Response to the TGA Consultation: Therapeutic Goods Advertising Code

Proposed improvements including proposed framework for Schedule 3 medicine advertising

August 2017

SANOFI CONSUMER HEALTHCARE

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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 Therapeutic Goods Advertising Code – Proposed improvements including proposed framework for Schedule 3 medicine advertising, dated August 2017.

Summary:

Sanofi supports the development of an objective new therapeutic goods advertising code, to minimise subjectivity and enable clear interpretation of the provisions by all stakeholders and designed to suit the new advertising framework.

- The new code needs to be objective, expressed in plain english, with clearly defined requirements and terminology. The inclusion of detailed examples on non-compliance and compliance, either in the code or guidance documents, would greatly assist all stakeholders with supporting compliance with the new advertising framework.

- We believe much of the existing code requirements are still valid within the new advertising framework and should remain within the new code, specifically regarding warnings to be displayed on a general sale or OTC product advertisement.

- Sanofi supports the core principles in general, however we do not agree with some of the terminology and additions included in the proposed requirements under these objectives, some of which require further clarification and examples for effective review of the likely impact.

- We support a guidance document co-designed with sponsors, advertisers and industry members, other stakeholders and TGA representatives to ensure real life scenarios are utilised and examples are provided spanning the different medicine classifications. The guidance document should be included in the sponsor education program planned for the new advertising framework through seminars by TGA.

- Sanofi generally agrees that advertisements for Schedule 3 substances included in Appendix H should be subject to all general requirements as set out in the Code and the Act; however we are concerned that some of additional mandatory requirements proposed for advertisements for medicines containing S3 substances will lead to unnecessary confusion and have provided suggested alternatives where appropriate.

- An additional area that Sanofi believes needs to be continued from the existing code for inclusion in the new advertising code:

    - The exemption continuation for specific requirements as per the current code for picture/price/location advertisements in TGAC 2015, Section 6 (2)), with the current restrictions of this section remaining.

Sanofi additionally requests that the point below is considered for clarification in the new advertising framework.

1. Complaints process for materials directed to healthcare professionals for product of general sale, OTC or S3 medicines. Currently, only industry associations have a voluntary process for these type of complaints, since there are sponsors that are not members of industry associations there needs to be an avenue for these type of complaints.

We note that the feedback provided will be used to prepare an updated version of the Code that will be subject to the usual consultation processes for legislative instruments. For some of the proposals in this consultation document additional information or clarification is required in order to comment fully and this has been indicated where relevant. As part of any subsequent consultations we would strongly recommend the TGA use a workshop format to enable all stakeholders to understand different perspectives and together create a workable framework that reflects the recommendations of the MMDR review.

4.1. Changes to support effective sanctions and enforcement of advertising requirements

Consultation question:

Do stakeholders support minimising subjectivity in the interpretation of provisions in the new Code?

Sanofi supports minimising subjectivity in the interpretation of provisions in the new therapeutic goods advertising code. Sanofi supports the new code being objective and inclusion of specific detail of examples on non-compliance, either in the code or guidance documents. The new code must be expressed in plain english, with clearly defined requirements and terminology. Clear examples should be provided in the new code or guidance document to enable interpretation of compliance requirements.

We believe much of the existing code requirements are still valid within the new framework to be implemented and should remain within the code, specifically regarding warnings to be displayed on a general sale or OTC product advertisement:

- The mandatory warnings as already specified in the existing code are suitable and sufficient to direct the consumer to the location for additional information, namely the product packaging, packaging inserts and CMI/PI for relevant products.
    - The warnings “Always read the label. Use only as directed.” should remain as the warnings applicable on all advertisements. As per the current code specific categories should be required to include additional warnings.
- Providing a balanced message of benefits with these existing mandatory warnings are sufficient to enable the consumer to obtain additional information at the point of purchase.
- There is no evidence that the current warnings have been ineffective at communicating important safety information to consumers.
- The additional requirements already specified in the existing code for direct purchase via digital platforms should be maintained allowing these consumers to have the opportunity to view the full packaging information prior to digital platform purchase.

As the formal advertising compliance program for sponsors and advertisers to be implemented with the new advertising framework, we request further details of this program needs to be consulted with sponsors and advertisers prior to development as various questions have been raised regarding this program, such as if the program will be a formal certification program requiring individuals to be granted rights to approve advertisements after completion of the program or an education program without formal certification of individuals.

