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23rd August, 2012

TGA Packaging and Labelling Review
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RE: TGA Medicine Labelling and Packaging Review (Consultation paper version 1.0, May 2012)

Sanofi welcomes the opportunity to respond to the consultation paper on the labelling and packaging review. The company is engaged in the research, development, manufacture and marketing of complementary, over-the-counter and prescription medicines including vaccines. We are therefore fittingly placed to comment on the implications of the paper across the spectrum of therapeutic goods.

Sanofi is supportive of the TGA regulatory framework underpinned by a risk based approach to regulation. We agree that the use of all therapeutic goods carries risk and that the TGA does not seek to avoid all risks – that would be impossible – but its risk management approach is about reducing the impact of risk to an acceptable level. The amount of regulatory control needed to manage risks depends on the product. As the risks are different for different medicines, the requirements should also be different. There is very little evidence within the paper of a risk-based approach to the identification of issues and the formulation of reforms to address those issues. Sanofi believes that the one-size-fits all approach to labelling that has been applied across the entire spectrum of medicines is not the best way to address the separate and distinct issues which are relevant to different classifications of medicines.

Sanofi recognises the importance of ensuring health care professionals and consumers receive information about medicines that supports their appropriate use to achieve optimum health outcomes. We understand that the label is an important source of this information, especially for non-prescription medicines. A well designed label, one which is easy to read, enables consumers to readily find information. It is considered, however, that health literacy is a key component of reducing medication errors by consumers and the review does not address this critical element. Education, starting in schools is needed to increase the general understanding of the public on how to manage their health and use medicines appropriately.

Sanofi also notes that there are many inconsistencies and errors within the consultation paper which have resulted in a lack of clarity and made interpretation of the document difficult. The figures include material which is not explained in the text, which do not comply with current labelling requirements, demonstrate a lack of internal consistency within the paper and imply additional proposals. As such, Sanofi's comments are made based on our interpretation of the proposed requirements.

As a member of both the Australian Self- Medications Industry (ASMI) and Medicines Australia (MA) groups Sanofi was involved in the development of industry feedback and is supportive of the detailed analysis of the consultation paper provided by these bodies. In addition to the points made in the industry responses, we would like to draw your attention to the key issues under each heading of the consultation paper which we believe are major concerns for Sanofi.

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Executive summary

- Inconsistencies within the document make it difficult in interpret the recommendations.
- Proposals are unnecessarily prescriptive.
- Little evidence of a risk-based approach to the identification of issues and the formulation of reforms.
- A 'one-size-fits' all approach has been applied to the entire spectrum of medicines. Not only has no differentiation been drawn between prescription and non-prescription medicines, there is no differentiation between categorises of non-prescription medicine spectrum i.e. lower risk listed medicines and higher risk non-prescription medicines.
- "Equal prominence" would have a detrimental impact on brand recognition and may lead to unnecessary clutter, which could reduce the readability of medicine labels and the ability of patients to locate important information.
- A standardised back-of-pack format has merit but any proposed format should be consumer tested prior to adoption. A different design will be required for OTC and complementary medicines.
- The current requirements for prescription medicines in relation to signal heading placement restricts the ability to optimise label formats or implement symbols that could free up space on labels to improve readability or communicate key safety information.
- The simplistic and blanket approach to both prescription and non-prescription medicines in relation to Look-a-like and sound-a-like medicine brand names and look-a-like packaging and branding does not meet the complex and multi-faceted issues in this area.
- The proposal to include batch and expiry more frequently on the blister strip does not address the identified risk associated with safe use of medicine when blister strips are stored away from the pack. This proposal will have far-reaching consequences throughout the manufacturing and supply chain and will result in substantial cost increases.
- An appropriately constituted Committee may add value in objectively applying clear guidelines and protocols to expedite evidence-based decision making in relation to medicines labelling and packaging.
- The proposals would likely lead to companies having to implement Australian-specific labelling, which would reduce moves towards international harmonisation and would further increase costs. This could affect the viability of some products.
- Any changes resulting from the consultation need to be considered in the light of ANZTPA joint agency.
- The TGA should also consider non-regulatory approaches (eg consumer education) to mitigate the risks identified in the paper.

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Key concerns relating to each section of the consultation paper

Prominence of active ingredients on medicine labels

Sanofi acknowledges the importance of consumers being aware of the active ingredient in their medicine and supports the view that this could be achieved by giving due prominence to the ingredient names. For prescription and over-the-counter medicines (including complementary medicines), the name of the active ingredient is already placed below or close to the brand name and can be readily found on the main label.

Equal prominence reduces readability: Sanofi does not support the proposal for equal prominence as the brand name. Our key concern is the unnecessary clutter this will create, which could have detrimental impact on brand recognition and reduce the readability of medicine labels. This is especially the case with herbal medicines where the herbal ingredient name is required to include the name together with the extract/dry/fresh equivalent and the identification of the plant part. It is worth noting that in the UK and Canada, the active ingredient is required to be only 50% of the size of the brand name. It is also important to note that mandatory word placement and size is not the only way to differentiate between products – there are many different elements that can be utilised to effectively communicate the information required by the pharmacist and patient, e.g. font, colour, bold, italics and overall label design.

