



Australian Self-Medication Industry Inc
Suite 2202, Level 22, 141 Walker Street,
North Sydney NSW 2060
PO Box 764, North Sydney NSW 2059
Ph +61 2 9922 5111 Fax +61 2 9959 3693
Email: info@asmi.com.au www.asmi.com.au
ABN 55 082 798 952

31 July 2014

Senate Standing Committee on Economics
PO Box 6100
Parliament House
Canberra ACT 2600

By email to: economics.sen@aph.gov.au and uploaded via the "Make a submission to an Inquiry" page

Dear Committee Secretariat,

Senate Inquiry into Australia's Innovation System

Introduction

The Australian Self Medication Industry (ASMI) 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. Further information about ASMI and ASMI members is available on our website (www.asmi.com.au).

Many of ASMI's members also have manufacturing operations in Australia producing a range of self-care products for both the Australian and export market. As with much of the manufacturing industry in Australia, these operations are under pressure from the high value of the dollar, increased international competition (particularly from low cost sources) and rising domestic costs. Key to maintaining a competitive position as an investment destination will be an increased focus on research and development.

ASMI believes the Government has an important role to play in establishing an appropriate regulatory framework. In the health sector, such a framework balances the protection of consumers whilst also providing an environment conducive to industry investing in new products and services that meet the health needs of the Australian population both now and into the future.

ASMI welcomes the opportunity to provide comment in relation to the above Inquiry.

ASMI would be happy to discuss any of the following material in more detail should that be desired.

Summary

Non-prescription medicines (both over-the-counter and complementary) do not benefit from the same level of intellectual property protection as do prescription medicines and so, measures designed to encourage investment in innovation need to be tailored to suit these differences between the different types of therapeutic goods. ASMI makes the following recommendation for stimulating innovation in the non-prescription medicines sector:

- Recommendation 1 Reforms designed to encourage innovation in the therapeutic goods area must accommodate the different protections available for prescription medicines, over-the-counter medicines and complementary medicines.
- Recommendation 2 The many unfinished TGA reviews should be completed. Firstly to provide the certainty of requirements necessary for innovation. Secondly to provide an opportunity to develop solutions which are innovative in themselves or which facilitate innovation.
- Recommendation 3: The medicines scheduling policy should be revised so as to encourage and reward innovative approaches to medicines scheduling.
- Recommendation 4: The ASMI proposed model for direct to consumer communication of S3 medicines in a responsible, structured and balanced way should be implemented.
- Recommendation 5: Remove impediments to industry growth and viability by providing appropriate incentives to develop new ingredients, new claims, new products and rescheduling applications.
- Recommendation 6: Implement data protection arrangements for non-prescription medicines (e.g. by allowing a period of market exclusivity commensurate with the degree of innovation and investment).
- Recommendation 7: Increase the research investment into complementary medicines to more appropriately reflect their market share.
- Recommendation 8: Provide acknowledgement and support for the industry Working Group that has been established to examine research incentives in the non-prescription medicines industry.

ASMI and the Australian Market

The Australian Self Medication Industry (ASMI) is the peak industry body representing manufacturers of consumer healthcare products in Australia. Our members research, develop and produce the range of health and wellbeing products that include over-the-counter medicines and complementary medicines.

The industry seeks to increase access to medicines by expanding the range and availability of healthcare products, to support the trend towards greater self-care and to contribute towards Government's efforts to make better use of scarce healthcare resources and improve health outcomes. This can only occur through investment in research and innovation and an appropriate regulatory framework, which balances the protection of consumers whilst also providing an environment conducive to industry.

Self care encompasses all the things individuals, families and communities can do to improve or restore health, prevent disease and manage illness, in partnership with a healthcare professional.

ASMI estimates that the consumer healthcare industry turnover in Australia is around \$4 billion, with 5% p.a. growth^{1,2}.

ASMI members make up 85% of this market in which the main retail channels are pharmacy (59%), supermarkets (24%) and health food stores (11%).

The highest value product categories per annum³ are:

- Vitamins and minerals (>\$900M)
- Pain relief (>\$750M)
- Cough & cold (>\$500M)

ASMI research shows that the consumer healthcare products industry in Australia:

- Contributes approximately \$2.1 billion pa toward local manufacturing
- Exports products worth approximately \$1.2 billion pa
- Employs approximately 18,000 people in Australia
- Includes 17,000 registered and listed product variants on the market.

