



**Hazardous
Substances**

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TĀIAO



Issue of a New Group Standard:

**Pharmaceutical Active Ingredients Group Standard
2010**

**Environmental Risk Management Authority -
Assessment of Matters to be Considered**

2nd Consultation

July 2010

Table of Contents

TABLE OF CONTENTS	2
BACKGROUND	3
THE PROPOSED GROUP STANDARD	3
OPTIONS FOR THE NEW GROUP STANDARD	4
NOTIFICATION REQUIREMENTS	4
ASSESSMENT OF THE MATTERS REQUIRED UNDER SECTION 96C(1)(A), (B), (C), (D) AND (E) OF THE HSNO ACT	6
THE NEXT STEPS	15
MAKING A SUBMISSION	17

Background

ERMA New Zealand wishes to consult on its assessment of the matters that are required to be considered before issuing or amending a group standard.

On 1 February 2010, ERMA received an application to issue a new group standard for active ingredients used in the manufacture of human pharmaceuticals. Further details of the proposed group standard are provided in the following section.

In accordance with section 96C(1)(h)(i) of the Hazardous Substances and New Organisms Act 1996 (the Act), the application to issue a new group standard was publically notified on ERMA New Zealand's website and in the four main metropolitan newspapers on 22 January 2010.

Various government departments, Crown entities and interested parties, which in the opinion of the Authority would be likely to have an interest in the application, were notified of the receipt of the application and provided with an opportunity to comment or make a public submission on the application.

Submissions closed on 15 March 2010. One submission was received and the submitter did not wish to be heard. The Agency prepared a consideration paper to aid the Authority in its decision making process. This consideration paper contained a Summary of the Submissions received. The consideration paper and proposed group standard document are available at:

<http://www.ermanz.govt.nz/find/WebResults.aspx?search=hsr08030> .

Consideration of the proposal to issue a new group standard for pharmaceutical active ingredients was held on 2 June 2010.

In accordance with section 96C(1)(h)(ii) of the Act, it is now necessary to undertake further consultation on the Authority's assessment of the matters required under subsection (1)(a), (b), (c), (d) and (e) in relation to the proposed new group standard.

The Proposed Group Standard

A new group standard has been proposed by Douglas Pharmaceuticals Limited ("the applicant").

It is proposed that the scope of the group standard be restricted to active ingredients for use in medicines that have been approved by Medsafe when intended for the New Zealand market; or another equivalent governmental regulatory body (i.e. USA, European Union, Japan, and Australia) when manufactured solely for the export market.

It is proposed that the definition of Pharmaceutical Active Ingredient should include both single component chemicals and formulated products containing a pharmaceutically active chemical, where that formulated product is used in the manufacture of a human pharmaceutical product as if it were a single component pharmaceutical active ingredient.

The scope of the proposed group standard includes ingredients with the following hazard classifications:

- Flammable Liquids: HSNO 3.1B, 3.1C, or 3.1D;
- Flammable Solids: HSNO 4.1.1B;
- Oxidising Liquids or Solids: HSNO 5.1.1C;
- Toxic Solids or Liquids: HSNO 6 (All sub classifications);
- Corrosive Solids or Liquids: HSNO 8 (All sub classifications);
- Ecotoxic Solids or Liquids: HSNO 9 (All sub classifications).

The applicant believes that issuing a group standard for pharmaceutical active ingredients meets the requirements of the Act, in terms of providing a more efficient and effective way of managing the risks of these substances, and that the circumstances of use for these substances are similar, allowing one set of conditions to manage the risks of the substances despite a broad range of hazard classifications being covered by the group standard scope. This consideration paper contains the assessment carried out by ERMA New Zealand staff (“the Agency”) of these matters, and those required by the Act.

Options for the new group standard

One submission was received, from Nuplex Industries (Aust) Pty Ltd (Appendix 2), in favour of the proposal to issue a group standard for pharmaceutical active ingredients. The submitter requested that the scope of the group standard be expanded to include veterinary active ingredients.

