24th August 2012

GlaxoSmithKline

Level 4, 436 Johnston Street
Abbotsford Victoria 3067
Australia

PO Box 18095
Melbourne Victoria 8003
Australia

Tel: +61 03 9721 6000
Fax: +61 03 8761 2410
www.gsk.com.au

TGA Labelling and Packaging Review
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Email: labellingreview@tga.gov.au

Dear Sir/Madam

Re: TGA Medicine Labelling and Packaging Review Consultation Paper (Version 1.0, May 2012)

GlaxoSmithKline Australia (Pharmaceuticals Division) makes the following submissions in relation to the above name consultation paper.

This submission is made on behalf of the GSK Pharmaceuticals business in Australia. A separate submission has also been made by our OTC division – GSK Consumer Health. It should be noted that both GSK divisions are aligned on the points made in each submission. GSK Pharmaceuticals division would also like to note that they are also in alignment with the comments made in the Medicines Australia submission on this consultation paper.

GSK Pharmaceuticals welcomes viable initiatives to further support the safe and effective use of medicines and agrees with the principles behind the proposed regulatory changes to labelling and packaging. However, the proposals as they are currently presented need to be tempered with the potential for unintended consequences and knock-on effects in other areas of the National Medicines Policy, such as the cost/affordability of medicines and the viability of the industry *per se*. There are also questions as to whether some of the proposed changes will actually achieve their intended benefit. We have outlined in our submission where we do not agree with the TGA proposals and provided alternative recommendations for consideration.

Please do not hesitate to contact me (mandy.l.cooke@gsk.com) should you require any further information on any of the points made.

Yours sincerely,

Dr Mandy Cooke
Head of Regulatory Affairs & Commercial Quality

CONSULTATION SUBMISSION COVER SHEET

This form accompanies a submission on:

TGA Medicine Labelling and Packaging Review Consultation Paper	
Name and designation:	Dr Mandy Cooke - Head of Regulatory Affairs & Commercial Quality
Company/organisation name and address:	GlaxoSmithKline Australia Pty Ltd (Pharmaceuticals)
Contact phone number:	03 9721 5566
☐ Yes ☒ No	I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*
☐ Yes ☒ No	I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: (*tick all that apply*)

Business in the therapeutics industry (please tick sector):

☒ Prescription Medicines ☐ OTC Medicines

☐ Complementary Medicines ☐ Medical Devices

☐ Blood/Tissues ☐ Other

☐ Sole trader ☒ Business with -1600t employee(s)

☐ Importer ☐ Manufacturer ☐ Supplier ☐ Industry organisation

☐ Government ☐ Researcher ☐ Professional body

☐ Consumer Organisation ☐ Institution *(eg. University, hospital)*

☐ Reg. Affairs Consultant ☐ Laboratory Professional

☐ Healthcare Practitioner - please indicate type of practice

☐ Other (please specify):

If you would like to be kept informed on TGA reform consultation activities, please subscribe to the TGA-UPDATE email list via
http://www.tga.gov.au/newsroom/subscribe-tga-consultations.htm

1) EXECUTIVE SUMMARY - GSK PHARMACEUTICALS POSITION ON LABELLING & PACKAGING CONSULTATION PAPER

This submission is made on behalf of the GlaxoSmithKline (GSK) Pharmaceuticals business in Australia. A separate submission has also been made by our OTC division – GSK Consumer Health. It should be noted that both GSK divisions are aligned on the points made in each submission. We are also in alignment with the comments made by our peak industry association, Medicines Australia, in their submission on this consultation paper.

GSK Pharmaceuticals welcomes viable initiatives to further support the safe and effective use of medicines and agrees with the principles behind the proposed regulatory changes to labelling and packaging. However, the proposals as they are currently presented need to be tempered with the potential for unintended consequences and impacts in other areas of the National Medicines Policy, such as the cost/affordability of medicines and the viability of the industry. There are also questions as to whether some of the proposed changes will actually achieve their intended benefit.

GSK Pharmaceuticals has not provided comments on the following proposals outlined in the consultation paper:

- Dispensing label space GSK Pharmaceuticals agrees with the proposal)
- Small containers (GSK Pharmaceuticals agrees with the comments made by GSK Consumer Health in their submission).
- Pack inserts (GSK Pharmaceuticals agrees with the comments made by GSK Consumer Health in their submission).

