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**Submission on: The Proposed Australia New Zealand Therapeutic Goods Authority Regulation of Complementary Medicines**

1. This submission is made by:

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Deer Industry New Zealand (DINZ) appreciates the opportunity to comment on The Australia New Zealand Therapeutic Goods Authority Regulation of Complementary Medicines proposal. DINZ points out that the views expressed in this submission are not necessarily the views of all individual companies in the New Zealand deer industry. However the submission has been developed with input from all industry sectors.

Further, the submission focuses on concerns that relate to the New Zealand deer industry rather than the therapeutic products landscape as a whole because DINZ's key concern is the proposal's impact of the New Zealand deer industry.

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## The New Zealand Deer Industry

2. DINZ was established in 2004 by the Deer Industry New Zealand Regulations 2004 under the Primary Products Marketing Act 1953. Prior to that it operated under the Game Industry Board Regulations 1985. It exists to "promote and assist with the orderly development of the deer industry" as well as various other functions.

DINZ does not trade in products. Its responsibility is solely for products derived from farmed deer, and it is not involved with other game animals. Further detail can be located on [www.deernz.org](http://www.deernz.org).

The New Zealand deer industry exports approximately NZ\$269 million in exports per annum, of which, NZ\$ 22 million is from velvet exports, and 9 million from co-products.

3. Product forms of velvet and co-products include the following:
  - Frozen
  - Dry Whole Piece (traditional: cooked and air dried)
  - Dry Whole Piece (freeze dried)
  - Traditionally Dried and Sliced
  - Freeze Dried Powder
  - Encapsulated Freeze Dried Powder
  - Traditionally Processed Powder
  - Encapsulated Traditionally Processed Powder
  - Various extracts taken from powder using various techniques
  - Tablets, capsules, tabs and sprays made from extracts.
4. DINZ acknowledges the good working relationship it has with Medsafe on this issue, and appreciates the work that has been done on velvet with respect to the Permitted Ingredients List Project, however, DINZ has concerns with the proposal which are listed below.
5. In principle, DINZ does not support the proposed ANZTPA, because:
  - a) The proposal represents a higher level of regulation and compliance which appears unjustified. While there are claims made that this additional regulation will safeguard consumers, DINZ is not aware of any significant evidence in New Zealand or Australia that demonstrate the need for such regulation.
  - b) DINZ does not believe that New Zealand interests will be represented effectively by the Agency. DINZ believes the 'weight of influence' will come from the Australian side, and can not see enough evidence of mechanisms in the structure of the proposal to even the balance.
  - c) The cost of the agency will be borne by industry, with this cost being passed on to consumers. Ultimately, this means higher prices. DINZ does not believe this is in consumers' interest.

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- d) The proposed regulation has loopholes. Spirulina is an example. DINZ's understanding is that in a powdered form it would not be managed under the joint agency, but in a pill form it would. Velvet is one such product that may be treated differently under the proposed regulations, depending on form (powdered, capsulated, dry whole stick etc). Medsafe's previous advice on this issue is that powdered velvet, if sold with no claims, would still be able to be sold as a food product. DINZ requests confirmation that this is still the case.
  - e) DINZ would not be supportive of any regulations to control intermediary products that are for sale only to trade, or for export. DINZ would not support this because of the already very high compliance required under current food law (Risk management Programmes, for example).
  - f) The proposal involves health supplements being treated more like drugs than food products. Deer products being marketed currently under existing food law are known to be safe by virtue of their longevity of sale and nil incidence of serious adverse health events. Under the proposal, these products would no longer be able to be marketed until a registration process is undertaken. Effectively, this means products will be forced off the market (especially when operators are small or recent start-ups and can not afford the registration process). This does not appear in the interests of consumers who consume these products and will favour corporate entities over sole traders, partnerships or other smaller entity types.
  - g) Following on from this, DINZ is of the view that given a lack of 'issue' with existing products and ingredients from deer, product marketers should not have to *prove* their products are safe, that further regulation is *only appropriate* if the products in question are actually proven unsafe. On this argument, existing deer ingredients that do not have any evidence suggesting they are dangerous do not need higher levels of regulation, and if the joint agency goes ahead, these ingredients should be included on the Permitted Ingredients List automatically.
  - h) There is no evidence in Australia that the TGA has improved consumer safety.
  - i) Twice, Parliamentary Select Committees have concluded that a joint agency is not in the interests of New Zealand.
  - j) DINZ believes existing New Zealand law is adequate in regard to health supplements, and where inadequacies arise, they should be dealt with by New Zealand law, not by adopting Australian law.
  - k) The companies marketing New Zealand deer product dietary supplements have expressed concern that they would be losing their sovereign rights under this joint agreement.
  - l) DINZ is concerned that there will be less consumer choice under the ANZTPA and associated legislation.
  - m) The New Zealand deer industry has a positive position in the world market for deer products being the largest farmed deer industry in the World. This position needs to be nurtured and improved by encouraging investment in further development. DINZ is concerned that the ANZTPA will result in an
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increased cost burden for little tangible benefit and will weaken the industry's position.

