Food/medicine interface issues

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Why do we need to know whether goods are food or therapeutic goods?

- TGA and state and territory food regulators need to ensure the legality of inspection and seizure of goods; recall of unsafe goods; and enforcement action taken against individuals and companies.
- Industry needs to know which regulatory regime to comply with as there are criminal and civil penalties for importing, manufacturing unapproved therapeutic goods. In addition, there are pre-approval requirements (e.g. GMP licences).
Why do we need to know whether goods are food or therapeutic goods?

- TGA needs to:
  - identify goods that are on the Register but are in fact “food” and cannot be regulated by the TGA
  - respond to advertising complaints about unfair competition from goods that are not on the Register
  - provide accurate information to consumers, industry and the public about their legal obligations and responsibilities
How can a food be therapeutic goods?

• Definition of “therapeutic goods” (s.3(1) of the Act):
  – goods that are:
    ▪ represented to be for “therapeutic use”, or
    ▪ likely to be taken to be for “therapeutic use”:
      • because of the way in which they are presented, or
      • for any other reason
  – goods that are in a class, the sole or principal use of which is, or ordinarily is, “therapeutic use”

• 1st concerned with apparent intended use of goods

• 2nd concerned with actual use of that class of goods
How can a food be therapeutic goods?

• “Therapeutic use” includes:
  – preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury
  – influencing, inhibiting or modifying a physiological process

• If such goods are for oral use/human consumption then they also come within the definition of “food” in FSANZ Act and therefore come within the regulatory jurisdiction of the states and territories
How does the Act deal with food?

- Act excludes particular types of “food” from definition of “therapeutic goods”

- Goods will not be “therapeutic goods” if they are:
  - goods for which there is a standard under the FSANZ Act (paragraph (e) of the definition)
  - goods which in Australia or New Zealand have a “tradition of use as foods” in the form in which they are presented (paragraph (f) of the definition)
Goods excluded by paragraph (e) – goods for which there is a standard under the FSANZ Act

- Relevant standards include:
  - 2.9.4 – Formulated supplementary sports food
  - 2.9.5 – Food for special medical purposes

  But need to carefully consider what goods the Standard actually applies to

- If a product comes within paragraph (e) (ie covered by a Food Standard) then the fact that:
  - therapeutic claims are made on the label or in advertising, or
  - goods do not comply with requirements in the Standard, or
  - product includes undisclosed S4 substance
  does not make it a therapeutic good
Goods excluded by paragraph (f) -
goods which in Australia or New Zealand have a “tradition of use as foods” in the form in which they are presented:

• “Tradition of use” in Australia/NZ:
  – is there a history of significant human consumption in the broad community?
  – does there exist adequate knowledge in the broad community such that there is reasonable certainty no harm will result from intended use?

• In the ‘form’ in which it is presented
  – examples: coffee, cocoa (kumabe), tea in teabags? chocolate?

• If a product comes within paragraph (f) then the fact that:
  – therapeutic claims are made on the label or in advertising, or
  – product includes undisclosed S4 substance
  does not make it a therapeutic good
Listed complementary medicines

- certification process so no consideration by TGA before listing whether goods come within paragraph (e) or (f) of the definition of therapeutic goods and may not in fact be therapeutic goods

- Sumabe [2012]:
  the AAT found that Leptin Green Coffee and Leptin Green Hot Chocolate properly cancelled from Register on the basis covered by paragraph (f) exclusion i.e. tradition of use in Australian/New Zealand as food in that form (sachets)
Recent developments

• Section s.7AA included in the Act in Feb 2014
  – ministerial instrument - exclude goods that not appropriate to regulate under Act (eg wrist bands; could include food)

• Section 9F included in the Act in Feb 2014
  – specific power for Secretary to remove individual products that are not therapeutic goods from the Register(eg has tradition of use in Australia as food in the form in which it is presented) after giving notice to sponsor
  – opportunity to make submissions before decision made
  – subject to internal and external (AAT) review
  – decisions to be published on TGA website when effective
Recent developments

- TGA working with DoH, FSANZ, Agriculture and state and territory food/health regulators on a Guidance Tool to help come to a view about whether products for oral use are therapeutic goods or food

- To ensure common understanding of ‘therapeutic goods’ definition and ensure no gaps where regulatory action has to be taken

- Explanatory material (including Guidance Tool) soon to be published on TGA website
5 questions

1. Are there clear rules in place such that products that could be both food and therapeutic goods are regulated as one OR the other?

