- The proposed criteria for determining the suitability of overseas regulators
- The proposed criteria for determining the suitability of reports from comparable overseas regulators, as some reports may not meet all criteria the option for the applicant to provide additional data is also supported.

2. Sources of evidence for *de novo* assessments.

Sanofi considers the criteria for the source of evidence for *de novo* assessment to be in English to be inconsistent with the criteria stated for use of regulatory reports from comparable overseas regulatory that permits a certified translation (p18). To ensure consistency in the criteria specified, a source of evidence not in English should be acceptable where provided as a certified translation.

Other sources of evidence that should be considered as acceptable for *de novo* assessment are evaluation reports from EU bodies including EFSA and HMPC.

3. Proposed pre-market assessment process

Sanofi generally supports the proposed process and principles for the pre-market assessment process.

As the pre-market assessment process will be in development over the next few years, Sanofi considers the restriction of a single round of requests for information should be extended to at least two rounds until the process is embedded and requirements are well understood by applicants. This allowance could be flagged with the intention to return to a single round after the transition period for implementation of the new pathways for complementary medicines.

4. Proposed legislated assessment timeframes and new fee structure to support application categorisation

Sanofi does not support the proposed fee structure for the new application categorisation. Comparison with the evaluation timeframes and fees for Registered OTC medicines (refer Table 1) indicates there is no consistency between timeframes and the total cost of the application.

The proposed costs for Registered Complementary Medicines (RCM2-5) are considerably higher compared to similar application types for more complex, higher risk Registered OTC Medicines (N2-5). Additionally, the same evaluation costs are proposed for Listed Assessed medicine categories L(A)2 and L(A)3, given the evaluation requirements and timeframes for L(A)2 are considerable lower this should be reflected in a lower cost for this application category compared to L(A)3.

We propose the fees and timeframes are re-evaluated to correct this inconsistency. In addition, an annual review of performance statistics should be used to ensure timeframes remain appropriate based on actual experience; a similar approach was successfully used after implementation of the revised OTC medicines evaluation framework.

Table 1: Comparison complementary medicines vs OTC medicine timeframes and fees

Current Listed Complementary Medicine		**Current Registered Complementary Medicine**		**New assessed Listed medicine**			**Registered complementary medicine**			**Registered OTC Medicine**		
Fees: **A**pplication **E**valuation **T**otal	**Approval time** work days (screen days)	Fees: **A**pplication **E**valuation **T**otal S11830 - $73330	**Approval time** work days (screen days)		Fees: **A**pplication **E**valuation **T**otal	**Approval time** work days (screen days)		Fees: **A**pplication **E**valuation **T**otal	**Approval time** work days (screen days)		Fees: **A**pplication **E**valuation **T**otal	**Approval time** work days (screen days)
A $ 800 E not applic T $800	3 - 4 (not applicable)	A $1530 E $10300 to $71800 (depends on page count 50 pages to >30000 pages) T $11830 - $73330	Not defined	L(A)1	A $ 430 E $1640 T $2070	45 (5)	RCM1	A $ 530 E $3060 T $3590	45 (15)	N1	A $1590 E $3930 T $5520	45 (not stated)
							RCM2	A $1910 E $20500 T $22410	90 (15)	N2	A $1590 E $5570 T $7160	75 (not stated)
				L(A)2	A $1760 E $13400 T $15160	60 (10)	RCM3	A $1910 E $20500 T $22410	150 (20)	N3	A $2550 E $8590 T $11140	150 (not stated)
							RCM4	A $ 2530 E $27800 T $30330	180 (20)	N4	A $3720 E $14200 T $17920	170 (not stated)
				L(A)3	A $1760 E $13400 T $15160	150 (15)	RCM5	A $2770 E $35500 T $38270	210 (25)	N5	A $5520 E $21100 T $26620	210 (not stated)

5. Enhanced post-market compliance monitoring scheme for listed medicines.

Sanofi supports the proposed enhanced post-market compliance monitoring scheme for listed medicines.

We note the proposed online training as a prerequisite to obtain access to the Electronic Listing Facility is proposed to be repeated for sponsors that have intentionally and repeatedly contravened the Act. Sanofi does not object to using online training to obtain access to the ELF however we consider this will not achieve the desired outcome. If the non-compliance is intentional, a requirement to complete online training will do little to curb this behaviour. The proposed plan to target continued intentional and repeated non-compliance is more likely to achieve the desired alteration of behaviours.