GSK Pharmaceuticals has made comments on the following proposals outlined in the consultation paper:

- Size and position of active ingredients on front of label (primary display label)
- Look-alike and sound-alike medicine names and look-alike packaging
- Look alike medicine branding
- Standardised information format: the Medicine Information Box
- Blister strip labelling.

An executive summary of these comments is provided below. GSK is an active participant in the regulatory policy environment. We are committed to providing frank advice on implications of proposed reforms and we welcome the opportunity to provide comment on the proposed labelling and packaging reforms.

Size and position of active ingredients on front of label (primary display label)

- GSK believes that standardizing the location of the active ingredients on the front of pack may aid consumers in locating this information.
- Whilst there is some merit in having both pieces of information (brand name and active ingredients) adjacent to one another, having them of equal size creates clutter and obscures readability.
- How differentiation between the brand name and the active ingredients is achieved should be open to the label designer and should include such possibilities as typefaces, colour and use of upper and lowercase text.
- In relation to the proposal for printing of active ingredients on at least 3 non-opposing faces of a carton, we propose that a more practical approach would be repeating the information as often as space allows, with a mandated minimum of it appearing on the front label and one additional face of the packaging.

Look-alike sound-alike (LASA) names and look-alike (LA) packaging

- A clear system would need to be put in place to aid in determining whether the degree of similarity in names is problematic. Particular focus should be placed on developing a system to adequately assess the consequences of the patient missing the pharmacological action of the intended drug and the pharmacological actions and toxicities of the unintended drug.

Look-alike medicine branding

- GSK urges consideration of an amendment such that companies may be permitted to put forward a health-based risk-benefit argument for retention of existing (and future) look-alike medicine branding on a case-by-case basis.

Standardised information format: the Medicine Information Box

- In principle, GSK Pharmaceuticals agree that the standardised format approach could be acceptable and agree with the proposals from GSK Consumer Health. However, some of the details of how this can be implemented require some further thought
- GSK would also propose that the TGA could consider electronic versions of the Medicine Information Box be made available to patients within pharmacy, as for prescribed products with the CMI

Blister Strip Labelling

- GSK Pharmaceuticals agrees that it is important that the printed blister strip contains the brand name, active ingredients and quantity as well as the batch and expiry date of the medicine.

- In relation to the proposal for printing the active ingredient and brand name on every two blister units - GSK Pharmaceuticals already has the brand and active ingredient name on every two units for most products. However, where there is more than one active ingredient, this starts to become impractical. GSK proposes that where practicable, the brand name and strength of the product should appear over each blister pocket or be oriented centrally across the pack.
- In relation to the proposal for printing the batch and expiry number on every two blister units - these proposed changes have not taken into account the specifics of manufacturing process. Such changes place a considerable financial burden on the manufacturer. The investment required is disproportionate with the costs involved and the perceived consumer safety benefits. More importantly, they are likely to have multiple negative implications for the end users, in terms of increased costs of goods, deceptively increased package sizes and reverting back to bottle packaging of loose pills.

2) INTRODUCTION

GlaxoSmithKline (GSK) is a global research-based pharmaceutical and healthcare company operating in more than 100 countries around the world. Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

Here in Australia we have a proud history dating back to 1886, delivering the highest quality medicines, vaccines and over-the-counter healthcare products. Our contribution to the Australian economy continues to grow in-line with our success, with new approaches to agriculture and manufacturing, and investment in local research and development (R&D).

GSK is sub-divided into a prescription division and a consumer healthcare division. The entire company concurs on the overall merits and issues of the proposals raised within the consultation document. However, given the differences in how prescription and OTC medicines are regulated, labelled and supplied to consumers each division has put in its own response to the consultation document. This submission, therefore, focuses on the proposals and their implications as they relate to the prescription sector of the market.

Our medicines treat major disease areas such as asthma, virus control and infections and we are pioneering new treatments for complex diseases, like melanoma and lupus. Our vaccines protect millions of Australians and we are the largest supplier of childhood vaccines to the *National Immunisation Program*.

We invest around $58 million a year in local R&D, making us one of Australia's top investors in this area and supply $477 million to Australia's pharmaceutical and medicinal exports.

Our scientists work with Australian researchers and doctors to discover new ways of treating and preventing disease and our Medicines Research Unit is the only Phase 1 facility supported by a pharmaceutical company in Australia.