4.2 Core objectives for the new Code

Consultation question for section 4.2

We wish to obtain feedback to support the development of a new Code that is proposed to contain clearer and more specific details of what is and is not permitted in respect of advertisements about therapeutic goods.

The TGA seeks the views of stakeholders on the proposed requirements under the new Code as described above, and any other details or requirements that stakeholders believe should be clearly specified under the new Code.

Additionally, some stakeholders have called for guidelines to be available for advertisers (see Section 4.4 below).

Do you agree with guidelines to the new Code being developed? How should this guidance be made available to stakeholders?

Sanofi supports the development of a new code that is proposed to contain clearer and more specific details of requirements for compliance of advertisement for therapeutic goods.

Sanofi has detailed our comments on the proposed requirements described in the consultation document and advised additional requirements that should be specified in the new code.

We agree a guidance document should be written, in consultation with stakeholders, to provide clear examples of non-compliance and detailed explanation of requirements. The examples included need to be those that are 'close to the line' of non-compliance so as to be of use practically.

The UK Proprietary Association of Great Britain (PAGB) has an electronic portal that is a good model used for OTC medicines creating user friendly guidance for consumer advertising (www.pagb.co.uk/codes-guidance). The information includes practical tools such as a medicines advertising checklist; advertising case studies, glossary of product claims that supports Sponsors being compliant with code requirements.

This guidance document should be co-designed with industry members, other stakeholders and TGA representatives to ensure real life scenarios are utilised and examples are provided spanning the different medicine classifications. The guidance document should be included in the sponsor education program planned for the new advertising framework through seminars by TGA officers.

Core objective 1. Advertisements must comply with the Therapeutic Goods Act 1989, regulations made under this Act, and the Therapeutic Goods Advertising Code (page 9)

Sanofi supports core objective 1.

Core objective 2. Advertisements must be truthful, balanced and not misleading. Claims about therapeutic goods must be consistent with the entry of the goods in the ARTG (Page 10)

Sanofi supports the principle of core objective 2 and agrees advertisements must be truthful, balanced and not misleading and only use claims consistent with the ARTG entry, however we do not agree with some of the terminology used in the proposed requirements under this core objective, details of these are explained below.

"exploit the superstitious" (page 10), the term is vague and open to interpretation depending on the beliefs or experience of the reader. We need to be provided examples or detailed explanation of how this will be interpreted in an objective code.

"*not contain any claim, statement or implication that …. it is effective for specific demographic groups of patient (particularly where this may be a vulnerable group) without*

detailing the supporting evidence." (page 10), we require further clarity on the addition of this requirement particularly in relation to the need to detail the supporting evidence to enable comment on the suitability of the inclusion of this requirement in a new code. As this requirement is applicable to product label mentioned in the consultation document, this needs detailed explanation to ensure compliance with labelling orders as well as advertising codes.

"vulnerable group" (page 10), Sanofi does not agree with the inclusion of the term "vulnerable group" within the advertising code without a clear definition that is supported by inclusion within legislative definitions. Definition of this term should be consulted with stakeholders and legal representatives in future consultation groups.

*"Advertisements **must contain all mandatory and applicable information** to provide consumers relevant information that encourages responsible use and promotes safe use of the therapeutic good. Mandatory information, (e.g. requirements to include contraindications and warning statements) will be listed in the new Code."* (page 10)

Sanofi does not agree with the statement above to include contraindications and "other applicable information" in all advertisements. Sanofi believes the current mandatory warnings of "Always read the label. Use only as directed" are appropriate to instruct consumers to find this information on the packaging in retail store. This is aligned with the UK for OTC medicines where contraindications are not included in the advertising (Rule 57 PAGB Code section 1.5.15 Essential Information in Consumer Advertising).

The recent update to the labelling order for therapeutic goods ensures these warnings and contraindications are clearly and easily located on the product labelling; therefore, duplication of this information should not be required on advertising material. This information is required to be on product labelling for consumer information at point of purchase. This requirement is only suitable for direct marketing advertisements where the product can be purchased directly via the advertisement on digital platforms. Additionally, this requirement could be altered to only be required where there is a specific contraindication and/or warning associated with the scheduling classification of the substance or medicine.

Inclusion of contraindications and additional warnings, other than those in the existing code, should not be mandated for products available for general sale or non-prescription medicines (S2 and S3) as these products are suitable for self-selection or for supply without prescription. Furthermore for S2 and S3 medicines available from a pharmacy, the advice of a healthcare professional is either available or required to obtain supplies. This provides specific risk mitigation that supports quality use of medicines in the Australian environment.

