Submission No. 42

sanofi-aventis australia pty ltd.
12-24, Talavera Road
Macquarie Park NSW 2113

CONSULTATION RESPONSE

Review of the low value turnover exemption scheme

Version 1.0 May 2014

Date: May 2014 Total number of pages: 6

1 INTRODUCTION

Sanofi welcomes the opportunity to respond to the TGA consultation paper 'Review of the low value turnover (LVT) exemption scheme' which covers a policy and operational review of the scheme that allows Sponsors to seek an exemption from annual fees, where the annual turnover is less than or equal to 15 times the annual charge for a Register entry. The need for the agency to fully recover costs for regulatory functions which cannot be reasonably assigned to individual businesses or where such assignment would act as a deterrent to the effective regulation of therapeutic goods is acknowledged. It is also noted that the current LVT exemption scheme predates the introduction of full cost recovery in 1998.

Sanofi is a diversified health care company supplying a broad range of therapeutic goods in both Australia and New Zealand with a portfolio comprising complementary, OTC, medical devices and prescription medicines including vaccines and biologicals. As such it holds a large number of registrations with over 1200 ARTG entries across all the business units and annual fees therefore form a major part of the total regulatory expenditure for the business.

Sanofi participates in the current LVT exemption scheme primarily for its prescription medicine portfolio, which attract higher annual fees than other medicine/device categories, reflecting the higher risk status. The vast majority of products for which an exemption is requested are those that are not marketed. Whilst the largest number of register entries are held for complementary medicines, considering the number of changes in the product portfolio to reflect the needs of what is essentially a fast moving consumer goods business, the administrative burden of the current LVT exemption scheme, in particular the certification of sales turnover, does not warrant the resource investment for any potential fee savings that could be gained.

2 RECOMMENDATIONS

The TGA consultation paper includes five potential options for the current LVT exemption scheme:

- **Option 1:** Retain the LVT scheme in its current form
- **Option 2:** Retain the LVT scheme with some amendments
- **Option 3:** Replace the LVT scheme with one that only grants exemptions for register entries which are not supplied to the Australian market
- **Option 4:** Replace the LVT scheme with one that only grants exemptions for register entries where the sponsor is a small business
- **Option 5:** Cease the scheme completely

In considering the original intention of the LVT scheme as described in the consultation paper under 'History and objectives of the LVT exemption scheme', and having reviewed the TGA options, Sanofi considers that the existing LVT exemption scheme should be adapted to deliver appropriate cost recovery for post marketing activities undertaken by the TGA and that additional provisions are needed to better support small businesses considering the current operating environment. The recommended approach incorporates a number of the principles outlined in TGA Option 3 and would include:

1) implementation of a simplified annual fee scheme

2) establishment of a new policy framework to support small businesses and ensure continued supply of low volume products for important unmet medical needs.

Sanofi does not consider that the alternative options included in the consultation paper provide an improvement over the existing arrangements. The following summary outlines the reasons for expressed preferences and recommendations for improving operation of the scheme. Based on the twofold approach described above, it is considered that the business impacts for Sponsors would be neutral or positive, the intent of the original LVT exemption scheme would be better reflected and there would be no impact to supply of products on the Australian market.

2.1 SIMPLIFIED ANNUAL FEE SCHEME

The simplified annual fee scheme should deliver:

- Cost recovery for post-marketing activities undertaken by the TGA including safety monitoring and compliance:
  - Management and processing of adverse drug reaction reports;
  - Management and processing of recalls of therapeutic goods, including recalls for product correction;
  - Testing of therapeutic goods by the TGA laboratories;
  - Post-market compliance reviews for listed complementary medicines and class 1 medical devices;
  - Management of advertising and complaints resolution functions; and
  - Other regulatory costs which cannot be easily assigned to individual sponsors or products.
- Exemptions from annual fees for non-marketed products and export only listed products for which no post-marketing activities are undertaken by the TGA and cost recovery is therefore not warranted
- Streamlining of the exemption administration process for both TGA and industry to simplify and reduce resource burden, including elimination of third party certification requirements

Pharmaceutical portfolios usually comprise products that are actively marketed as well as those that are not marketed. As outlined in the consultation paper around 75% of the Register entries for

prescription medicines report zero annual turnover. Sponsors may choose not to market products for a number of reasons including lack of reimbursement on the Pharmaceutical Benefits Scheme (PBS) and the commercial operating environment which is influenced by the overall market size and availability of alternative therapeutic options. Sponsors may continue to hold registrations and keep them up to date whilst pursing reimbursement or to support future commercial agreements such as co-marketing arrangements with other Companies. The registration of alternative product trade names at the time of the initial application for approval provides commercial flexibility to rapidly execute such arrangements.

In other cases generic competition can result in the innovator products being deemed to be no longer commercially viable in a particular market, however the registration remains a potential asset for future divestment. The existence of a registration itself can be beneficial to allow a rapid response where market conditions may change the commercial viability of a product or even in situations where unexpected drug shortages arise, to facilitate import of supplies to alleviate a temporary supply disruption.

