

PROPOSED RESTRICTED SUBSTANCE REGULATIONS

Explanatory Note

1. The Social Tonics Association of New Zealand (“STANZ”) has instructed Public Law Specialists, Chen Palmer, to draft Restricted Substances Regulations for submission to the Associate Minister of Health, Hon Jim Anderton, as he considers whether to reclassify BZP and related piperazines as a Class C drug or to retain BZP as a Restricted Substance.
2. STANZ’s strongly held view is that the best way to protect the public is to properly regulate restricted substances using the measures available under the existing legislation; legislation which STANZ has always supported. Accordingly, STANZ respectfully asks that the Minister consider promulgating the proposed regulations under The Misuse of Drugs Amendment Act 2005 (“**the Act**”).
3. The proposed regulations should be read with the Code of Good Manufacturing Practice for Restricted Substances (“**the GMP**”) also prepared by STANZ and attached as Annex 1.
4. If the Minister decides not to promulgate regulations, STANZ will take steps to self-regulate as a harm reduction measure. A Code of Practice (“**the Code**”) which closely follows the proposed regulations (and incorporates the GMP), will be available as a voluntary mechanism for any business or person that imports, manufactures, distributes or sells any restricted substance.
5. A copy of the Code is provided with the proposed regulations and the GMP. STANZ reiterates that **legally enforceable** requirements would best achieve the objectives of the Act.

Background

6. The Act currently places restrictions on:
 - (a) The sale or supply of restricted substances to a person under 18 years and on persons under 18 years selling restricted substances;
 - (b) Free of charge distribution and rewards of restricted substances;
 - (c) Advertising on television, radio or newspaper or periodical; and
 - (d) Persons who can sell or manufacture restricted substances.
7. The Act contemplates that all other matters relating to the manufacture, distribution and sale of restricted substances will be addressed through regulation (sections 44 to 51 and section 53 of the Act).

8. Under section 62 of the Act, the Governor-General, by Order in Council, has the power to make regulations for the purposes set out in that section. Under section 63 of the Act, the Director-General of Health has the power to issue, approve, amend or revoke a code of practice for the manufacture of restricted substances. No regulations or code have been issued despite the limited nature of the existing restrictions in the Act.
9. The proposed regulations cover all matters where the Act contemplates further prescription including all purposes outlined in section 62 of the Act.
10. As Section 63 does not prescribe matters to be covered by a code of practice for the manufacturing of restricted substances. The GMP is modelled on the comprehensive New Zealand Code of Good Manufacturing Practice for Medicinal Products and is submitted for approval by the Director-General of Health.

Interpretation

11. The interpretation section of Part 3 of the Act is adopted for the purposes of the Proposed Regulations.

Quality, dosage, form and serving restriction and requirements

BZP

12. BZP must be sold or supplied to retailers or consumers in tablet or capsule form only.
13. Any tablet or capsule for sale or supply must contain no more than 200 milligrams of BZP.
14. Any recommended dose must be no more than 200 milligrams of BZP.
15. Any tablet or capsule for sale or supply containing BZP must contain no more than 50mg of trifluoromethylphenyl-piperazine (“TFMPP”).
16. A retail sale pack containing BZP tablets or capsules must contain no more than 600 milligrams of BZP in total.
17. BZP raw material used in the manufacture of tablets or capsules must be at least 99% pure, in the form of a dihydrochloride salt.

Place of Sale or Supply of Restricted Substances

18. A restricted substance must only be sold or supplied by any person from the following places or premises:
 - (a) Premises where entry is restricted to persons aged over 18 years; and
 - (b) Premises licensed to sell liquor but not including;
 - (i) A convenience store; or

(ii) A supermarket.

19. Premises referred to in clause 18 must not be located in close proximity to schools, recreational centres and playgrounds. Close proximity means a distance less than 250 metres.

Restrictions on advertising restricted substances

20. No person will advertise restricted substances unless the advertisements comply with the following requirements:
- (a) Are restricted to places where restricted substances are sold or premises where persons can only enter if they are over 18 years, and must not be visible from the street;
 - (b) Include a Health Warning (in accordance with clause 23 for BZP);
 - (c) Comply with the requirements for labelling, packaging and marketing set out in clauses 24 to 27; and
 - (d) Include contact details of the manufacturer for the stated purposes of obtaining detailed product information and reporting adverse events.
21. No business associated with the manufacture, distribution, sale or supply of restricted substances must provide sponsorship to any person, organisation or business.
22. If a person has any doubt about compliance with this clause the advertisement in question should first be sent to the Therapeutic Advertising Pre-Vetting Service, Advertising Standards Association, for pre-vetting and approval.

Health Warning Requirements

BZP

23. The Health Warning for BZP must include the following:
- (a) Do NOT exceed the maximum recommended dose within a 24 hour period. Maximum 2 doses per week;
 - (b) Do NOT use with alcohol or other restricted substances or illicit drugs;
 - (c) Drink plenty of water or fruit juice to avoid dehydration;
 - (d) Small build or first time users should try half the recommended dose;
 - (e) May cause increased heart rate and short term insomnia;
 - (f) Do not use these products if currently on medication or suffering from a medical condition or mental illness without first consulting a doctor;
 - (g) Do not use when pregnant or breast feeding; and

- (h) Keep out of reach of children.