The Authority considers that such an expansion in scope would be a significant deviation from the applicant’s intent when this new group standard was proposed, and would broaden the scope of the proposed group standard, and require further consultation. The applicant considers that the scope of the group standard should remain as proposed, on the basis that the submitter’s proposal “will widen the proposed Group Standard significantly outside what was proposed and justified. The submitter suggests veterinary pharmaceuticals and human pharmaceuticals are subject to similar regulatory requirements. While on surface the regulations are similar there are substantial differences in the details of the regulations particularly as they are regulated under different acts by different regulatory bodies”.

Notification Requirements

Notification of the Authority’s Assessment of the Matters required under section 96C(1)(a), (b), (c), (d) and (e) of the Act

Section 96C(1)(h) of the Act states that:

Before issuing or amending group standards under section 96(B), the Authority must,-

(h) in accordance with section 53, publically notify—

(i) the proposal to issue or amend (as the case may be) group standards; and

- (ii) *its assessment of the matters required under subsection (1)(a), (b), (c), (d) and (e) in relation to the group standards as proposed to be issued or amended.*

The requirements of section 96C(1)(h)(i) were addressed by the public notification of the proposal on 22 January 2010. The notification of the proposal met all the requirements of sections 53 to 61 of the Act.

The requirements of section 96C(1)(h)(ii) are yet to be addressed. This consultation document and the consultation process that will follow will address these requirements.

Public notification of the assessment is achieved by:

1. by placing a public notice in the four main metropolitan newspapers; and
2. providing information on the ERMA New Zealand website, including the date for receipt of submissions by the Authority.

In accordance with section 54 of the Act, any person may make a written submission on the application, which includes the Authority's assessment of the amendment. Section 54(2) of the Act requires that a submission:

- (a) *shall state the reasons for making the submission;*
- (b) *may state any decision sought; and*
- (c) *shall state whether the person making the submission wishes to be heard.*

Assessment of the Matters required under section 96C(1)(a), (b), (c), (d) and (e) of the Act

Matters to be considered by the Authority

Before a group standard can be issued or amended, the Authority must be satisfied that:

1. the group standard is a more efficient and effective way of managing the risks of all the substances in the group; and
2. all the substances or products in the group standard have a similar nature, are of a similar type, or have a similar circumstance of use, such that the risks of the substances or products can be effectively managed by one set of conditions.

The Authority's assessment of these matters is considered in the following sections:

Efficiency and Effectiveness

Before issuing the group standard, sections 96C(1)(a), (b) and (c) of the Act require the Authority to be satisfied that:

issuing the group standard is a more efficient and effective way of managing the risks of all the hazardous substances in the identified group

The applicant has provided the following information regarding the likely efficiency and effectiveness of the proposed group standard:

Regulatory Efficiency

- (a) The group standard approval will reduce potential delays for commercialisation of products and potential market loss associated with tight launch timing and international competition for markets.*
- (b) The group standard will reduce time and resource making individual applications should the medicine development project fail just prior to manufacture for commercial sale.*
- (c) Reduced legislative costs and lost time associated with individual applications for both ERMA New Zealand and the company developing commercial product, where similar products are effectively controlled utilising the controls proposed in the Group Standard.*
- (d) Reduction in duplication in effort assessing and approving pharmaceutical ingredients (used in producing pharmaceutical products) between ERMA New Zealand and Medsafe (or other recognised regulatory body).*
- (e) This streamlined procedure will promote growth of high tech, high value added products that could be supplied domestically or exported to the international markets with significant returns for the New Zealand economy.*
- (f) The conditions require Medsafe or a recognised international equivalent regulatory body (i.e. in Europe by the European Medicines Agency, in Australia by the Therapeutic*

Goods Administration, in Japan by the Pharmaceutical and Food Safety Bureau (PFSB) or the United States by the Food and Drug Administration (US FDA)) to have completed thorough investigation regarding the safety of the medicine and its components, and its method of manufacture prior to being approved for use and included in the official pharmacopeia:

