

CODE OF PRACTICE FOR RESTRICTED SUBSTANCES

Preamble

1. The Code of Practice for Restricted Substances (“**the Code**”) is a voluntary code for any business or person that imports, manufactures, stores, distributes or sells any restricted substance. It includes the Code of Good Manufacturing Practise for Restricted Substances (“**the GMP**”) attached as Annex I which is modelled on the New Zealand Code of Good Manufacturing Practice for Medicinal Products.
2. The Code and GMP have been introduced by the Social Tonic Association of New Zealand (“**STANZ**”). It is compulsory for STANZ members to comply with the Code.
3. All persons must comply with the requirements of the Misuse of Drugs Amendment Act 2005 (“**the Act**”). The Code and GMP are in addition to those requirements and has been established to further the harm reduction objectives of the Act.
4. The Code and GMP cover the regulatory requirements expressly contemplated by the Act’s regulation making powers, in the absence of any regulations having been made. STANZ has respectfully requested the Associate Minister of Health, Hon Jim Anderton to consider the use of powers under to Act to promulgate **legally enforceable** regulations (based on the Code) and issue or approve a code of manufacturing practice (based on the GMP).
5. STANZ believes that introducing regulations under the Act remains the best option for ensuring the safe and responsible supply of restricted substances throughout New Zealand, because the requirements would be binding on all, and not just those who voluntarily abide by the Code, and any person who contravened certain regulations would commit an offence.

Interpretation

6. The interpretation section of Part 3 of the Act is adopted for the purposes of the Code.

Sale and Supply Restrictions

Evidence of age documents

7. As required by section 37 and 38 of the Act no person will sell or supply restricted substances to any person under 18 years or sell a restricted substance unless over the age of 18 years.

8. All persons selling or supplying restricted substances will sight an evidence of age document (within the meaning of section 2A of the Sale of Liquor Act) before selling a restricted substance from any person who appears to the person selling the restricted substance to be aged 25 years or younger. Evidence of age documents mean:
- (a) A New Zealand passport; or
 - (b) An overseas passport; or
 - (c) A driver licence issued under the Land Transport Act 1998; or
 - (d) A document in the form set out in the Sale of Liquor (Evidence of Age Document) Notice 1999.
9. All retail personnel must receive training on the Code and the Act before selling restricted substances. All retail personnel must be provided with their own copy of the Code and Act by the retailer and a copy of the Code must be available to personnel at the retail premises at all times.

Quality, dosage, form and serving restriction and requirements of restricted substances for sale or supply

BZP

- 10. BZP must be sold or supplied to retailers or consumers in tablet or capsule form only.
- 11. Any tablet or capsule for sale or supply must contain no more than 200 milligrams of BZP.
- 12. Any recommended dose must be no more than 200 milligrams of BZP.
- 13. Any tablet or capsule for sale or supply containing BZP must contain no more than 50mg of trifluoromethylphenyl-piperazine (“TFMPP”).
- 14. A retail sale pack containing BZP tablets or capsules must contain no more than 600 milligrams of BZP in total.
- 15. 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

- 16. 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.

17. 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

18. As required by section 43 of the Act, no person will advertise a restricted substance on television, radio or in any newspaper or other periodical publication printed and published in New Zealand. In addition every person will adhere to the following guidelines in relation to any permitted advertisements:
- (a) Advertisements must be 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) All advertisements must include a Health Warning (in accordance with clause 19 for BZP);
 - (c) All advertisements must comply with the requirements for labelling, packaging and marketing set out in clauses 20 to 23;
 - (d) All advertisements must include contact details of the distributor for the stated purposes of obtaining detailed product information and reporting adverse events;
 - (e) No business associated with the manufacture, distribution, sale or supply of restricted substances will provide sponsorship to any person, organisation or business; and
 - (f) If a person has any doubt about compliance with this code it is recommended that the advertisement in question is sent to TAPS¹ for pre-vetting and approval. STANZ will keep a database of approved advertisements for access by members.

Health Warning Requirements

BZP

19. 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;

¹ Therapeutic Advertising Pre-Vetting Service, a commercial division of the Advertising Standards Association

- (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;

Labelling, Packaging and Marketing Restrictions

General

- 20. 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.
- 21. In relation to labels, the requirement in clause 20 must be displayed on the main label (that identifies the product) in font size in the typeface known as Helvetica no smaller than 10.
- 22. In relation to advertising, the requirement in clause 20 must be displayed prominently on all advertising material.
- 23. 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; and
 - (f) Be sexually provocative or suggest any link between restricted substances and sexual attraction and performance.