#### 6. The Draft Medicines Rule

- a) Page 11, 1.05. DINZ does not agree with the definition of a 'Complementary Medicine'. A health supplement can not be a medicine if it is only a supplement to good health and *not given for the treatment of a disease*. Most health supplements are undeniably safe, and by labelling them 'medicines' wrongly suggests they need a higher level of regulation. Where there are health supplements considered dangerous for one reason or another, specific attention should be focused on them, and New Zealand regulations enacted by exception rather than blanket, bureaucratic regulations across all health supplement products.
- b) Page 18, 3.02: Product licenses. It seems unreasonable that a product licence must be held for any persons or entity selling 'complementary medicines'. For example, DINZ questions whether it is the intent of the proposal that a smoothie stand selling spirulina shakes should hold a product licence for that milkshake?
- c) Page 22, 3.10: DINZ believes that 'dosage form' should not differentiate therapeutic products. Take for example spirulina powder and spirulina tablets, these are in fact the same product and should not be differentiated by form. Adding this level of complexity to regulations only increases cost to producers and consumers. If one form of an ingredient or product does not need additional regulation (such as powdered forms sold with no claims made), then a different form (pills/capsulated) of the same ingredient should also be able to be sold without additional regulation if no claims are made.
- d) Page 25, 3.13: Approved herbal material. DINZ believes that New Zealand industries that are not well represented in Australia, such as the deer industry, will be disadvantaged by the requirement that materials and ingredients not on the Australian permitted list and not part of the Medsafe Permitted Ingredients List project will have to go through an expensive registration process. DINZ believes that where therapeutic products or ingredients have been sold in New Zealand for many years with no adverse effects AND the products are part of Korean and Chinese pharmacopoeias, they should be grandfathered onto the Permitted Ingredients List. This is especially relevant for deer products which have a long tradition and a long clean record of safety.
- e) Page 26, 3.14: In terms of inclusion on the Permitted Ingredients list, as per d) above, ingredients with a long safe history should be grandfathered.
- f) Page 46, 3.43 1a: In regards to claims, it is DINZ's understanding that health supplements in powdered form (ie, not a 'final dose form') that are not marketed with any claims on labeling will not fall under this Rule of Law. DINZ requests clarification of this point.
- g) Page 48, 3.46, Discretionary Conditions: the fact that the Authority 'may impose conditions on a product license, in addition to the conditions mentioned in other provisions of this Division...' is of concern to DINZ. This suggests the Authority's mandate is beyond what is documented and defined by the Rule,