In Australia, GSK has four manufacturing facilities making products for more than 30 different countries. We also supply approximately 25 per cent of global demand for opiate alkaloids, the chemicals derived from poppies and used for pain relief.

We believe that providing patients with equitable access to medicines goes hand-in-hand with advancing our industry. In Australia, our clinical trials and early access schemes give patients access to new medicines, while our clinical partnerships offer access to medicines unavailable in Australia.

Our guiding principles are to: focus on patient needs; respect people; communicate honestly and act with integrity. We provide around 1600 jobs for men and women across Australia and we are particularly proud to be an EOWA *Employer of Choice for Women*.

The pharmaceutical industry is one of the most highly regulated industries in the world. We are committed to bringing safe and effective medicines to patients and working with regulatory agencies to do so. Regulatory reforms, including changes to labelling and packing requirements, is therefore a key issue for our industry and has a material impact on the industry's viability.

Labelling and packaging requirements for pharmaceuticals and healthcare products is a complex and multi-factorial issue and inadequacies in this system can be present at many different stages of the supply chain: from manufacturing, prescription or administration by health care professionals, through to dispensing at the pharmacy level and consumption by the patient.

Reforms to labelling and packaging requirements must be designed with the complexity of this system and the entire supply chain in mind, in close consultation with all affected stakeholders.

Bearing this complexity in mind, the following submission makes a number of comments on the proposed recommendations outlined in the *Labelling and Packaging Review* released by the Therapeutic Goods Administration (TGA) in May 2012.

GSK supports reforms to make labelling and packaging requirements more efficient, transparent and nationally consistent. This is in line with numerous Government reviews and reports[1-4] which cite the need for Government to adopt smarter approaches to regulation and reduce unnecessary regulatory burdens on business.

In relation to TGA labelling and packaging requirements, we encourage the Government to ensure that changes to these regulatory systems strike the right balance between reducing the potential for patient misadventure and addressing safety concerns, whilst not unduly increasing the regulatory and cost burden on industry.

One major area of clarification regarding the implementation of any changes to packaging and labelling is whether these changes will only be applied to new packaging or to all packaging retrospectively.

On the one hand if they are to be applied retrospectively, then this would be a significant and costly undertaking for both the TGA and industry. However, if the new regulations are to apply only to new medicines, this could introduce unfair and anti-competitive regulations into the system.

Both these scenarios will require further consultation in order to determine the right course of action. Importantly, in either scenario, fair transition arrangements for manufacturers and clear communication to the pharmaceutical supply chain, dispensers, clinicians and patients will be required.

Both independently and through Medicines Australia, we are fully committed to continuing to work with the TGA and other stakeholders to ensure that reforms to labelling and packaging requirements in Australia are nationally consistent, reasonable and of real and lasting benefit to patients.

3) A NOTE ON THE USE OF SERIALISATION TO REDUCE DISPENSING ERRORS

GSK is currently working with global agencies to adopt serialisation technology within the next 4 years. The use of serialisation codes on packs would also have a significant impact on reduction of potential dispensing errors and therefore should be considered by the TGA in regards to the current proposals.

Serialisation involves the manufacturer printing a machine readable code, similar to a barcode, on each individual pack. This code is stored on a database along with other information about the item (eg. manufacturer, batch info etc). Items can then be scanned and verified against the database using the unique identifier for authenticity and/or can then be traced throughout the supply chain using the unique identifier or at a specific point (eg. at the dispensing point).

Further information on serialisation codes can be found on the EFPIA (European Federation of Pharmaceutical Industries and Associations) website: http://www.efpia.eu/serialisation.

The use of serialisation codes would reduce medication errors by introducing bedside verification of medications using a standardized point of care system at point of dispensing.

4) SPECIFIC GSK RESPONSES TO THE RECOMMENDATIONS

a) Prominence of active ingredients on medicine labels

GSK agrees with the overall proposal to ensure that the active ingredient has prominence on medicine labels. However, GSK does not believe that the detailed proposals of how this should be done may always be appropriate.

Care needs to be taken to improve the clarity of labelling to patients, pharmacists and healthcare practitioners. If the font size is equal size to the brand name, this could result in overcrowded labels – particularly for products containing multiple active ingredients or for those with very long active ingredient names (such as vaccines).