Typical R&D in the consumer healthcare products sector includes:

- New indications, claims and/or dosage regimes for products or ingredients.
- New formulations of (previously patented) active ingredients.
- Alternate delivery platforms for active ingredients (e.g. slow release formulations, liquids, coating technologies, encapsulation technologies etc).
- New combinations of well-established ingredients.
- New processing technologies.
- Packaging and labelling innovations.
- Rescheduling applications.

¹ Nielsen Scan Data Year End 2011 Pharmacy & Grocery Combined. Extrapolated for Health Food Channel.

² AC Neilson 2012.

³ Nielsen retail scan data 2010, 2011 & 2012

Due to the imperatives imposed by the nature of the market, innovations are typically incremental and need to be progressed rapidly to market. Innovation is critical to the continued success and growth of the sector.

ASMI is committed to finding ways of encouraging investment into consumer healthcare products as a means of maintaining and expanding this important and valuable sector as well as increasing consumer access to new effective medicines.

Regulation of Therapeutic Goods in Australia

Therapeutic goods are regulated in Australia by the Therapeutic Goods Administration (the TGA). Prescription medicines, over-the-counter medicines and complementary medicines are all subject to different levels of oversight by the TGA.

Getting an over-the-counter or complementary medicine onto the market in Australia requires a significant initial capital investment, and investment in research. Currently, the lack of investment protection available deters investment in research to support product innovation.

Unlike innovator prescription products, non-prescription medicines generally lack standard patent protection. This affects both over-the-counter and complementary medicines. This lack of intellectual property protection means that sponsors of these products need to find other ways to protect their investment. Typically, this has meant keeping the information out of the public arena. Another option (which is not currently available in Australia) would be to take advantage of some sort of data protection arrangement (ASMI's position on data protection reforms is discussed later in this submission).

However, sponsors' attempts to keep product information out of the public arena could be negatively impacted by two significant reform programs recently undertaken by the TGA:

1. The Transparency Review of the TGA⁴ was conducted to examine concerns about the amount of information made available by the TGA. In relation to the different product types, the final report⁵ indicated that:

"... what is commercial-in-confidence will vary with the type of therapeutic good. Not all therapeutic goods have the benefit of patent protection. Sponsors of products without such protection may seek to protect their intellectual property, by keeping information about the product out of the public arena. Publication of the full application to the TGA may therefore devalue the sponsor's asset". [emphasis added]

2. A review of the TGA's approach to disclosure of Commercially Confidential Information (CCI) has recently been conducted⁶ and concluded⁷. In ASMI's view the TGA needs to strike the right balance between stakeholder access and maintaining a viable medicines industry as the poorly considered release of CCI has the potential to devalue sponsors' assets. Importantly, once information is released it cannot be retrieved and so the damage cannot be remedied.

⁴ <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>

⁵ Review to improve the transparency of the Therapeutic Goods Administration, Final Report, June 2011 at: <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>

⁶ <http://www.tga.gov.au/newsroom/consult-disclosure-cci-130627.htm>

⁷ <http://www.tga.gov.au/industry/regulation-basics-disclosure-cci.htm#.U8ipoUx--Uk>

At the same time, the TGA's complementary medicines reforms⁸ will inevitably lead to an increase in regulatory burden and an increased need to generate scientific data to support product claims.

So, on the one hand it is getting harder to protect a research investment and on the other more research will be required.

This tension is made more complex due to the fact that over-the-counter medicines and complementary medicines are not afforded the same intellectual property protections as prescription medicines.

Recommendation 1

Reforms designed to encourage innovation in the therapeutic goods area must accommodate the different protections available for prescription medicines, over-the-counter medicines and complementary medicines.

Regulatory Certainty

Certainty in relation to regulatory requirements provides clarity for industry and a stable setting in which to innovate. Regulatory uncertainty prevents this stability and therefore hampers innovation.

The review of regulatory processes and requirements also provides an opportunity to develop solutions which are innovative in themselves or which facilitate innovation.

ASMI therefore seeks completion of the many unfinished TGA reviews, to provide this clarity and certainty in the regulatory environment. Among the most important of these reviews are:

Labelling and Packaging reforms – ASMI seeks a risk-based approach to labelling and packaging regulation, with proper consideration of business impacts (e.g. costs of manufacturing) together with appropriate transition arrangements.