Labelling, Packaging and Marketing Restrictions

General

24. All labels and advertising must display the following in a **prominent** position:
- It is illegal to sell or supply BZP products to any person under 18 years.
 - Do NOT consume with alcohol.
25. In relation to labels, the requirement in clause 24 must be displayed on the main label (that identifies the product) in font size in the typeface known as Helvetica no smaller than 10.
26. In relation to advertising, the requirement in clause 24 must be displayed prominently on all advertising material.
27. No labels, graphics, artwork, brand names, packaging, containers and other marketing materials (including advertisements) must:
- (a) Be designed specifically to have appeal to persons under the age of 18 years by way of design, motifs, cartoon characters or other device;
 - (b) Lead to confusion with confectionary;
 - (c) Encourage immoderate consumption;
 - (d) Encourage the use of illegal drugs;
 - (e) Portray unrealistic outcomes;
 - (f) Be sexually provocative or suggest any link between restricted substances and sexual attraction and performance.

Labelling

28. In addition to the requirements in clauses 24 to 27, all labels on packages containing restricted substances shall state the following;
- (a) The milligrams of restricted substance per tablet or capsule (200 milligrams maximum for BZP);
 - (b) The maximum recommended dose (200 mg for BZP) specified by reference to the number of tablets or capsules;
 - (c) The total milligrams of restricted substance per retail pack (600 milligrams maximum for BZP);
 - (d) A list of all other ingredients (this does not have to include the milligrams of each other ingredient);
 - (e) Batch number;

- (f) Expiry date;
 - (g) Health warning (in accordance with clause 23 for BZP); and
 - (h) Contact details of the distributor.
29. The information referred to in clause 28 (a) to (g) must be printed in black on a white background in roman font in the typeface known as Helvetica and no smaller than font size 6.
30. The total milligrams of the tablet must not be referred to on the label as it may be confused with milligrams of BZP;

Packaging

31. All retail packaging containing restricted substances must comply with the following requirements;
- (a) Must include labels or on the outside of the package include all information in accordance with the requirements in clauses 28 and 29;
 - (b) Must be of a size sufficiently large to incorporate the labelling requirements in clauses 28 and 29;
 - (c) Must be tamper evident and child proof;
 - (d) Must include inside the package an information leaflet in black print on white paper. The font size must be no smaller 12. The information leaflet must not include any marketing or advertising information or graphics. The information leaflet must include the following information:
 - (i) The milligrams of restricted substance in each tablet or capsule;
 - (ii) The maximum recommended dose specified by reference to the number of tablets or capsules;
 - (iii) The milligrams of restricted substance in each retail pack;
 - (iv) A list of all other ingredients (this does not have to include the milligrams of each other ingredient);
 - (v) Health warning (in accordance with clause 23 for BZP);
 - (vi) Any additional contraindications not included in the Health warning;
 - (vii) Where to seek help;
 - (viii) Contact details of the manufacturer for the purposes of obtaining more detailed product information;
 - (ix) Details for reporting adverse events;

- (x) Batch number; and
 - (xi) Expiry date.
- (e) Must not mimic containers or shapes associated with anti-social behaviour.

Storage and Display Requirements

32. Restricted substances displayed for the purposes of sale or supply must be kept behind a counter where they can not be accessed by the public and where they are not visible from the street.

Signage Requirements

33. Every person who sells restricted substances must display signage in the premises where the restricted substances are sold which includes the following information:
- (a) It is illegal to sell or supply restricted substances to any person under 18 years; and
 - (b) Do NOT consume these products with alcohol.
34. Signage must be placed in a prominent position behind the counter where the restricted substances are stored and be in sufficiently large print so that it can be easily read from the public side of the counter.

Manufacture of restricted substances

35. Every person who imports, manufactures, stores or distributes a restricted substance must comply with the GMP attached as Annex 1.

Record Keeping

36. Every person who, in the course of any business, imports, manufactures or distributes any restricted substance must keep in a secure place at the person's place of business those records specified in the GMP that relate to that person's business including but not limited to records of:
- (a) Origin and purity of imported goods;
 - (b) Manufacturing formula including all products combined with the restricted substance;
 - (c) Certificates of analysis from an approved laboratory for each batch of product;
 - (d) Analysis of products, including the pharmacological activity of the restricted substance when mixed with other ingredients included in the products being manufactured;

- (e) Sampling and testing procedures;
 - (f) Any deviations in quantity and quality of a product;
 - (g) Each batch of product to enable a trace of both the raw materials throughout the manufacturing process and each batch of product manufactured; and
 - (h) Instructions for manufacture, processing and storage; and
 - (i) All reports of adverse events to include details of event, action taken and outcome.
37. Records must be retained in a comprehensible and accessible form.
38. Records must be kept for a minimum period of 12 months.