- *The New Zealand Regulatory Guidelines for Medicines, 6th Edition, November 2008, parts A-E provided by Medsafe prescribes the requirements for application for approval to sell a medicine in New Zealand. The necessary toxicological information to ensure a pharmaceutical ingredient meets the Pharmaceutical Ingredients Group Standard would be collected as part of the pre-clinical data set.*

- *Part C of The New Zealand Regulatory Guidelines for Medicines (Requirements for application types, section 2) defines the formats for new medicine applications which comprises two sections. Section one is the administrative section and section two is the dossier of supporting data to establish the quality, safety and efficacy of the product [2.1.1]. This supporting data includes pre-clinical and toxicology documentation.*
 - (i) *The NZ guideline states the preferred format for the dossier is either the International Conference on Harmonization (ICH) format or the European Community (EC) Format.*

 - (ii) *The ICH format is modular, where module 4 covers non-clinical study reports, including pharmacological, pharmacokinetic and toxicological data sets. These data sets will provide the necessary information to accurately assign class 6 (Toxic) and potential class 8 (Corrosive) hazards. These pre-clinical data set tests are conducted on the active component, rather than finished form pharmaceutical product.*

 - (iii) *The EC format requires similar data sets to establish safety prior to initiating clinical studies on healthy human volunteers.*

 - (iv) *The pharmacological data identifies the dose-response curves in humans and is used to identify the therapeutic range. Typically the therapeutic range is lower compared with animal lethal doses, and is established from the pre-clinical animal studies.*

 - (v) *Repeat-dose and chronic toxicity tests are conducted, again developing the data set necessary to confirm suitability for inclusion in the Pharmaceutical Ingredients Group Standard.*

- *Ecotoxicity, while not specifically mentioned in the Medsafe guideline, is addressed by requirements of both the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) that require Medicinal Product Environmental Risk Assessments for all new medicines. While these assessments focus on the fate of medicines following treatment in the human population, it*

does require the necessary data set for HSNO class 9 classification to be developed throughout the pre-clinical (animal in-vivo and in-vitro tests) and clinical trials (Healthy human volunteers), prior to commercialisation of the medicinal product. It is highly unlikely that a medicine developed in New Zealand would not also be made available for either of these two major markets, ensuring the relevant data would be available.

Compliance

- (g) This group standard should achieve an effective compliance rate because the information on what is required to manage the substances in the group is in one, easy-to-access document with more user-friendly language and prescriptive elements. This should lead to a greater level of understanding; thereby encourage compliance, particularly by small to medium sized enterprises.*
- (h) The conditions included in this group standard would meet the requirements set out under an individual application and will effectively manage the risks associated with each class of chemical hazard.*
- (i) The set of conditions used to manage the risks of the pharmaceutical ingredients group standard are primarily drawn from the HSNO Control Regulations. These controls are presented with a greater level of guidance and in a simplified format. That is, information is expressed in a more direct, user-friendly way than in the regulations, which allows for a variety of alternate means of compliance. This will ensure a predictable regulatory outcome, which also facilitates innovation.*
- (j) The manufacturer of a novel pharmaceutical active ingredient would have the responsibility under international transport legislation to conduct the necessary assessments to establish if the substance was dangerous for transport, whether this assessment is based on chemical and structural reviews, or when necessary based on established threshold tests. The result of this transportation legislation assessment would ensure data is available for dangerous goods properties included in the Pharmaceutical Ingredients Group Standard.*

Costs

- (k) The applicant has demonstrated increased efficiency in processing costs, based on expected numbers of applications that will be required annually. The applicant expects that the application cost savings will be realized in the first year after issuing of the proposed group standard, with significant savings projected for following years for the applicant's organisation. Other industry members could expect to see approval cost savings through the establishment of the proposed group standard. The applicant also suggests that, through a reduction in application processing arising from the issuing of this group standard, ERMA New Zealand could expect efficiency and cost benefits.*