Complementary Medicines Reforms – ASMI advocates for the adoption of a “light touch” approach to the regulation of vitamin and mineral supplement products. There have been many reviews into complementary medicines guidance documents and these are currently at varying levels of completion. ASMI seeks an efficient, streamlined process and avoidance of duplication in the evaluation of compositional guidelines and in the listing of new ingredients. Completion of complementary medicines reforms such as the Coded Indications project are important in providing clarity and predictability for industry. Effective post-market auditing and surveillance are needed to assure high levels of compliance and maintain consumer confidence.

Advertising Reforms – The TGA's review of advertising arrangements should be completed, and reforms in the area of pre-approvals and complaints handling processes are long overdue. ASMI seeks a single pre-approvals body, effective sanctions, clear guidelines, increased TGA transparency and faster decision making in relation to determinations on advertising breaches. The Therapeutic Goods Advertising Code requires immediate update (it was last updated in 2007). The self-regulatory and co-regulatory elements of therapeutic goods advertising control should continue, with non-association members being required to adopt an industry code of conduct.

⁸ <http://www.tga.gov.au/newsroom/consult-cm-evidence-listed-medicines-120423.htm>

Recommendation 2

The many unfinished TGA reviews should be completed. Firstly to provide the certainty of requirements necessary for innovation. Secondly to provide an opportunity to develop solutions which are innovative in themselves or which facilitate innovation.

Regulatory Innovation

The areas of therapeutic goods advertising and the scheduling of medicines are two areas where innovation ought to be encouraged.

ASMI therefore seeks reforms in relation to the advertising of Pharmacist Only Medicines as well as reforms in relation to the Scheduling Policy.

Scheduling policy

Increasing access to medicines will support greater self-care

The wider availability of safe, proven and affordable medicines has the potential to make a positive impact on public health by providing consumers with easier, more convenient and faster access to therapeutic products to treat illness and maintain health. ASMI seeks reforms to the Scheduling Policy Framework (SPF) to provide a more streamlined regulatory framework which encourages re-scheduling, or “switch”.

The National Coordinating Committee on Therapeutic Goods (NCCTG), which had policy oversight of the SPF, is no longer operational and there has therefore been no effective mechanism in place for policy oversight, review, and amendment of the SPF. As a result, guidance documents, concurrent switch, product application processes and S3 advertising guidance have not been updated for many years.

The scheduling environment in Australia is risk-averse compared to comparable markets such as the UK and New Zealand. This discourages sponsors from allocating financial and staff resources into compiling rescheduling applications.

ASMI believes that there should be urgent clarification of scheduling policy arrangements and update of scheduling guidance and administrative procedures to deliver an effective, predictable and timely scheduling environment.

It should be noted that the Government commissioned a review into the SPF in 2013 and the response to this review has not yet been announced.

Advertising of Pharmacist Only (Schedule 3) Medicines

Under the Therapeutic Goods Legislation a Pharmacist Only (Schedule 3 or S3) Medicine is not permitted to be advertised directly to consumers, unless an exemption has been granted through approval of an Appendix H entry in the Poisons Standard. Consumers are seeking more information on medicines, yet there is a very low level of awareness of Schedule 3 medicines and the role of the pharmacist in provision of these medicines.

The most recent guidelines on advertising Schedule 3 medicines are the “Guidelines for brand advertising of Schedule 3 medicines” published by the NCCTG in 2000; there is currently no effective mechanism in

place to update these guidelines. The arrangements for Appendix H applications and guidance have not been considered or updated for the past 14 years. These requirements are inconsistent with practices in the UK, EU, New Zealand and Canada.

There are currently more than 80 substances in Schedule 3, and of these only 10 have Appendix H approval and may be advertised. Despite repeated applications to the Scheduling Committee, the most recent Appendix H entry was approved in 2006.

The inability of sponsors to create awareness of S3 medicines is the main reason why in Australia the full potential of Schedule 3 medicines as legitimate treatment options has not been realised. The existing arrangements disempower consumers because “they are not allowed to know” about these medicines. It is therefore difficult to mount a public health benefit argument in support of the current restrictions. Consumers will continue to consult GPs for conditions which could safely be managed by pharmacists. ASMI has developed a proposal for an alternative regulatory model that allows direct to consumer communication of S3 medicines in a responsible, structured and balanced way. The primary aim is to create consumer awareness of this class of medicines and to encourage consumers to seek the advice of their pharmacist.