2. If there are, do the rules ensure that products are regulated under the APPROPRIATE regime?

3. Are there mechanisms for moving products that are in inappropriate regime? (eg section 7; section 9F; section 7AA)

4. What are the criteria for moving products?

5. Are there administrative and coordination processes in place to support effective and timely consideration of individual products, including an accurate and comprehensive Guidance Tool?

Answering questions 1-5 will not resolve all the uncertainty at the interface in relation to individual products.
QUESTIONS/COMMENTS?
The Food Medicine Interface (FMI) Guidance Tool

- The FMI Guidance Tool is:
  - designed to take the user through the relevant definitions in the *Therapeutic Goods Act 1989*
  - used to work out whether particular products are likely to be therapeutic goods or not
  - endorsed by States and Territories and used when regulators need to work out whether or not the TGA is responsible for regulating a particular product.

- When answered in the order in which they are posed, the series of questions reflects the process by which the TGA comes to a view about whether a product at the FMI is likely to be a therapeutic good and therefore regulated by the TGA.
The Food Medicine Interface (FMI) Guidance Tool

What happens after the Tool has been used?

• If judged to be a therapeutic good:
  – the TGA may take action against the importer, exporter, manufacturer or supplier if the product is not included in the ARTG or is otherwise not exempt or approved under the Therapeutic Goods Act 1989.
  – if the product may be a health risk to the public (for example, it contains substances that are only available when prescribed by a health professional), the TGA can publish an alert and order a recall of the product.

• If a product is not a therapeutic good and it is in the ARTG, the TGA can remove it from the ARTG under Section 9F of the Act.

• If not considered to be a therapeutic good, likely to be the responsibility of state and territory food regulators. In such a case the TGA contacts relevant state or territory food regulators for appropriate action to be taken.
Food Medicine Interface

- Presentation is only one of the factors relevant to whether a product is a therapeutic good (usually a medicine) or a food.

- For example, minced or crushed garlic in a bottle that makes claims that ‘garlic relieves cold symptoms’ is likely to be a food, as there is a tradition of use of garlic as food in that form.

- However, if the garlic is concentrated and marketed in a capsule with claims that it can be used to relieve cold and flu symptoms it might be considered a medicine.
GUIDANCE TOOL DIAGRAM – IS THE PRODUCT A “THERAPEUTIC GOOD”?

Q1. Is the product for oral use for humans?
   Yes
   No

Q2. Is there a s.7 declaration that the product is a therapeutic good?
   Yes
   No

Q3. Is the product covered by a s.7AA declaration?
   Yes
   No

Q4. Is the product goods for which there is a standard in the Food Standards Code?
   Yes
   No

Q5. Is the product goods which, in Australia or NZ, have a tradition of use as foods for humans in the form in which the product is presented?
   Yes
   No

Q6. Is the product any of the following:
   (1) represented in any way to be for a therapeutic use?
   (2) likely to be taken [by someone] to be for a therapeutic use because of the way in which it is presented?
   (3) likely to be taken [by someone] to be for a therapeutic use for any other reason?
   Yes
   No

Q7. Is the product in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use?
   Yes
   No

If it is not a biological or medical device, the product is not a therapeutic good. It may be food within state/territory food regulation legislation.