The Authority considers that, when assessed against alternative HSNO approval processes for hazardous substances, group standards are a more effective way of managing the risks of a group of substances having a similar nature, type or circumstance of use, in particular for Pharmaceutical Active Ingredients not included in the “transfer of NOTS”¹. The compliance and risk management

¹ Prior to the Hazardous Substances and New Organisms (HSNO) Act 1996, toxic substances were regulated by the Toxic

framework that will be in place after a group standard has been issued will be consistent with that for new approvals under Part 5 or individual transfers under Part 160A of the Act as the conditions that will apply are largely drawn from the suite of regulations that would apply to Part 5 approvals or individually transferred substances.

The Authority considers that, based on the reasoning put forward by the applicant, the proposed group standard will provide a mechanism for the effective and efficient approval of pharmaceutical active ingredients for use in the manufacture of human medicines.

Similar Circumstance of Use

The substances (pharmaceutical active ingredients) have been grouped on the basis of a similar circumstance of use, in accordance with the requirements of Part 6A of the Act for establishing a group standard.

The applicant has provided the following information regarding the similar circumstances of use of the substances to be covered by the proposed group standard:

- (a) All the hazardous substances covered by this group standard have similar circumstance of use, which is inclusion as an ingredient of a pharmaceutical product, with an active function, where manufacture of the human pharmaceutical product will be conducted in a licensed and regularly inspected facility following strict procedural controls.*
- (b) Use of all pharmaceutical active ingredients covered by the proposed groups standard will only be used in a facility that holds a current Medsafe Licence to Manufacture Medicines, Such facilities will adhere to Good Manufacturing Practice (GMP) conditions to provide the organisational framework to effectively manage the risks associated with the substances throughout their lifecycles, providing a mechanism to meet the conditions of aspects of the proposed Pharmaceutical Active Ingredients Group Standard. Medsafe licences require companies manufacturing human medicines to have a system and facility that achieves current GMP. The GMP rating ensures components of an effective chemical management systems exist, and evidence to show established procedures are followed. The Medsafe licence provides endorsements appropriate to the level of risk posed by ingredient e.g. highly potent ingredients require a class “e” endorsement.*

The Authority notes that the proposed group standard has been developed using existing group standard conditions for the relevant hazardous properties, consistent with the management of existing and new hazardous substances under Part 5 of the Act, the transfer of existing substances under Part 160A of the Act, and the United Nations Model Regulations for the Transportation of Dangerous Goods. Approval under the proposed group standard would allow substances which may have a range of hazardous properties to be grouped based on their circumstance of use. Some of the hazardous properties will require more stringent conditions to apply to the substance than other hazardous substances, and the requirements to meet certain conditions may be met by meeting the requirements necessary to adhere to the more stringent controls.

Substances Act 1979. Section 32 of the Toxic Substances Act required any person who intended to import or manufacture a toxic substance to notify the formulation of the substance. These became known as NOTS (notified toxic substances). Although the formulated medicines were exempt from needing a HSNO approval, the active ingredients in medicines manufactured in New Zealand need a HSNO approval, and only those active ingredients which were notified were given such an approval.

Overall, the Authority considers that substances meeting the requirements of the scope of the proposed group standard can be considered to be of a *similar circumstance of use*, and that the proposed group standard contains a single set of conditions that will provide a mechanism to manage the risks associated throughout the lifecycle of substances that fulfill the requirements of the scope of the proposed group standard.

The Authority notes that substances that are extremely acutely toxic (6.1A) or extremely corrosive to skin (8.2A) do not fall within the scope of any existing group standards. The Agency considers that the conditions proposed in this group standard are equivalent to those applied to 6.1A or 8.2A substances included in the Hazardous Substances (Chemicals) Transfer Notice (*New Zealand Gazette* Issue No. 72, 28 June 2006). In addition, the restriction on use of such substances to pharmaceutical manufacturing sites will ensure that these substances will only be used in environments with personnel trained and equipped to safely handle them.