The European Commission guidelines on the readability of labelling and package leaflets of medicinal products suggest a minimum usability level of 81%. This means that any user should be able to find 90% of what they are looking for and then understand 90% of what they find (90x90=81%)[5]. Research undertaken in Europe has shown that consumers could find over 90% of answers in a package insert irrespective of the font size (fonts ranged from 7pt to 16pt)[6]. In this study, other factors were found to influence readability — use of simple language, avoiding abbreviations, long sentences and repetition, use of different font colours.

Recent revisions have been made to labelling regulations in both the EU and the USA; neither of these explicitly recommends that the active ingredients should be the same size font as the brand name. Although the US legislation does not require the ingredient name to be adjacent to the brand name, it specifies that the ingredient name be[7]:

- At least one-quarter as large as the size of the most prominent matter on the primary display label; or
- At least as large as the size of the “Drugs facts” title (which should be no smaller than 8 pt type size).

European requirements also provide considerably more flexibility in regards to prominence of active ingredient as proposed in the recent consultation paper[8]:

- The active substance(s) should appear on the front of the pack in the same field of vision as the name of the medicine.

- Where the medicine contains up to three active ingredients, the common names of these active ingredients should immediately follow the name of the medicine on the pack, unless these are part of the name. There should be no intervening text of any kind.
- Prominence should be given to active substance(s) through the choice of type size, font type or emboldening.

Overview of comments from GSK Pharmaceuticals:

GSK believes that standardizing the location of the active ingredients on the front of pack may aid consumers in locating this information.

Whilst there is some merit in having both pieces of information (brand name and active ingredients) adjacent to one another, having them of equal size creates clutter and obscures readability.

GSK Pharmaceuticals does not agree with the proposal that the active ingredient should begin with an uppercase letter but the remainder should be in lower case.

- GSK is unclear why this proposal would be helpful in differentiating active and brand names. This goes against international naming conventions and has the potential to cause further confusion amongst patients
- This recommendation could not be applied to some active ingredients in vaccines - where upper and lower case letters denote important features and longstanding nomenclature of the active ingredient. For example 'dTPa'.

How differentiation between the brand name and the active ingredients is achieved should be open to the label designer and should include such possibilities as typefaces, colour and use of upper and lowercase text.

GSK Pharmaceuticals would propose that a similar approach to that taken in Europe[8] would be more appropriate:

- The active substance(s) should appear on the front of the pack in the same field of vision as the name of the medicine
- Prominence should be given to active substance(s) through the choice of type size, font type or emboldening

In relation to the proposal for printing of active ingredients on at least 3 non-opposing faces of a carton – GSK proposes that a more practical approach would be repeating the information as often as space allows, with a mandated minimum of it appearing on the front label and one additional face of the packaging.

b) Active ingredients on at least 3 non-opposing faces of a carton

The proposal (1.5) states that the active ingredients and the brand name should be imprinted on 3 non-opposing faces of the carton and should be of equal proportion. We have discussed the issue of equal proportion above; having both pieces of information in the same size will not necessarily improve legibility of this information. Where this information is to be provided, a disparity in the proportion of the font size used should be provided for. Furthermore, in the case of small labels this requirement could force critical information onto a leaflet.

Overview of comments from GSK:

GSK believes that standardizing the location of the active ingredients next to the brand name may aid consumers in locating this information.

GSK proposes that some flexibility be allowed to accommodate products with more than one active ingredient and products supplied in small packages. This could be achieved by repeating the information as often as space allows, with a mandated minimum of it appearing on the front label and one additional face of the packaging.

c) Look-alike sound-alike (LASA) names and look-alike (LA) packaging

The existence of confusing drug names is considered one of the leading causes of medication errors. The proposed changes provide a reasonable starting point from which LASA names and LA packaging can be monitored and improved moving forward. These proposals focus primarily on applications for new medicines. There is a potential to automate screening to identify proposed names that are orthographically and/or phonetically similar to existing medicines, as implemented by US FDA.[9]

The assessment criteria to be applied are not clear. With a view to transparency and providing industry with a means of anticipating the risk levels of proposed names, the TGA should seek to ensure scientific validation and reproducibility of the proposed assessment methods for predicting the risks of confusion between different brand names.