The consultation paper recognizes that exemption of nonmarketed products from annual fees would offer the benefit of being simpler to administer than the current scheme and more fairly represent the intention of cost recovery for activities undertaken. Similarly, at the point a product is marketed an annual fee would be incurred to ensure cost recovery.

To administer the scheme it is proposed to require Sponsors to provide a ‘no supply’ declaration to claim the exemption from annual charges. In order to further reduce the administrative burden an alternative option that would potentially allow easier automation of annual fee invoices would be for Sponsors to be required to accurately reflect the marketing status of therapeutic goods in the register entry, such that any therapeutic good entry indicated as being marketed on 1 July of a given year would be eligible for an annual charge. Products approved but not launched later in the financial year would be exempt from charges, wheras those indicated as marketed would receive an invoice notice. Similarly, any change in marketed status for existing entries during the year would trigger an annual charge payment.

This approach is aligned with the expectations for Good Pharmacovigilance Practice that requires Sponsors to have information on marketed products to support pharmacovigilance activities, including oversight of additional local risk minimization actions associated with approved risk management plans and the preparation of periodic safety update reports which require an accurate global marketing history.

To realize this option would require an investment in IT infrastructure and an appropriate transition period well in advance of the annual fee payment due date that allows Sponsor access to manage information, similar to the options for updating PI and CMI on the TGA website. Applying the marketed and non-marketed differentiation on the ARTG would also allow Sponsors to readily estimate annual fee costs and support the TGA to better predict annual fee revenues. Up to date information on marketed products would also assist the TGA in instances of drug shortages to determine availability of potential therapeutic alternatives.

For small businesses with low numbers of registrations providing information on marketed status of goods is an easily administered activity. Sponsors with large portfolios will typically be those from global organizations with global pharmacovigilance oversight where this information will be expected to be readily available. Consistent with the approach to random audits conducted for

complementary medicines, a similar scheme could be implemented to ensure compliance with the marketing status notifications, with selection based on an established Sponsor risk profile.

Overall the simplified scheme should significantly reduce the administration burden for the TGA and industry and better reflect compliance with cost recovery principles.

2.2 NEW POLICY FRAMEWORK FOR SMALL BUSINESSES

The policy framework should be designed to

- Reflect the current business environment and bring Australia into line with other international jurisdictions, recognizing that 'pre-market' costs are potentially a greater barrier to market entry than annual fees, particularly for small, innovative start-up companies requiring financial support to manage very large drug development costs and initial regulatory submission fees.
- Support activities that encourage innovation in the pharmaceutical sector which has the potential to provide significant public health benefit and in turn to increase research, investment and employment opportunities within Australia making an important contribution to the national economy.
- Align with the National Medicines Policy of ensuring a responsible and viable pharmaceutical industry by providing a consistent and supportive environment for the industry, and appropriate returns for the research and development, manufacture, and supply of medicines.
- Ensure provision of essential therapeutic goods that might otherwise not be viable in the market

Consideration should be given to schemes similar to those in the EU, where potential benefits for a company meeting a small business criteria, include research funding, competitiveness and innovation funding. Contributions to funding should be derived from departments supporting industry and innovation rather than solely from within the TGA budget which will inherently result in cross subsidization of smaller businesses by those Sponsors contributing the larger proportion of fees which is not in compliance with cost recovery principles. Options that could be considered for a broader range of incentives include:

- fee waivers/deferrals for small businesses meeting specific eligibility criteria
- provision of regulatory advice to optimize development programs and increase likelihood of realising value of R&D investments
- market exclusivity incentives

Overall the policy framework should support Australian business being competitive in a global market and better reflect the original intent of the LVT exemption scheme.

3 SUMMARY

In summary Sanofi considers that the existing LVT exemption scheme should be adapted to deliver appropriate cost recovery for post marketing activities undertaken by the TGA and that additional provisions are needed to better support small businesses considering the current operating environment. The recommended approach would incorporate a number of the principles in TGA Option 3 and include:

1) implementation of a simplified annual fee scheme

2) establishment of a new policy framework to support small businesses and ensure continued supply of low volume products for important unmet medical needs.

- Cost recovery through annual fees would be applied only to products that are marketed and therefore require post-market monitoring and compliance with TGA standards and guidelines.
- The scheme for managing annual fee exemptions would be streamlined to reduce administrative burden for both the TGA and industry and include an option for automation of annual invoices based on the assigned marketing status of register entry,with random TGA audits to confirm compliance selected by an established business risk profile.
- The policy framework for small business should be benchmarked against international jurisdictions, such as the model used in the EU, to ensure Australian business can compete in a global market.

Sanofi does not consider that the alternative options included in the consultation paper provide an improvement over the existing arrangements. Based on the expressed preferences and recommendations for improving operation of the scheme, it is considered that the business impacts for Sponsors would be neutral or positive through implementation of the above twofold approach, the intent of the original LVT exemption scheme would be better reflected and there would be no impact to supply of products on the Australian market.

The Company will be pleased to work together with the TGA and industry groups as relevant to find a solution that provides the best option for both the regulator and industry.

If you require any further information or clarification on this submission please do not hesitate to contact us.