***Core objective 3. All claims used in advertisements for therapeutic goods must be substantiated* (Page 10)**

Sanofi supports the principle of core objective 3 and agrees all claims used in advertisements must be substantiated, however we do not agree with some of the terminology used and proposed requirements under this core objective, details of these are explained below.

"Details of the scientific information relied upon must be publicly accessible." (page 10), Sanofi agrees reference to scientific information relied upon should be publicly accessible, however the requirement needs to be clarified to the extent of the identification of the

scientific information and restricted to citation of a published scientific paper by inclusion of the author name, year of publication, journal name, volume and/or page number for identification (unless the journal name contains a restricted representation within the title and then the citation must only require author and year). We would assume that if the scientific information is not published in a publicly available journal then the sponsor should make the information available on a public website and provide details of the location.

This requirement must also define how the public can obtain the journal paper by their own devices recognising the potential cost implications to ensure copyright laws are not breached by the Sponsor becoming a supplier of articles.

Sanofi agrees this above statement should be clearly defined to prevent 'data on file' references for comparison of products or specific scientific information, however Sanofi wishes to point out this provision must not be interpreted as requiring the publication of evidence relating to any therapeutic indications used in the advertising of complementary medicine as per the government's rejection of the MMDR recommendation to require sponsors to provide evidence summaries on public websites. This provision must also not be interpreted as requiring registered medicines to publish the evidence supporting the therapeutic indications on the ARTG and used in advertising.

We would suggest examples of non-compliant and complaint advertising are included in guidance documents with the new code, particularly as this requirement will require more detail and explanation due it being a clear addition to the existing code requirements.

*"The advertisement must **identify the sponsor of the scientific study** and must also detail if the sponsor of that study has or had any direct or indirect commercial interest in the therapeutic good or the ingredients being promoted in the advertisement*." (page 11), Sanofi does not object to identifying the sponsor of the scientific study but seeks detail of the intention on the proposed requirement to declare commercial interest as that requirement is open to very broad interpretation.

Additionally details of the mechanism to determine such an interest will need to be provided, particularly as the inclusion of the requirement "had" a direct or indirect commercial interest will require detail of the timeframe to be considered, such as in a case of a sponsor or raw material supplier sponsoring a study on their product or ingredient which has been subsequently supplied by multiple businesses after exclusivity or patent restrictions have been expired or where no exclusivity on the raw material was available.

The provision for identification of the sponsor of the study must define how situations will be permitted where the sponsor of a study available in the public domain is a government body or government research organisation, as identifying that body may subsequently breach other provisions of the code that do not permit implication of government body endorsement.

"The person providing the testimonial must be accurately identified" (page 11), Sanofi generally agrees with the requirements for testimonials included in the consultation document. However we would require clarity in the new code that the requirement above regarding 'accurately identified' is in reference only to the documentation held to support the testimonial and not in the advertisement. Identifying first name and state of a consumer in a testimonial in the advertisement would be the maximum allowed due to privacy concerns for the individuals that are not known in the public domain.

Core objective 4. Advertisements of therapeutic goods must give adequate and appropriate information on the risks, cautions and side effects as well as provide a balance between promoting responsible self-treatment and encouraging consumers to seek timely professional help. (Page 11)

Sanofi acknowledges the intention of core objective 4 and is supportive of advertisements providing a balanced view of therapeutic products, however we do not agree with many of the proposed requirements under this core objective, details of these are explained below.

"Promotion of therapeutic goods must be consistent with current social expectations for public media …. content in advertisements must also be consistent with any relevant public health or safety campaigns of the Commonwealth, State or Territory governments."(page 11)

Sanofi does not agree with the above inclusion regarding consistency with any government public health and safety campaigns. The requirement is far too broad to enable accurate vetting without a specific list provided by the commonwealth government and each state or territory government detailing all the public health and safety campaigns that are current or planned and details of the intent of each campaign to ensure a planned promotion is consistent with these campaigns.

A promotional campaign can be developed over 12 months or more, without being forewarned of planned governmental public health and safety campaigns this requirement could not be adequately defined in an objective code and is not suitable for inclusion in the new code. Additionally, it is not clear what exactly will constitute such a campaign or how such information is found (for example, many government websites and public material contain general information that may or may not be considered a campaign).

Sanofi agrees with the requirement "to be consistent with current social expectations for public media" and this should be sufficient to cover requirements for advertisements to be socially responsible.