Issue of the food medicine interface does not arise (may be a therapeutic good)

The product is a therapeutic good, not food

The product is not a therapeutic good. It may be food within state/territory food regulation legislation and/or regulated under other state/territory legislation

The product is not a therapeutic good. It is likely to be food within state/territory food regulation legislation and/or regulated under other state/territory legislation

The product is a therapeutic good, not food

The product is a therapeutic good, not food
Example 1

Herbal wine
Example 1

Q1. Is the product for **oral use** for humans?
- Yes
- No

Q2. Is there a **s.7 declaration** that the product is a therapeutic good?
- Yes
- No

Q3. Is the product covered by a **s.7AA declaration**?
- Yes
- No

Q4. Is the product goods for which there is a standard in the **Food Standards** Code?
- Yes
- No

**Issue of the food medicine interface does not arise (may be a therapeutic good)**

**The product is a therapeutic good, not food**

**The product is not a therapeutic good. It may be food within state/territory food regulation legislation and/or regulated under other state/territory legislation**

**The product is not a therapeutic good. It is likely to be food within state/territory food regulation legislation and/or regulated under other state/territory legislation**

Historical document
Example 2

Green tea (bag)
Example 2

Q1. Is the product for **oral use** for humans?
   - No
   - Yes

   **Issue of the food medicine interface does not arise (may be a therapeutic good)**

Q2. Is there a **s.7 declaration** that the product is a therapeutic good?
   - No
   - Yes

   **The product is a therapeutic good, not food**

Q3. Is the product covered by a **s.7AA declaration**?
   - No
   - Yes

   **The product is not a therapeutic good. It may be food within state/territory food regulation legislation and/or regulated under other state/territory legislation**

Q4. Is the product goods for which there is a standard in the **Food Standards Code**?
   - No
   - Yes

   **The product is not a therapeutic good. It is likely to be food within state/territory food regulation legislation and/or regulated under other state/territory legislation**

Q5. Is the product goods which, in Australia or NZ, have a **tradition of use** as foods for humans in the form in which the product is presented?
   - No
   - Yes

   **The product is not a therapeutic good. It is likely to be food within state/territory food regulation legislation and/or regulated under other state/territory legislation**

Historical document
Example 3

Coriander powdered capsule
Example 3

Q1. Is the product for oral use for humans?
   Yes \rightarrow
   No

Q2. Is there a s.7 declaration that the product is a therapeutic good?
   No \rightarrow
   Yes

Q3. Is the product covered by a s.7AA declaration?
   No \rightarrow
   Yes

Q4. Is the product covered by a standard in the Food Standards Code?
   No \rightarrow
   Yes

Q5. Is the product goods which, in Australia or NZ, have a tradition of use as foods for humans in the form in which it is presented?
   Yes \rightarrow
   No

Q6. Is the product any of the following:
   (1) represented in any way to be for a therapeutic use?
   (2) likely to be taken [by someone] to be for a therapeutic use because of the way in which it is presented?
   (3) likely to be taken [by someone] to be for a therapeutic use for any other reason?
   No \rightarrow
   Yes

Q7. Is the product in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use?
   No \rightarrow
   Yes

If it is not a biological or medical device, the product is not a therapeutic good. It may be food within state/territory food regulation legislation.

Yes

No
Example 4

Sports supplements
Example 4

Q1. Is the product for oral use for humans?
   Yes → Issue of the food medicine interface does not arise (may be a therapeutic good)
   No → Q2.

Q2. Is there a s.7 declaration that the product is a therapeutic good?
   Yes → The product is a therapeutic good, not food
   No → Q3.

Q3. Is the product covered by a s.7AA declaration?
   Yes → The product is not a therapeutic good. It may be food within state/territory food regulation legislation and/or regulated under other state/territory legislation
   No → Q4.

Q4. Is the product goods for which there is a standard in the Food Standards Code?
   Yes → The product is not a therapeutic good. It is likely to be food within state/territory food regulation legislation and/or regulated under other state/territory legislation
QUESTIONS/COMMENTS?