Best International Practices and Standards

Before issuing or amending a group standard, section 96C(1)(f) of the Act requires that the Authority consider:

the best international practices and standards for the safe management of hazardous substances and products

To meet this requirement to consider best international practices and standards for the safe management of hazardous substances, the Authority has assessed the proposed group standard against:

- The Globally Harmonised System of Classification and Labelling of Chemicals;
- International codes of practice and standards; and
- Overseas legislative requirements.

Globally Harmonised System

The conditions applied to the group standard covered by this application are based on the HSNO Controls Regulations for managing physical and biological hazards, and the lifecycle control regulations, including those for information, disposal, and emergency management. These regulations meet the requirements of section 141(1)(b) of the Act on best international practices and standards for the safe management of hazardous substances. In particular, the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), published by the United Nations, has formed the basis of the HSNO hazard classification system and the requirements for the provision of information on hazards.

Consideration has also been given to the Recommendations of the Transport of Dangerous Goods Model Regulations, also published by the United Nations. For example, this group standard adopts directly the packaging provisions of the UN Model Regulations, and similarly they provide for compliance with the labelling provisions via compliance with the GHS.

International Codes of Practice and Standards

Some conditions specifically related to particular group standards draw on international standards or codes of practice of relevance to the industry to which the particular group standards relate. For example, in managing a flammability hazard, the conditions allow compliance with an Australian Standard for the establishment of a hazardous atmosphere zone.

The transportation conditions of the group standard requiring the segregation of incompatible substances cross-references to the requirements of the Land Transport Rule, the Maritime Rule and the Civil Aviation Rule, which are based on the international UN Transport of Dangerous Goods Model Regulations, the International Maritime Dangerous Goods Code and the International Civil Aviation Organization Regulations.

The applicant has provided the following information the proposed group standard's alignment with Best International Practices and Standards:

- ***Good Manufacturing Practice (GMP)***
 - (a) *It is proposed that use of these substances under the conditions of this group standard will be in accordance with GMP practice, and, as such, the premises are secure and public access is prohibited. Key access (e.g. swipe cards and Personal Identification Numbers) are the usual methods to control access of authorised personnel within such facilities).*
 - (b) *GMP Supply chain management requires full tracking of all chemicals used in the manufacture of medicines, and includes controlled disposal of rejected raw materials at the end of their medicinal life.*
 - (c) *GMP is established by international expert working groups including the International Conference of Harmonisation (ICH). The ICH provides guidance documentation developed in consultation with regulatory parties, the Pharmaceutical Inspection Convention (PIC), and Pharmaceutical Inspection Co-operation Scheme (PIC/S). This is recognised in the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods GMP.*
 - (d) *Adherence to the principles of GMP by a holder of a cGMP licence is audited by governmental bodies and clients for the markets in which the product is sold. GMP auditors utilise the guidelines established by the above mentioned international expert groups when conducting GMP audits. As the guidelines are subject to constant improvement processes, international best practice ensures continuous improvement occurs in all areas of pharmaceutical manufacture including the storage, use and disposal of pharmaceutical ingredients*
- ***Pharmaceutical Inspection Convention and Co-operation Scheme (PIC/S)***
 - (e) *The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP;*
 - (f) *PIC/S achieves this by developing and promoting harmonised GMP standards and guidance documents; training competent authorities, in particular inspectors; assessing*

(and reassessing) inspectorates; and facilitating the co-operation and networking for competent authorities and international organisations.

The Authority considers that the conditions of the proposed group standard are in line with International Codes of Practice and Standards.

Overseas Legislative Requirements

Provision has been made in the proposed group standard for the importation into New Zealand of substances that are labelled in accordance with the labelling requirements in place in the major trading partners, such as Australia, United States and the European Union.