The proposals do not address the issue of the currently available products with LASA names and LA packaging. Other risk reduction strategies will be required to address this. Several workflow practices and technological solutions have been recently proposed in the literature and include font variation (including Tallman lettering), physical alerts, and automated alerts in dispensing software, barcode scanning and improved methods of reporting errors. If serialisation codes were introduced, scanning of these at point of dispense would significantly reduce the risk of potential dispensing errors.[9]

For existing medicines an arbitrary cut-off point for LASA brand names has defined as brand names that differ by less than three letters. No rationale has been provided for this definition. The Institute for Safe Medication Practices (ISMP) has compiled an eight-page list of look-alike, sound-alike pairs involved in errors reported to its National Medication Errors Reporting Program. Not all of these medicines would be identified if the proposed "less than 3 letters difference" criteria came into play. Indeed, amongst the medicines in a list of examples of LASA drug names identified in a recent Australian review, some (e.g. Diflucan and Diprvan) did not meet this criterion.[9] A better definition might be "Products that have a similar written name or similar phonetics to those of another health product".

It has been suggested that a checklist be determined to guide industry for assessment of LASA names. A clear system would need to be put in place to aid in determining whether the degree of similarity in names is problematic. Contributor factors could include the marketing status (Rx or OTC), therapeutic category, indication(s) and directions for use, the clinical setting for dispensing or use, the packaging and labelling, posology, the proposed dose and dosing interval.

Overview of comments from GSK Pharmaceuticals:

- A clear system would need to be put in place to aid in determining whether the degree of similarity in names is problematic. Particular focus should be placed on developing a system to adequately assess the consequences of the patient missing the pharmacological action of the intended drug and the pharmacological actions and toxicities of the unintended drug.

GSK Pharmaceutical proposals:

- GSK does not agree with the proposal for names differing by no more than 3 letters. Instead, a more appropriate guide would be -"Products that have a similar written name or similar phonetics to those of another health product".
- Many of these proposals would be extremely difficult for sponsors to comply with and should not be necessary if other improvements to labelling are made.
- There is already a system used by the TGA for checking names. We recommend that the TGA works with sponsors and the wider industry to make this system more effective, including providing clear guidelines so that industry can develop appropriate brand names.
- GSK Pharmaceuticals would also strongly recommend consideration of introduction of serialisation codes or at least barcode scanning at point of dispensing.
- It is unclear how a risk assessment on the name and look of a pack can be conducted nor who or what the risk assessment would be addressing. A risk assessment for potential patient error for example, would be quite different to a risk assessment for potential pharmacist or doctor error. Further work is required to make this recommendation more specific.

d) Look-alike medicine branding

GSK Pharmaceuticals agree with the comments and proposals put forward by GSK Consumer Health:

Brands are a principal asset for the development and promotion of self-care. The value of brands is well recognised and their use results in a strong interest from the manufacturers' side in preserving the goodwill adhering to a product and, consequently, maintaining a high level of quality. Experience shows that umbrella brands are valuable asset for companies. Confidence in OTC products is enhanced and, within an umbrella range, all products are endowed with a quality seal. There is no evidence to suggest that this causes any substantial consumer confusion or risk to public health.

With specific regard to OTC medicines, there are no safety data to substantiate that confusion is enhanced by the use of umbrella brand names provided the products are appropriately labelled and sufficient consumer information is made available. Equally, there is no evidence to date that the manufacturers' freedom to choose a particular brand name jeopardises the safety of the patient in the correct use of medicines. As such, the benefits of the proposed changes are likely to have minimal if any impact on consumer safety. Further, within the OTC setting in particular, confusion risk mitigated or diminished by number of features, including the form of the product, basic pack design, pack colour, use of prefixes, suffixes, sub-brands and adequate labelling.

It is not clear from the information provided how these proposed changes will be implemented and how currently available products will be reviewed, identified and amended. Any changes should first be reviewed and specific categories stratified by risk, with all brands within a low risk categories (e.g. sensitivity toothpastes) being exempted. In determining the suitability and risk-benefit of umbrella branding for other categories due consideration of the negative impact must also be assessed.

GSK urges consideration of an amendment such that Companies may be permitted to put forward a health -based risk-benefit argument for retention of existing (and future) look-alike medicine branding on a case-by-case basis.

The proposals for look-alike medicine branding seek to improve consumer safety. However, there are no safety data to substantiate that confusion is enhanced by the use of umbrella brand names provided the products are appropriately labelled and sufficient consumer information is made available.