Labelling

- 24. In addition to the requirements in clauses 20 to 23, 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 19 for BZP); and
 - (h) Contact details of the distributor.
25. The information referred to in clause 24 (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.
26. The total milligrams of the tablet must **not** be referred to on the label as it may be confused with milligrams of BZP;

Packaging

27. 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 than 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 19 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

28. 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

29. 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.
30. 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

31. Every person who, in the course of any business, imports, manufactures, stores or distributes any restricted substance **must comply with the GMP** attached as Annex 1.
32. Without detracting from the requirements in clause 31, key elements of the GMP include;
- (a) A clear delineation of personnel duties (organisational structure);
 - (b) Independence of the head of Production and head of Quality Control;
 - (c) The manufacturer to provide training for all personnel whose duties either take them into production areas (including maintenance and cleaning personnel) or could affect the quality of the restricted substance or restricted substance product.

- (d) Detailed hygiene procedures should be established and implemented. Eating, drinking, or chewing, or the storage of food, drink, smoking materials or personal medication in the production areas should be prohibited.
- (e) Requirements for premises and equipment including measures to avoid contamination/cross contamination; security (external/internal); **maintenance and accuracy of measuring/weighing equipment**; adequate lighting, ventilation and dust removal facilities; ancillary areas (e.g. toilets) separate from production areas; adequate storage facilities (visibility / security); and general cleanliness;
- (f) General safety - mechanisms to deal with accidents; disposal of ingredients/final product and protective clothing ;
- (g) All personnel should receive a medical examination upon recruitment. It is the manufacturer's responsibility to ensure that health conditions that can be of relevance to the quality of restricted substances come to the manufacturer's knowledge;
- (h) Quality control to include certification by an approved testing laboratory of each batch prior to release for sale or supply. STANZ members must provide STANZ with copies of all certificates of analysis on request;
- (i) Independent audit process to include regular and random quality assurance testing of at least two products per year or 10 percent of the manufacturer's' product range, whichever is larger. The costs of such tests are to be met by the manufacturer;
- (j) All manufacturers must have in place a mechanism to address complaints about products manufactured to include procedures for investigating the complaint and taking appropriate measures should any quality defects be identified in order to reduce the likelihood of reoccurrence;
- (k) The reporting of adverse events and follow-up action; and
- (l) Systems and procedures to enable the recall of any batch of product from sale or supply. STANZ members must provide STANZ with copies of recall systems and procedures.

Record Keeping

- 33. Every person who, in the course of any business, imports, manufactures, stores 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;
 - (h) Instructions for manufacture, processing and storage; and
 - (i) All reports of adverse events to include details of event, action taken and outcome. STANZ members must provide all adverse event records to STANZ. An adverse event that involves serious harm must be reported to the Ministry of Health. Serious harm means a hospital admission (a visit to the Emergency Department does not constitute a hospital admission).
34. Records must be retained in a comprehensible and accessible form.
35. Records must be kept for a minimum period of 12 months.
36. STANZ will maintain product information records that will be publicly accessible by website or a 0800 number to include:
- (a) Contact details of all STANZ members;
 - (b) Anonymised adverse events reports;
 - (c) Specific product and member details in relation to an adverse event report where considered necessary;
 - (d) Provision for on-line adverse event reporting;
37. All STANZ members must have product information freely available via a website or 0800 numbers.

Quality Mark Requirements

38. Compliance with the Code and GMP is mandatory for existing STANZ members within 12 months of the Code and GMP becoming operational and for new STANZ members within 12 months of joining STANZ.
39. A Gold STANZ Quality Mark will be available to fully compliant members for use in advertising, labelling and packaging;

40. A Silver STANZ Quality Mark will be available to members for use in advertising, labelling and packaging who have in place **a recall procedure** in accordance with the GMP, have provided **certificates of analysis from an approved testing laboratory** for their products and are committed to working towards full compliance with the code and GMP. A member will be entitled to use the Silver Quality Mark for a maximum period of 12 months while attaining full compliance.
41. STANZ will assess and regularly monitor ongoing compliance by members. Monitoring will be funded by membership fees. If a member fails to comply with either standard STANZ will withdraw the right to use the Quality Mark and/or issue a notice to remedy any compliance defect within a specified period.