"An advertisement about therapeutic goods ***must not encourage, or be likely to encourage inappropriate or excessive use of the goods.*** *An advertisement must also not unduly glamorise products or prey on the vulnerability of particular consumers. In assessing compliance of an advertisement under this particular requirement, the following public interest criteria are to be applied:* (Page 11)

- *the advertisement must not impair the ability of a member of its audience to choose an appropriate therapeutic product to treat, manage or avoid a disease, condition, ailment or defect because of the vulnerability of the member of the audience;*
- *an advertisement for a medicine must be consistent with Quality use of Medicines (QUM) objectives and in relation to non-prescription medicines, that the advertisement must be for a condition that is suitable for self-diagnosis or self-management and must not impair the ability of a member of its likely audience to self-diagnose and/or self-manage that condition;*
- *the advertisement should not encourage or result in consumers or members of the public refraining from seeking timely and appropriate professional advice about the disease or the condition as it is important to prevent negative health consequences, deterioration or progression of disease;*
- *the advertisement is not likely to create a false expectation in its likely audience that the product will deliver health benefits or improvements to their quality of life;*

- *the advertisement is not likely (alone or through repetition or together with other references) to have a negative impact on public health or on persons to whom the advertisement is not directed); …"*

Sanofi agrees that advertisements should not encourage inappropriate or excessive use of therapeutic products; however the detail within this proposed requirement is not clear for some of the terms and specific clauses and needs detailed clarification of some of the proposed clauses and terms.

"*not unduly glamorise or prey on the vulnerability of particular consumers*", Sanofi advises this terminology is not clear and needs detailed clarification or examples to determine the impact on interpretation of the new code. As discussed previously, a vulnerable group needs to have a clear, legal definition to enable clear understanding of the intent of this clause.

Additionally the fourth and fifth points above could be interpreted in multiple ways and should be rewritten to ensure clarity of the intent of the requirements. The fourth clause can be interpreted that an advertisement cannot express the approved therapeutic indications. This should be revised to be clear that the advertisement does not cause the audience to expect benefits beyond those approved for the therapeutic product taking into consideration the different classes of medicines that will be covered by the new code. The fifth clause is not clear to the intention of this requirement and we require clarification and examples to be provided in future consultations to evaluate this proposed requirement.

"in relation to medical devices: (Page 12)

– *the content of the advertisement is balanced and adequately sets out warnings, precautions and risks that make a particular treatment or procedure inadvisable;*

As outlined previously, we consider the existing code wording in relation to ' Always read the label and Use only as directed' provide sufficient information to refer consumers to the device pack instructions or any leaflets contained therein.

"In relation to ***sponsorship advertisements****, it is proposed that a sponsorship advertisement must:* (Page 12)

- *clearly and primarily promote the team, individual, competition, event or activity being sponsored; and*
- *not contain a direct or implied claim or a sales message including any brand tag-line for a therapeutic product, other than product name, or in the case of a medical device, a purpose for use; and*
- *not imitate or use any part of a therapeutic product advertisement from any medium, or refer or link the advertisement from any medium."*

And

"Similarly, any sponsorship advertisements promoting a team, individual, competition, event or activity will be subject to the advertising requirements."

Sanofi does not agree with the specific details of requirements for sponsorship advertisements and further discussion and consultation with government is required to determine if this proposal is supported by government policy.

Further the last statement above that any sponsorship advertisements will be subject to the advertising requirements is contradictory to the three points above that no direct or implied

claim or a sales message is permitted to be included in the advertisements, where advertisements for therapeutic products must include a reference to a therapeutic indication on the ARTG. Additionally, the above requirements regarding sponsorship advertisements have not considered the real world situation of brand name advertising as opposed to product name advertising and must be considered in all sections of the new code. The impact of these proposed requirements needs to be discussed with industry stakeholders and consideration of impact on celebrity endorsement or testimonial advertisements to ensure clarity of each situation.

"It is also proposed that any disease awareness campaigns by sponsors of therapeutic goods, healthcare professionals, associations and other groups (e.g. Heart Foundation, Cancer Council) require that the campaign must be factual and balanced and support consumers in making informed health choices. Such campaigns must not identify a specific therapeutic good or sponsor either expressly or by implication." (Page 12)

Sanofi does not agree with the above specific requirement only with regard to the sponsor not required to be identified in disease awareness campaigns. All advertisements and promotional material should be required to identify the person or business responsible for the advertisement. Not identifying the sponsor for a campaign thereby prevents a person knowing who is responsible for an advertisement or campaign material to enable objection or complaint or request for further information. Sanofi agrees a specific therapeutic good should not be identified.