Overview of comments from GSK Pharmaceuticals:

- *GSK urges consideration of an amendment such that Companies may be permitted to put forward a health -based risk-benefit argument for retention of existing (and future) look-alike medicine branding on a case-by-case basis.*
- In relation to the proposals on "Umbrella" branding, GSK Pharmaceuticals believe that a more appropriate approach would be to pursue similar regulatory requirements that are practiced in the UK,[10] namely:

  An umbrella segment of an invented name is a section of invented name that is used in more than one medicinal name to create a brand or range of products. Where an umbrella segment is proposed to be used for more than one product, the umbrella segment should not be used if its use is likely to result in safety or efficacy concerns resulting from confusion between the products sharing the same umbrella segment
- The TGA recommendations as they currently stand would have a significant impact on brand equity and would have very high implementation costs for industry. Further consultation and discussion on the implications of these reforms are required before changes are instigated, to ensure the correct balance between patient safety and industry compliance with the new arrangements.
- Clarification is also required on whether this recommendation relates to vaccines. As with Recommendation 1, if the purpose of these proposals is to reduce patient confusion, then we would seek an exemption for vaccines as they are only administered by healthcare practitioners. Furthermore, as Vaccines are recommended for use as part of a National Immunisation Program, there is specific training and education of HCPs in place precisely to minimise incorrect use of Vaccines and any potential confusion amongst different vaccines.

e) Standardised Information Format: the Medicine Information Box

GSK Pharmaceuticals agrees with the comments and proposals put forward by GSK Consumer Health:

The proposal to standardize the back of the pack to contain a "Medicine Information Box" represents a reasonable proposal that will greatly aid consumers when locating information on the label. Such standardization presents the information in a uniform

manner, uses simple to read language and an easy to use format that enables consumers to compare and select OTC medicines and follow the required dosage instructions.

Research conducted to assess the US "Drugs Facts" box suggests that formatting can improve the ease of acquiring important information from a drug label[7]. One of the main reasons is that the standardized label format allows consumers to learn where each of the sections are located which in turn reduced the time needed to find specific information. Other advantages include the use of horizontal lines to separate information under each major heading and use of a bullet point format to list chunks of information.

Notwithstanding this, recent data from the US demonstrates that individuals with low health literacy continue to struggle to read labels; in a recent study nationally representative study of more than 6100 parents 59.2% reported difficulty with understanding OTC medication labels and subjects with below-basic health literacy were 3.4 times more likely to struggle[8]. In addition, US data presented by the TGA in support of specific warning labels for paracetamol products shows that despite the "drugs facts" box having been mandated for almost 15 years only 6% of participants were able to correctly identify the active ingredients in 5 common OTC pain relievers[9].

Overview of comments from GSK Pharmaceuticals:

In principle, GSK Pharmaceuticals agree that the standardised format approach could be acceptable and agree with the proposals from GSK Consumer Health. However, some of the details of how this can be implemented require some further thought.

Specific comments from GSK Pharmaceuticals:

- These proposals would have implications for Schedule 3 (S3) products, given there is a spacing requirement on S3 products for labels and additional changes outlined in Recommendation 1. Furthermore, there is already a requirement for S3 products to have a Consumer Medicine Information (CMI) leaflet, which contains the same information as that proposed in the Medicine Information Box.

- The TGA should consider electronic versions of the Medicine Information Box, which could be made available to patients within the pharmacy, as is currently the practice for prescribed products using the CMI.

f) Blister Strip Labelling

GSK Pharmaceuticals agrees that it is important that the printed blister strip contains the brand name, active ingredients and strength as well as the batch and expiry date of the medicine. However, proposal 6.1 stipulates that this information must appear at least once every two units.

Printing of Active Ingredient and Brand Name

GSK Pharmaceuticals already print the brand and active ingredient name on every two units for most products. However, where there is more than one active ingredient, this starts to become impractical. GSK Pharmaceuticals proposes that where practicable, the brand name and strength of the product should appear over each blister pocket or be oriented centrally across the pack.

Printing of Batch and Expiry Number

It is usual practice for the foil covering used in the manufacture of blister packs to be pre-printed in bulk with the brand and active ingredient details. The batch number and expiry date information are then printed (or in some cases embossed) onto the blister packs after the doses have been inserted. The current practice is to include this information once per blister strip.

Whilst sourcing a manufacturing plant capable of printing multiple batch and expiry information on a single blister strip is not an impossible task, it presents many practical barriers that would considerably slow production and increase costs. Some manufacturers may have access to such equipment, however it may not be practical to use for all lines.

GSK Pharmaceuticals has investigated the feasibility and costing of doing this which has revealed some significant issues and cost barriers.