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- allowing it to regulate in ways the industry may not expect and in a way that is unreasonable, unpractical, or not in the interest of consumers.
- h) Page 62, 4.02, Manufacturing Principles. DINZ believes that limiting manufacturing principles to the codes of Good Manufacturing Practice ignores the excellent codes in place for deer related health supplements in the form of Risk Management Programmes (RMPs). Further compliance costs, over and above those enforced through RMPs is symptomatic of over regulation industry in New Zealand faces, and is unnecessary given the risk deer related health supplements pose (and most other health supplements). DINZ requests Medsafe to provide evidence that GMP principles are really necessary for health supplement products.
  - i) Page 63, 4.03. Need for Manufacturing License. DINZ comments that this section appears vague. In the extreme, it could mean farmers need a manufacturing license (does Medsafe consider they are part of the process as they produce the raw material?). Medsafe has previously said that only those manufacturers that produce the final form would need a manufacturing license, however, this is not clearly communicated in this clause. DINZ requests clarification of this point.
  - j) Page 63, 4.03. Need for Manufacturing License. DINZ questions whether a manufacturing license will improve consumer safety. DINZ believes that consumer safety is already covered by the need for deer product manufacturers to have a RMP.
  - k) Page 72, 4.14, Discretionary conditions. As for g) above, it appears that the limits of the Authorities powers are not defined.
  - l) Page 79, Part 5, Exemption from Standards and Licencing. DINZ believes that supplements that are not used to treat a disease, but rather, used for general health and well being, should be exempt from the standards. There is no evidence DINZ is aware of that supplements need to be controlled as a drug or medicine.
  - m) Page 90, Division 5.4. Exemptions – Manufacturing. DINZ believes that the Rule needs to be clearer about its application to producers and manufacturers of raw materials (ingredients). DINZ, through previous discussions with Medsafe, was under the impression that producers and manufacturers of raw materials (ingredients) would not be subject to a Manufacturing licence. DINZ requests clarification on this point.
  - n) Page 107, Schedule 1, Part 1, Complementary medicine substances. DINZ finds these definitions all encompassing, providing the Authority too much leeway to exert its control. For example, item one ‘a plant or a plant material’ could include spinach (rich in iron), and item 6, ‘a mineral compound’ could include common salt. DINZ disagrees that it is in the consumers’ interest to have such a wide definition of complementary medicines. This implies too much needless regulation and cost.
  - o) Page 115, Schedule 4, Product licensing exemptions. DINZ believes that supplements that have a long, safe history of use should be exempt from control by this Authority.
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- p) Page 124, Part 2, Exempt manufacturer. There is no clear indication in the texts that support Medsafe's comments (from previous meetings) to DINZ that primary producers and raw material processors will not have to have a manufacturing license. There is not enough definition in terms of how far down the supply chain this regulation applies.
6. A draft guideline on transition provisions for product licensing
- a) DINZ is concerned that the transition cost will put smaller operators out of business, especially where operators' ingredients are not listed on the Permitted Ingredients List. In this situation the question of who should list the ingredient, pay for any research required, and then how they recover costs from other operators that receive the benefit of the listing will be a very real problem. This could conceivably lead to business failures and will lead to higher prices and less consumer choice.
  - b) For the reasons stated in a), DINZ feels deer products that have a long safe history of use should be grandfathered onto the Permitted Ingredients List, including pizzle, tail, deer blood, and sinew.
7. Draft Administration Rules
- a) DINZ feels that the cost of additional administration of a sector that does not appear to be causing significant risk to consumers is unjustified, and ultimately will impact on the consumer.
  - b) Page 18, 8.17: Constitution. DINZ feels that the constitution of the Expert Advisory Committee could lead to conflicts of interest given members of the committee must be from backgrounds where potentially the products they represent or represented in a commercial sense may compete with products being evaluated. There is no reference to New Zealand representation on the Expert Committee, potentially, the Committee could be entirely made up of Australian members.
8. Fees and Charges under the Australia New Zealand Therapeutic Products Regulatory Scheme.
- a) Page 16, Section C, Cost Recovery. DINZ believes that ultimately the cost recovery will be borne by the consumer in the way of higher prices. This disadvantages consumers as the additional cost is disproportionate to the risk of most health supplement products.
  - b) Page 24, Pricing Parity. The fact that fees and charges will be determined in Australian Dollars means New Zealand entities will be susceptible to exchange rate movements, whereas Australian entities will not. This is evidence that the Authority may favour Australian industry.
  - c) Page 38, Fees for Manufacturing Assessments. Fees described in this table will stretch the financial limitations of many small operators. GMP audits represent costs that are considered unnecessary because they relate to GMP standards that are not justified for low risk supplements, already covered by RMPs.
  - d) Page 50, Pre-market Assessment of new substances. The pre-market application fee will result in a barrier to new and innovative products.
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- e) Page 50, New substances. The sponsor system forms a barrier to new products and innovation as there is no way a sponsor can protect the benefit of registering a new substance on the ingredients list. Other parties can immediately begin to use that ingredient but without having to contribute to the cost of listing. The system as proposed significantly disadvantages small, innovative companies that do not have a strong financial base or a significant market share. DINZ is not satisfied that Proposal 23 provides enough remedy to this situation.
  - f) Page 52, Proposed Fees for class 1 medicines. The fees and annual charges detailed in the table under 220 represent significant additional costs to small companies in our industry. Operators that are operating small scale businesses will be disadvantaged against bigger companies that can spread the additional costs over a higher turnover. The additional fees may have the effect of changing the structure of the health supplement industry, favouring corporates over small businesses and ultimately disadvantaging consumers.