In addition, whilst the Therapeutic Goods Advertising Code is primarily directed at advertising of non-prescription medicines to consumers, sponsors of prescription medicines also engage in disease awareness activities. The Medicines Australia Code of Conduct specifically requires that the name of a sponsor of a disease awareness activity must be identified, but should not be given prominence (Section 13.8.7, Code Edition 18) and we support the Medicines Australia position that the new code should not change this requirement.

*"Advertisements **must not offer any personal incentives** including product based contests, to pharmacy assistants, or other sales personnel employed by healthcare practitioners to recommend or supply therapeutic goods."* (Page 12)

Sanofi agrees the general prohibition to not offer personal incentives to pharmacy assistants and other sales personnel employed by healthcare practitioners to recommend or supply therapeutic goods is acceptable. Sanofi is unclear of the meaning and unfamiliar with the term "product based contests' and requires this to be defined to enable an effective response.

An additional area that Sanofi believes needs to be continued from the existing code for inclusion in the new advertising code:

1. The exemption continuation for specific requirements as per the current code for picture/price/location advertisements in TGAC 2015, Section 6 (2)), with the current restrictions of this section remaining.

4.3 The Council recommendations

Consultation question for section 4.3

> *Are stakeholders supportive of including the recommendations in section 4.3 proposed by the Council for incorporation in a new Code?*

Sanofi does not support including the recommendations in section 4.3 from past consultations, preceding the 2016 consultation. These recommendations from the council would have been proposed and responses considered based on the existing advertising framework and may require to be reconsidered for the new advertising framework.

Sanofi however agrees that new and expanded definitions of restricted representations and prohibited claims may need to be developed based on the new framework, these should be co-designed with stakeholders to ensure current products and services are considered.

Sanofi considers the development of a clear definition of restricted representation needs to firstly clearly define the limitation of the term 'serious form of a disease, condition,…', this definition should consider the ability of a consumer or patients to self-manage their condition after initial diagnosis if that condition does not require ongoing treatment with regular evaluation by a healthcare professional.

"Reference in an advertisement for a therapeutic good to any procedure (or product requiring such a procedure for its intended purpose), that can only be performed by a suitably qualified healthcare professional to become a restricted representation." (Page 13),

Sanofi does not support the addition of any the above requirement in the restricted representation definition. This is not supported due to current availability and emerging availability of home based, consumer testing kits for monitoring blood glucose, blood pressure, cholesterol or vitamin deficiency kits, all of which may be able to be included as medical devices and should remain suitable for advertisement to consumers for self-monitoring of conditions. We consider it unsuitable as part of the definition of a restricted representation to include the above proposal when this may no longer be valid for a range of procedures or testings of various biomarkers. The restriction needs to be based on whether the procedure refers to a serious form of a disease and whether self-care is able to be managed by consumer after initial diagnosis.

4.4. Consultation comments

Consultation question for section 4.3

> *Do stakeholders support the Code changes proposed in section 4.4 (1 to 3) in the 2016 advertising consultation comments?*

Sanofi supports the changes in section 4.4 being proposed for a new code for future public consultation, particularly a guidance document to assist the understanding of the code. A guidance document should be developed and maintained as a living document with specific examples regularly updated. This guidance document should be developed in conjunction with industry members, other stakeholders and TGA representatives to ensure real life scenarios are utilised.

5.Price Information Code of Practice (PICOP)

Consultation question for section 5

Do you consider that the PICOP should:

- *remain in the new Code, or*
- *be established as a separate legislative instrument under the Therapeutic Goods Act 1989, or*
- *are there other mechanisms for managing compliance with the PICOP?*

Sanofi supports retention of PICOP within the new Code to ensure there is a single point of reference for managing all aspects of advertising including price information.

6.An option for an Advertising Framework for Schedule 3 (pharmacist only) medicines

Consultation question for section 6

Stakeholders are asked to provide feedback on the proposed option for advertising of Pharmacist-only medicines containing Schedule 3 substances and inclusion in Appendix H.