Feasibility investigation of implementing inclusion of batch/expiry number on every 2 units

Using current technology, there are a number of ways to apply the additional batch and expiry dates, all requiring a considerable amount of capital, validation, time on-line and trial material costs. In addition, some of these will also result in an increase in blister size, and subsequently pack size, incurring further technical and regulatory burden.

Option 1 Embossing

This method relies on the addition of extra embossing windows to ensure batch and expiry are repeated at least once every two units. To implement this, manufacturing sites will have to purchase a new set of tooling for all Australian products with the exception of the blisters that have 2 tablets.

Due to the extra space required for embossing windows and to ensure that blister seal integrity is not compromised the blister size will have to increase. New artwork will be required for blisters and cartons. This has a flow on effect of increasing the pack size and the number of pallets used per product by 33%.

As well as an increase in cost of goods for the increase in the amount of materials used. The time taken to set up each batch will also increase as the number of batch and expiry repeats can increase by up to 8 times.

[New tooling, time on line, validation and cost of trial materials has been estimated to cost approx. $4,000,000 for GSK Australia. This will also impact the number of tooling changeovers resulting in an increase in labour costs associated with implementation.]

Option 2 Inkjet Printing

Inkjet print heads can be installed on the blister packers and the batch and expiry repeats can be printed on. There are a number of issues associated with this method:

- Problematic due to number of print heads required for each blister in terms of physically fitting them on the lines, and the difficulty in setting them up and keeping them in register.
- Constraints due to the solvent used by the inkjet printers (MEK has OHS issues).
- Cost of installation of a print verification unit for the inkjet printers
- New artwork would have to be create for every blister pack at considerable resource and cost

[In order to implement this option, GSK would estimate an approximate cost of over $1,500,000 due to time on line, validation, cost of trial materials and units for all lines that pack.]

Option 3 Laser printing

This method combines both option 1 and option 2 as blister will need to increase in size due to the window required for the laser printing, which needs to be away from pockets to ensure laser does not burn through the blister and compromise seal integrity. Laser units are also required to be mounted on line and have print verification.

[As a result of this the approximate implementation cost for GSK would be around $5,500,000.]

Option 4 HAPA Combination unit

This is a combination HAPA mat printer and a HAPA digital unit which will be required for every line that packs Australian product. The HAPA mat can print the artwork and the digital unit can print the batch and expiry details. This will require new artwork for the blister and a system to control the input of the variable data, as well as a print verification unit.

[The cost of installing the HAPA units, validation, time on line, and material costs is estimated to be over $1,500,000 for GSK Australia.]

Overview of comments from GSK Pharmaceuticals:

GSK Pharmaceuticals agrees that it is important that the printed blister strip contains the brand name, active ingredients and quantity as well as the batch and expiry date of the medicine. However, proposal 6.1 stipulates that this information must appear at least once every two units.

Printing of Active Ingredient and Brand Name

GSK Pharmaceuticals already print the brand and active ingredient name on every two units for most products. However, where there is more than one active ingredient, this starts to become impractical. GSK proposes that where practicable, the brand name and strength of the product should appear over each blister pocket or be oriented centrally across the pack.

Printing of Batch and Expiry Number

GSK Pharmaceuticals specific comments:

- If these proposals were adopted, GSK has calculated that the implementation costs would be between $1500 000 and $5 500 000 (some of this would be a one off cost but some ongoing additional cost would also be incurred due to increased time on lines and changeover times).
- The proposed changes to the blister strip have not taken into account the specifics of manufacturing process. Such changes place a considerable financial burden on the manufacturer. The investment required is disproportionate with the costs involved and the perceived consumer safety benefits. More importantly, they are likely to have multiple negative implications for the end users, in terms of increased costs of goods, deceptively increased package sizes and reverting to back to bottle packaging of loose pills.

- GSK would therefore propose that the TGA adopt a similar approach to that taken in the UK Best Practice Guideline on Packaging and Labelling[11]
  - Where practicable, the name and strength of the product should appear over each blister pocket or be oriented centrally across the pack.
  - In all cases it will be acceptable to apply the batch number and expiry date to the end of the blister strip. If technically possible this could be applied to both ends of each strip.
  - For blister pack presentations it is important that the particulars remain available to the user up to the point at which the last dose is removed. Often it will not be possible to apply all the information over each blister pocket, consequently where a random display of the information is proposed it should frequently appear across the pack.

5. References

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