Recommendation 3:

The medicines scheduling policy should be revised so as to encourage and reward innovative approaches to medicines scheduling

Recommendation 4:

The ASMI proposed model for direct to consumer communication of S3 medicines in a responsible, structured and balanced way should be implemented.

Data protection

Currently there is no provision for data protection in relation to non-prescription medicines and where competitors benefit from the data generated by the innovator, the latter is placed at a significant commercial disadvantage. Data protection is a means by which a sponsor's data (new R&D) is protected for a period of time from competitors, and this includes from a subsequent sponsor seeking similar approval for an equivalent therapeutic good. In this context, “data” refers to the information that a sponsor provides in relation to a therapeutic good when seeking some form of approval for that good under the Therapeutic Goods Act.

Other jurisdictions, particularly the European Union and the United States, have data protection regimes that are quite favourable to sponsors and make Australia's look rather restrictive by comparison.

Through some form of data protection, albeit brief, sponsors will be encouraged to invest in innovation if they have the opportunity to gain a return on their investment before competing products enter the market. Industry believes that appropriate data protection provisions in the Therapeutic Goods legislation will create an environment conducive to investment in R&D for this important range of medicines.

As discussed earlier, in ASMI's view there are three broad options for protecting a sponsor's investment in research into non-prescription medicines:

- Keeping the information out of the public arena (which is getting harder to do),
- Data protection (which is not currently available for non-prescription medicines), and
- Patent protection (which non-prescription medicines generally lack)

ASMI notes that both the industry and the community desire increased access to evidence based complementary medicines and that greater investment in scientific research and development will expand the range of well-evidenced non-prescription medicines available for self care.

ASMI believes that a period of marketplace exclusivity, commensurate with the degree of innovation and investment, is required to recoup investment costs and, importantly, act as an incentive to research new therapeutic claims and products.

In ASMI's view, there are two methods of implementing data protection, as follows:

- Data exclusivity. Which means a defined period during which subsequent sponsors of equivalent therapeutic goods may not, during the period of data exclusivity, benefit from data provided by the first sponsor. This data exclusivity may take different forms, all ultimately having the same effect, i.e. a prohibition on relevant regulatory bodies from granting approval to subsequent sponsors of equivalent therapeutic goods if the application in question is dependent upon referral to data provided or generated by the first sponsor. This is the form of data exclusivity currently in the Therapeutic Goods Act in so far as concerns new active ingredients (new chemical entities, as opposed to well-established entities). Section 25A of the Therapeutic Goods Act provides for a five-year period of data exclusivity, but only in respect of information about new active ingredients (i.e. active ingredients not contained in any already approved therapeutic good) which are not publicly available. This form of data exclusivity prevents the TGA from using data provided by the first sponsor in considering an application put forward by a subsequent sponsor. Emphasis is placed on not relying, as opposed to not disclosing, since generally most of the regulatory bodies under the Act already treat information supplied to them by sponsors as commercial-in-confidence. However, this provision does not apply to new complementary medicine ingredients. Put simply, data exclusivity prevents Person B from using Person A's data package (as submitted to the TGA) to register the same medicine. Unlike a patent, data exclusivity: generally does not require lengthy, complex litigation to enforce; does not prevent Person B, or anyone else, from doing any research; and does not prevent person B from lodging their own data package, if they have one, to register and bring to market a competitor medicine.
- Market exclusivity. Which means a defined, enforced period during which a sponsor that is successful in obtaining some form of approval for a therapeutic good is granted an exclusive market status that prevents subsequent sponsors from obtaining similar approval for equivalent goods during the period of market exclusivity, even if new data is provided. This is analogous to patent protection, which grants the patent holder a monopoly in relation to their innovation for the life of the patent, preventing others from making use of that innovation, even if it is arrived at independently. Currently there is no provision for market exclusivity and where competitors benefit from the data generated by the innovator, the latter is placed at a significant commercial disadvantage

There are regulatory impediments to innovation in the non-prescription and complementary medicines industry in Australia and measures need to be implemented to address this market failure and to create an

environment more conducive to investment in the generation of regulatory data to support innovative products.