The Authority considers that the labelling requirements of those countries specified within the group standard conditions will provided an equivalent level of safety to the HSNO/GHS requirements.

The applicant notes that the European Chemicals Agency, responsible for the REACH chemical legislation in Europe, has exempted pharmaceutical ingredients as well as medicines from this legislation in light of the many existing regulatory controls placed on medicine manufacture world wide.

The Authority considers that the proposed conditions are in line with International Best Practice and, although reliant on adherence to GMP requirements to manage the risks exhibited at various stages of the lifecycle of such substances, the obligatory requirement for site licensing for human pharmaceutical manufacture locations will ensure that these requirements are met.

Consideration of appropriate types of controls

Before issuing or amending a group standard, section 96C(1)(g) of the Act requires that the Authority consider:

the types of controls appropriate for the group in accordance with sections 77, 77A and 77B of the Act

The proposed group standard is centered on substances being of a similar circumstance of use and, as a result, one set of conditions can manage the risk of substances within the group.

The Authority notes that the conditions applied to the group standard are drawn primarily from the suite of HSNO control regulations. These controls, whilst hazard-based are designed to minimise exposure to a substance and therefore minimise the potential for risk. Consequently, the conditions of the proposed group standard will also manage any risk from the substances within the group in the same way that the HSNO Regulations manage risk for a new hazardous substance given a Part 5 approval.

In most cases, the trigger quantities applied to the proposed group standard conditions align with those set out in the HSNO Regulations. This is important to ensure consistency with existing HSNO substances approved under Part 5, and to facilitate compliance and enforcement.

In addition, these conditions have been supplemented by controls outside of the HSNO regulatory toolbox, but which are relevant because they are based on best international practice, align with overseas activities on hazardous substance management or enable information to be collected on the introduction of new highly hazardous substances into New Zealand.

The requirements to consider the conditions that would apply to a group if a Part 5 approval had been given can be demonstrated by comparing the way in which conditions have been identified with the way controls are identified under a Part 5 approval. That is, the hazardous properties of the substances within the group have been assessed and control regulations selected to manage the risks that may arise from those hazards from the HSNO regulatory toolbox. For the purposes of a group standard, these controls have been expressed as conditions. Thus for example, the conditions for a group standard to manage a flammability hazard are identical to the controls that would have been applied if a Part 5 approval were to be given.

Similarly, the “infrastructural regime” that underpins hazardous substances management under Part 5 of the Act, including, for example, the requirements for and the process to obtain a hazardous substance location test certificate, or an approved handler test certificate have been adopted *en bloc* and applied unchanged to group standard approvals, where such requirements are required to manage the risk of substances within the group.

Whilst the HSNO Control Regulations represent the starting point for establishing the conditions of the group standard, some changes have been made to make the conditions more user friendly, thereby aiding understanding and compliance. For example, the conditions of this group standard do not refer to the need to make information available on the hazards of a substance within 10 seconds or 10 minutes (as per the HSNO control regulations), but simply state that the required information must be available on a product label or safety data sheet respectively. Similarly, the labelling and safety data sheet provisions within the suite of HSNO Control Regulations have been compiled into a single point of reference with the conditions of the group standard.

There are a number of new conditions from outside the HSNO ‘toolbox’ are included in the proposed group standard. These are:

- a restriction specifying the license requirements necessary to be able to use the pharmaceutical active ingredient in the manufacture of human pharmaceutical products;
- a requirement for notification to the Authority if a pharmaceutical active ingredient is, or contains, a chemical that is not listed on the Inventory of Chemicals;
- a requirement for notification to the Authority of assignment of a pharmaceutical active ingredient to this group standard;
- a restriction is placed upon any chemical notified for the Inventory of Chemicals under the conditions of this group standard, such that use of that chemical is only allowed to be used under the Pharmaceutical Active Ingredients Group Standard 2010;
- a requirement for keeping a record of the basis for assigning any pharmaceutical active ingredient to this group standard, and keeping that record available for inspection.