3 most abundant ingredients may not be 3 most important: Sanofi does not support the TGA suggestion that where there are more than 3 active ingredients present in the formulation, the 3 most abundant ingredients must appear on the main label. While it may be relevant to list the 3 most abundant active ingredients on the main label, these may not be the 3 most *important* (from a functional and safety perspective) ingredients. This is especially the case with complementary medicines. Multi-vitamins may contain many active ingredients and the most important for a particular formulation may not be in the highest quantity. An example of this is pregnancy multivitamin products where folic acid would be seen to be the most important ingredient, however, this would not appear on the front label under this proposal. In this situation the status quo of listing the ingredients all together on the same panel may be a better approach.

3 non-opposing faces prescription only issue: While Sanofi acknowledges the TGA's proposal that the active ingredient must be included with, and of equal prominence as the brand name on 3 non-opposing faces of a carton may be important for prescription medicines due to dispensing practices, we do not agree that it should be applied to over-the-counter and complementary medicines. These products are generally available in front of the counter in pharmacy and in grocery stores where they are positioned on shelf with the main panel facing out. When considered in conjunction with the proposal for a medicine information box (discussed later in the paper), it would seem appropriate for the active to only be included on the front and back panels.

Sanofi therefore does not support these proposals in their current format. Sanofi believes the issues relating to prescription, non-prescription and complementary medicines need to be separated and a risk-based approach taken to the proposed changes. The TGA should demonstrate that increasing the prominence of the active is the most effective way to resolve the issue of accidental overdose. If prominence of the active is considered the best way to address this issue then the TGA should also consider achieving prominence of the active ingredients through other means (eg colour, graphics, position, different font etc) rather than increasing the size. The TGA should also consider non-regulatory approaches (e.g. consumer education) to mitigate these risks.

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Look-a-like sound-a-like (LASA) names and look-a-like packaging

Sanofi agrees that the ability to clearly indentify medicines is an important contributing factor in determining whether a patient receives the intended medication. We also agree that it is vital patients receive their intended medication.

Sanofi acknowledges that "look-a-like" issues are a complex and multi-faceted area in both prescription and non-prescription medicines. Sanofi believes that prescription and non-prescription issues and proposals need to be separated. The consultation paper confusingly amalgamates four interrelated issues into a single topic applicable to both prescription and non-prescription products. The four issues (look-a-like sound-a-like products; different strength within prescription medicine brand; umbrella branding; indication specific labelling) all apply differently to prescription and non-prescription medicines. Sanofi believes that the proposals should be consistent with a risk-based approach and should be reflective of the risks posed by different categories of products.

Prescription Medicines: Look-a-like sound-a-like (LASA) is predominantly an issue with prescription products as illustrated by the examples included in the consultation paper. The specific proposal, *"if a proposed medicine brand name differs from one already on the ARTG by 3 letters or less, then product labels should be different colours"* does not seem to have examined the long term impact or feasibility of this proposal. Nor is it clear why the TGA recommend selection of 3 letters versus other compilations. It would be useful to understand how these recommendations were reached and align with international standards.

Product Brand name is a valuable company asset which cannot be changed quickly or without significant cost. Similarly, changes to product packaging are expensive and time consuming. Sanofi contends changes diminishing the value of product branding or packaging must be supported by evidence and robust assessment of regulatory cost against measurable benefits.

Sanofi is supportive of a risk assessment approach for proposed labelling and packaging for a new medicine. However, clarity is required around the framework and impact of this course of action on the current TGA evaluation process, timelines and decision making.

Non-prescription Medicines: Branding and brand recognition are key area of non-prescription medicines, both from an industry viability and consumer self-selection perspective. Sanofi fully endorses the objective of avoiding possible harm which may result from confusing different medicines, however, we do not support the blanket and simplistic approach suggested in the consultation paper.

Umbrella branding issues are very situational and depend on the category, brand, packaging, graphic area/space and brand history/heritage. Non-prescription medicines include different cues to help consumers differentiate between products including brand, sub-brand, indication, graphics, colour etc. All of these need to be considered along with the risk profile of the product when determining if an ingredient or indication is allowable on a case by case basis.

LASA is not considered an issue for non-prescription medicines as these products are placed in therapeutic categories in pharmacies and grocery thus resulting in similar sounding products being kept in different parts of the store eg Zantac (GI section) and Zyrtec (Allergy section). Once these products are purchased the consumer uses these products based on the

detailed information which is provided on the product label. This is significantly different practice to prescription medicines. To apply the same changes across the spectrum of therapeutic goods ignores the higher risks of prescription medicines in comparison to non-prescription medicines and the already existing differences in the product information provided on the labels

Complementary Medicines: Most complementary medicines are umbrella branded. There is no evidence presented to indicate that a risk of accidental overdose that could result from consumers being given the wrong medicine or selecting the wrong medicine because of similarities in the names or packaging of the medicines is an issue with complementary medicines. Even if a theoretical risk exists, the risk would be very low risk and any solution proposed needs to consider the different safety profile of these products. This again reinforces why it is important that a risk based approach based on the different medicine classifications be considered by the TGA.