In ASMI's view, *data* exclusivity would be appropriate for:

- New indications, claims and/or dosage regimes for products or ingredients.
- New Listable ingredients.
- New formulations.
- New combinations.

Whereas *market* exclusivity would be appropriate for:

- Rescheduling.

The above forms of data protection will encourage investment in innovation, because they will give sponsors an opportunity to gain a return on their investment before competing products enter the market.

It is important to note that the solutions proposed are intended to address issues of regulatory failure in relation to non-prescription and complementary medicines only and are not designed to impact on prescription medicines generally, and the PBS in particular. ASMI supports measures to prevent any unintended consequences resulting from the introduction of these reforms.

As well, ASMI supports the principles of a free market and healthy competition. The proposed measures are not designed to restrict competition but to encourage investment in innovation through the ability of sponsors to recoup their investment in innovative products before competitor products enter the market.

In ASMI's view, data protection and confidentiality can both be used collectively to incentivise and protect research into innovative consumer healthcare products.

Expansion of the existing data protection provisions in the above ways would not require any budgetary outlay by the Commonwealth but would, in fact, be revenue positive for its encouragement of additional investment and employment.

Recommendation 5:

Remove impediments to industry growth and viability by providing appropriate incentives to develop new ingredients, new claims, new products and rescheduling applications.

Recommendation 6:

Implement data protection arrangements for non-prescription medicines (e.g. by allowing a period of market exclusivity commensurate with the degree of innovation and investment).

Research investment into complementary medicines

Increasing the investment by agencies such as the NHMRC into complementary medicines research will help capture and define the health benefits of complementary medicines and potential savings to the health care costs.

The NHMRC allocations for research into complementary medicines have been low at $\approx 0.2\%$ of total funding over the past ten years. (Source: NHMRC Research Funding Datasets 2003-2012). Given the widespread usage of complementary medicines, and the size and growth of the sector, the NHMRC should commit more project funds annually to complementary medicines research priorities. This could be administered as an NHMRC Targeted Call for Research (TCR), a solicitation for grant applications addressing a defined research topic. The topics could focus on the potential savings in the health care system via the proactive use of complementary medicines for health maintenance and treatment of minor ailments.

ASMI has previously supported an increase to at least 1.0% of the NHMRC allocation for research into complementary medicines. However, it may be more appropriate to allocate funds on the basis of market share. On this point ASMI data indicates that non-prescription medicines represent 23% of the total medicines market in Australia.

Other entities (for example the Australian Government Future Fund) should also allocate an appropriate portion of their healthcare research budgets into complementary medicines innovation.

Importantly, this would not require additional government funding (only a re-allocation) and would therefore not alter the overall budget for the NHMRC or any other agency.

Recommendation 7:

Increase the research investment into complementary medicines to more appropriately reflect their market share.

Working Group on R&D Incentives for Complementary Medicines

One of the biggest criticisms of complementary medicines is that there's not enough evidence to support them. While that is a controversial position, the only way to develop the right evidence base and to be able to communicate that evidence to consumers is to have the right framework to encourage innovation and research to happen. However, investment will only come from industry if it can recoup that investment.

A number of key stakeholders in the sector have taken on the challenge of encouraging greater industry-led investment in R&D. Under the leadership of the National Institute of Complementary Medicine (NICM), a working group has been established to examine data protection options and look at the international experience, all as a way of promoting innovation. ASMI is a member of this working group.

The objectives of the working group are:

To provide recommendations to the relevant Ministers on options for an improved environment for stimulating increased Research and Development in the complementary and non-prescription industry.

Initial meetings of the working group have been held, with the objectives of defining the nature and scope of the problems, generating evidence and developing potential solutions. Work is ongoing.

Recommendation 8:

Provide acknowledgement and support for the industry Working Group that has been established to examine research incentives in the non-prescription medicines industry.

Summary

Non-prescription medicines (both over-the-counter and complementary) do not benefit from the same level of intellectual property protection as do prescription medicines and so, measures designed to encourage investment in innovation need to be tailored to suit these differences between the different types of therapeutic goods.

ASMI welcomes the opportunity to provide comment in relation to the above Inquiry and to provide the preceding eight recommendations for stimulating innovation in the non-prescription medicines sector.

ASMI would be happy to discuss any of the preceding material in more detail should that be desired.

Yours faithfully,

Steven Scarff
Regulatory and Scientific Affairs Director