The Authority considers that these additional conditions will provide the necessary restrictions to limit the use of substances imported under this group standard to the desired purpose.

Overall Conclusion

The Authority considers that the group standard remain restricted to pharmaceutical active ingredients for use in human pharmaceutical products.

No changes to the proposal to issue a new group standard for pharmaceutical active ingredients, as detailed in Annex 1 are proposed as a result of information received during the first consultation period.

The Authority considers the issue of the new Group Standard is more efficient and effective than requiring individual Part 5 approvals for active ingredients used in human pharmaceutical products.

The Next Steps

Following Consultation

Following consultation on the Authority's assessment of the matters to be considered before amending the group standards:

1. Each written submission will be reviewed (please note that previous submissions received relating to this application will be considered and new submissions should include information not previously provided);
2. A summary of submissions will be prepared and sent to all submitters, and placed on the ERMA New Zealand website;
3. If required, a hearing will be held (a hearing will only be held if one is requested by a submitter and that submitter wishes to present information that was not included in the consideration paper);
4. If approved by the Authority, notice of the new group standard will be published in the *New Zealand Gazette*.

How To Have Your Say

Your feedback on the Authority's assessment of the matters to be considered before issuing the group standards is important in ensuring that the risks involved are adequately managed under the Hazardous Substances and New Organisms (HSNO) Act 1996.

Please take this opportunity to have your say on this assessment.

You can provide comment by making a submission on your own behalf or as a member of an organisation.

The submissions received will be summarised and presented to the Authority in a Summary of Submissions document, together with the proposal to amend this Group Standard. If approved by the Authority, the new Group Standard will be published in the *New Zealand Gazette*.

You can make a submission by writing your comments on the submission form entitled 'Making a Submission' on the following page of this document. Submissions can be made by mail, fax or email and should be addressed to:

ERMA New Zealand

PO Box 131

Wellington

Fax: 04 9140433

Email: submissions@ermanız.govt.nz

Please mark all submissions to the attention of Samantha Smith.

All submissions must be received by 5 pm, Wednesday 18 August 2010.

For any queries on the Authority's assessment contact;

Matthew Allen

Advisor

Hazardous Substances

Phone: +64 4 918 4881

Email: Matthew.Allen@ermanız.govt.nz

Making a Submission

Name of person or organisation
making submission (required):

Postal address (required):

Town (required):

Country (required):

Phone:

Fax:

Contact E-mail:

Are you submitting this as (tick one box only in this section)?

An individual (not on behalf of an organisation)

On behalf of a group or organisation

Other (please specify)

Please return your submission no later than **18 August 2010** by post to:

ERMA New Zealand
PO Box 131
Wellington
New Zealand

Name of Consultation:

Issue of a new Group Standard – Pharmaceutical Active Ingredients – Authority’s Assessment

Reason for submission (required):

What decision do you seek?

Do you wish to speak in support of your submission at a public hearing? (required – choose only one):

Yes

No

All submissions will be acknowledged by ERMA New Zealand and a summary of submissions will be sent to all those who request a copy. The summary will include the names of all those who made a submission. In the case of those who withhold permission to release personal details, the name of the organisation will be given if supplied.

Do you wish to receive a copy of the summary of submissions?

Yes No

Your submission may be requested under the Official Information Act 1982. If this happens, ERMA New Zealand may be required to release your submission to the person who requested it. If you are an individual, and we are required to release your submission, we will remove your personal details from the submission if you check the following box.

I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

Note:

In the case that a submitter **does not** tick the box, this does not mean that their personal information will necessarily be released in response to a request for information. Rather, objective consideration of all the facts and circumstances of that particular case will have to be undertaken (including Official Information Act and Privacy Act requirements) to determine whether a submission is to be released with their personal details included.

Submission on Proposed New Group Standard – Pharmaceutical Group Standard – Authority’s Assessment

Use additional paper if required.

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....