Case-by-case assessment of brand name required: Sanofi does not agree with the proposal that listed and registered products cannot carry the same brand name. In cases where the same active ingredient may be presented in both a Listed medicine and a Registered medicine, if the products have the same brand name the patient would be more likely to realise that they are similar, hence would be less likely to take an excess amount of that ingredient. In most cases, the scheduling of an active ingredient will determine how it may be distributed, and the appropriate level of information that should be included on the labelling. Complementary medicines can be either listed or registered and as such, complementary brands that range across both the listed and registered medicines already exist. The TGA has not presented any evidence that this practice poses significant risk to the consumer. Rather than implementing a prescriptive approach, Sanofi favours a specific risk assessment by the regulator for AUST R medicine applications on a case-by-case basis taking in to consideration the most likely consumer behaviour for each situation.

While Sanofi endorses the objective of avoiding possible harm which may result from confusing different medicines, we do not support the blanket and simplistic approach to both prescription and non-prescription medicines. Sanofi feels strongly that due to the complexity of these issues, this area requires a more in depth exploration and consultation with all stakeholders to generate confidence that the reforms will achieve the stated objectives and not result in unintended consequences.

Standardised Information Format: the Medicine Information Box

Sanofi understands the importance of clear, useful information on product labels for non-prescription and complementary medicines.

Standardised back-of-pack improves access to consumer information: Sanofi agrees in principle that a standardised back-of-pack containing information relating to active ingredient, uses, warnings, directions/dosage instructions and storage will improve access of information to consumers. However, we believe the details of the Medicines Information Box need to be properly developed, demonstrate measurable benefits and be based on the outcomes of consumer usability testing. Some flexibility needs to be incorporated into the design. A different design will be required for OTC and complimentary medicines bearing in mind the differences in aspects such as number of ingredients, uses and dosages which can exist with non-prescription products (e.g. many complementary products can have multiple doses which relate to different uses on a single product). It should also be noted that even though the proposals will lead to greater uniformity of product

labels and improve consumer access to information, an outcome of the labels all appearing the same may be a reduction in differentiation between products and an increase in safety issues.

Dispensing label space

Sanofi supports in principle a designated space on product packaging for a dispensing label, where space and/or pack size permits. Sanofi does not support the dispensing label proposals as a mandatory requirement. Sanofi try to maintain labels free of clutter wherever possible, and the labels of most prescription medicines already have space where a dispensing label can be affixed.

Blister Strip Labelling

Repetition of batch and expiry does not address cited issue: Sanofi notes that it is current practice for blister strips to be labelled with the trade name, active ingredient and amount of active ingredient at least once for every two units. However, Sanofi strongly disagrees with repeating of the batch number and expiry date at least once every two units. Mandating additional text will increase the clutter of information and may impact on readability. The feasibility of introducing these mandatory measures appears not to have been fully considered. Batch numbers and expiry dates are variable and cannot be pre-printed, requiring additional and multiple changes to tooling. The costs of this measure will be significant.

Sanofi would support non-regulatory approaches to mitigate risks e.g. consumer education on the risks associated with removing blisters from the packaging. The TGA may also consider the use of a standard statement on the blister and/or packaging advising consumers not to cut the blister and to keep the blister with the carton.

Small containers

Sanofi does not support this proposal. Mandating a primary pack for all small containers will be costly with uncertain impact on safety. The consultation acknowledges consumers regularly store medicines separately from the primary packaging and therefore the impact of this measure has not been fully examined. Additionally, there are environmental impacts on increasing primary packaging. Many measures already support delivery of relevant information on small packs such as flag labelling, CMIs, online resources.

Pack insert

Sanofi does not oppose the proposals for pack inserts as described in the Consultation Paper.

Labels and Packaging Advisory committee

Sanofi does not oppose an appropriately constituted Committee. This Committee may add value in objectively applying clear guidelines and protocols to expedite evidence-based decision making in relation to medicines labelling and packaging.

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Conclusion

Sanofi recognises the importance of ensuring that health care professionals and consumers receive information about medicines that supports their appropriate use to achieve optimal outcomes. We understand that the label is an important source of this information. Whilst some of the recommendation in the paper may be a starting point for improvements to the label, it is very clear that further work is required to determine the best approach to packaging and labelling.

Sanofi again highlights that health literacy is a key component of reducing medication errors by consumers and the review does not address this critical element. Education, starting in schools is needed to increase the general understanding of the public on how to manage their health and use medicines appropriately.

Sanofi remain committed to working with the TGA, industry and relevant stakeholders to develop and implement medicine labels that address the consumer safety risks identified in the consultation paper.

Yours sincerely,