In particular, we would appreciate feedback on

- *the specific requirements for advertisements containing Schedule 3 substances*
- *factors to be considered by the delegate*
- *restrictions on inclusion in Appendix H*
- *the proposed process*

Regarding the specific requirements for advertisements containing Schedule 3 substances, Sanofi generally agrees that advertisements for Schedule 3 substances included in Appendix H should be subject to all general requirements as set out in the Code and the Act; however we are concerned that the following additional mandatory requirements are proposed for advertisements for medicines containing S3 medicines:

"*Your pharmacist must decide if this product is suitable for you*"(Page 16), *with requirement this statement is being proposed to be included prominently in the advertisement, namely for print advertisements at the top of the advertisement, for broadcast media it is proposed to have this as the leading statement.*

Sanofi does not agree with the proposal above as the words "must decide" imply that a medical practitioner could not recommend an OTC medicine and that the pharmacist could be held liable in the case that a consumer had an adverse reaction to a medicine deemed to be suitable by the pharmacist.

We also believe that consumers expect that the mandatories would be in the one place within an advertisement. Adding this mandatory to the start of the broadcast advertisement could cause confusion as being related to the previous advertisement. We therefore propose that this mandatory be included with the other mandatory statements at the bottom of the advertisement.

In relation to the 'Ask your pharmacist about side effects relevant to you' statement we agree that it should be included prominently in the advertisement particularly in print media at the bottom of the advertisement.

In addition we have concerns with regards to including the above mentioned two proposed statements particularly in broadcast media. Currently the Therapeutic Goods Advertising Code 2015 section (7) (1) (c) Analgesics states that an advertisement for analgesics (other than product labels and radio advertisements which are 15seconds or less) must contain the following warning statement, prominently displayed or communicated….: 'Use only as directed. Incorrect use could be harmful. Consult your healthcare professional if symptoms persist.' Also section (7) (1) (d) states that radio advertisements which are 15 seconds or less must include the following: Always read the label. Use only as directed by a healthcare professional.' We are concerned that by adding the proposed two extra warning statements that would take up most of the 15 second or even 30 second radio advertisement and there would not be enough time for the actual claim. We ask that you re-consider this proposal to exempt this requirement for radio advertisements.

Regarding the factors to be considered by the delegate, Sanofi considers the delegate to look at the beneficial factors rather than the risk of the proposed substance to be added to the 'positive list' such as the reduced burden on doctors, more timely access to medicines, an increased ability for consumers to self-select for self-care of their minor ailments, raise public awareness as unfortunately there is limited consumer awareness of S3 medicines, as many people don't think to go to a pharmacist for minor ailments that could be treated fairly easily with an OTC without the need of a GP visit. In addition we would like the delegate to take the pharmacists role into account as ultimately they should continue to play an important role in determining whether a S3 product is appropriate for the particular consumer. As part of pharmacovigilance activities, pharmacists could be provided with additional, specific training on recently down-scheduled S3 medicines or additional tools such as questionnaire that would be completed at the time of consultation to help determine treatment suitability.

Regarding restrictions on inclusion in Appendix H, Sanofi believes the current advertising restrictions for many S3 medicines means that consumers may be unaware of the availability of treatment options that may be an effective means of managing a self-limiting condition without the need to visit a GP. As a consequence, they may spend additional time and incur costs prior to gaining relief, without realising that a pharmacist, who is typically more accessible to the community, could have advised on an appropriate treatment choice. This defeats the purpose of having approved OTC medicines and the benefits of freeing up GP resources to focus on more serious conditions that require medical intervention. We agree with the proposals on restrictions for inclusion in Appendix H especially for substances that are clearly not appropriate for direct-to-consumer advertising. We propose that a list of Schedule 3 substances is created which would clearly state which substances cannot be advertised to the public, where there is likelihood of misuse or abuse, or other specific risk mitigation needs that requires a more extensive interaction with a pharmacist to ensure the right choice of product based on benefit risk considering any specific individual circumstances. The proposal of a working

group would definitely add value to the decision process so long as it includes a wide range of stakeholders including medical practitioners, pharmacists, and consumer and industry representatives.

Regarding the proposed process, Sanofi believes that most S3 medicines should be allowed to be advertised to the public. We agree with the proposed process for adding a substance to Appendix H similar to the current process for re-scheduling, including public consultation which encourages debate and provides an opportunity to identify potential misuse or broader public concerns as well as the industry's perspective; however we would like to see the key decision makers consisting of a wider range of stakeholders as per above and for them to be more pragmatic when it comes to deciding if the substance should be added to Appendix H and to look more at the benefit rather than being risk-averse.