

TGA THERAPEUTIC
GOODS
ADMINISTRATION

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Dear Dr Siddiqui

YOUR REQUEST FOR REVIEW BY THE MINISTER.

Thank you for your letter of 10 July 2007 seeking review of the decision ("the initial decision") made on 2 July 2007 by Michael Wiseman, as Delegate of the Secretary, to cancel the listing of [REDACTED]

I am the Delegate of the Minister for the purposes of this review.

Results of my reconsideration of the initial decision.

I have decided to revoke the decision of Michael Wiseman.

Findings of fact

My findings on material questions of fact and the evidence on which these findings are based are given below.

The Therapeutic Goods Regulations 1990 define a herbal substance thus:

herbal substance means all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin):

- (a) that is obtained only by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol; and
- (b) that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form.

Extraction is not otherwise defined in respect of herbal substances within the TGA legislation.

The Online Macquarie Dictionary defines extraction thus:

- 'noun 1. the act of extracting.
- 2. the state or fact of being extracted.

3. descent or lineage.
4. something extracted; an extract.
5.
 - a. the act of extracting a tooth.
 - b. an instance of having a tooth extracted.'

It further defines an extract thus:

- 'verb (t) 1. to draw forth or get out by force: to extract a tooth.*
2. to deduce (a doctrine, principle, etc.).
 3. to derive or obtain (pleasure, comfort, etc.) from a particular source.
 4. to take or copy out (matter from a book, etc.), or make excerpts from (the book, etc.).
 5. to extort (information, money, etc.).
 6. to separate or obtain (a juice, ingredient, principle, etc.) from a mixture by pressure, distillation, treatment with solvents, or the like.
 7. *Metallurgy* to separate a metal from its ore by any process.
 8. *Mathematics* to determine (the root of a quantity).
- noun 9. something extracted.*
10. a passage taken from a book, etc.; an excerpt; a quotation.
 11. a crude solution or preparation containing the active principles of a vegetable or animal drug.
 12. a solid or viscid substance extracted from a drug, plant, or the like.
 13. *Textiles* a material made from old woollen and worsted fabrics with the addition of cotton or rayon. [Latin *extractus*, past participle, drawn out]
- extractable, extractible, adjective'*

The British Pharmacopoeia (BP) 2007 defines extracts broadly as follows:

'DEFINITION

Extracts are preparations of liquid (liquid extracts and tinctures), semi-solid (soft extracts) or solid (dry extracts) consistency, obtained from herbal drugs or animal matters, which are usually in a dry state.

'Different types of extract may be distinguished. Standardised extracts are adjusted within an acceptable tolerance to a given content of constituents with known therapeutic activity; standardisation is achieved by adjustment of the extract with inert material or by blending batches of extracts. Quantified extracts are adjusted to a defined range of constituents; adjustments are made by blending batches of extracts. Other extracts are essentially defined by their production process (state of the herbal drug or animal matter to be extracted, solvent, extraction conditions) and their specifications.

'PRODUCTION

'Extracts are prepared by suitable methods using ethanol or other suitable solvents. Different batches of the herbal drug or animal matter may be blended prior to extraction. The herbal drug or animal matter to be extracted may undergo a preliminary treatment, for example, inactivation of enzymes, grinding or defatting. In addition, unwanted matter may be removed after extraction.'

The Therapeutic Goods Act 1989 defines standard as follows:

'standard, in relation to therapeutic goods, means a standard that:

- (a) is specified in an order under section 10 that is applicable to the goods; or
- (b) if no such order is applicable to the goods but the goods are the subject of a monograph in:
 - (i) in the case of goods for use in humans—the British Pharmacopoeia; or
 - (ii) in the case of goods for use in animals—the British Pharmacopoeia (Veterinary);
 is constituted by the statements in that monograph.'

I find there is no Order that specifies a meaning for extraction in respect of a herbal substance.

The letter of cancellation of 2 July 2007 sets out the delegates reasons for cancellation and these relate solely to whether the medicine is eligible for listing because of concern over the status of the active ingredient *Piper nigrum* extract as meeting the definition of a herbal substance.

I have confirmed from TGA documents and the relevant Regulations that the ingredient *Piper nigrum* is included in the list of allowed listable ingredient as both an active and an excipient with no limit on quantities of other conditions related to its presence.

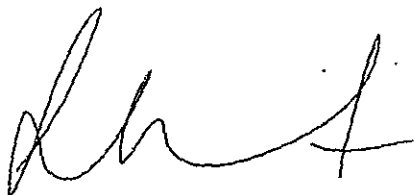
My consideration of your appeal.

I have considered the argument made in relation to the definition of *piper nigrum* as an herbal substance as set out in your letter of appeal dated 10 July 2007 and the description of its processing as in your company letters of 10 May and 14 June 2007. I have reviewed the processing described in your correspondence and consulted within TGA in the light of the BP 2007 definition of extraction. While I have reservations that the process meets the intended description of extraction for the purpose of an herbal substance as implied in relevant guidelines, I conclude that it could reasonably be interpreted as complying with the BP 2007 description of extraction and is not inconsistent with the Macquarie definitions. In the absence of a further legal definition of extraction for a herbal substance, and on balance, I find the process can be interpreted as being an extraction. I cannot find that the substance is not a herbal substance based on this assessment and therefore cannot agree with the stated grounds for cancellation of the product.

The Administrative Appeals Tribunal

If you are dissatisfied with this decision, then subject to the AAT Act 1975, you may make an application to the Administrative Appeals tribunal for review of my decision within 28 days of the notification of the decision.

Yours sincerely



Dr Leonie Hunt

Delegate of the Minister for Health and Ageing

7/9/07