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Problems at the Food-Medicine Interface: Neurofolin and Sports Supplements

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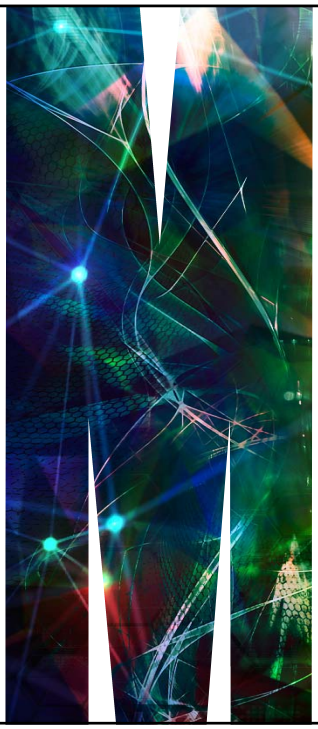

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Food-Medicine Interface

- A product that is swallowed is either a medicine or a food.
- Not automatically a therapeutic good if there are:
  - claims made about a product;
  - products appearance i.e. labelled dietary supplement;
  - product comes in capsules or powders.
- According to the *Therapeutic Goods Act 1989 (the Act)*:
  - Defines a therapeutic good as ***influencing, inhibiting*** or ***modifying*** a physiological process in person
  - States that products are not therapeutic goods if there is a relevant Food Standards Australian New Zealand (FSANZ) standard.
- The overlap between foods and medicines this is referred as the food – medicine interface.

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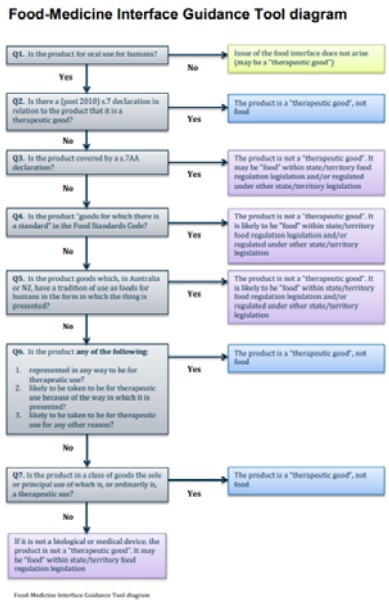
So is it a medicine or a food?

- Food Standards Australia New Zealand (FSANZ) are responsible for food with the Food Standards Code.
- The Code prohibits therapeutic or health claims being made in relation to foods, with the exception of:
  - claims about the benefit of maternal consumption of folate to reduce the risk of foetal neural tube defects;
  - nutrient content claims;
  - some health maintenance claims are permitted;
- Manufacturers, importers and consumers of products need to know whether the products are regulated as therapeutic goods or as food because different regulatory requirements apply.



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Food-Medicine Confusion

- **A lack of clarity** at the food-medicine interface requires further work by the Therapeutics Goods Administration (TGA) and FSANZ.
- Sponsors registering products via **FSANZ self-declare** that their products are beneficial for serious conditions without **independent** assessment of the available evidence.
- The FSANZ Code lacks advertising Code and is administered by State and territory food authorities.
  - Example: FSANZ Standard: 2.9.4 defines Formulated Supplementary Sports Foods as "a product that is specifically formulated to **assist** sports people in achieving specific nutrition or **performance goals**"
  - **Assisting performance** goals may influence the physiological process which therefore makes it a therapeutic good (as per the Act)

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Food for special medical purposes

- Standard 2.9.5 (food for special medical purpose) means:
  - a food specially formulated for the dietary management of individuals who have special medically determined nutrient requirements and;
  - whose dietary management cannot be completely achieved without the use of the food and;
  - is intended to be used under medical supervision.
- A claim in relation to food for special medical purposes **must not**:
  - (a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or
  - (b) compare the food with a good that is:
    - (i) represented in any way to be for therapeutic use; or
    - (ii) likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason.
- Serious concerns about food products being promoted as having ***'special medical purposes'*** For example*:
  - Souvenaid – for patients with mild Alzheimer's
  - Neurofolin – treatment of depression

Claims made by both product would **breech many sections of the Therapeutic goods Advertising Code 2015 if these products were medicines.*

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Neurofolin

- Soluble powder added to water.
- Contains 15 mg of L-methylfolate calcium (L-5MTHF) a bioavailable form of folate.
- Manufactured by a Melbourne based biotechnology company called - *Grünbiotics.*
- Promoted as:

'a food for special medical purposes for the dietary support of depression management.'

*'It may be used **alone** or with antidepressants under the supervision of a healthcare professional.'* *(chemistdirect.com.au)*

'an active form of folate known to be deficient in individuals with depressive disorders and helps nutritionally support mood regulation.' *(neurofolin.com.au)*

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Is Neurofolin a food or a medicine?

Key points:

- There are listed medicines solely containing L-5MTHF where the TGA indication states product presentation **must not** imply or refer to mental illnesses, disorders or condition.
- Mental illnesses such as depression are regarded as **restricted** representations by *the Act*.

- Concerns:
  - Advertising concerns – misleading the public;
  - Insufficient evidence to support the use of L-5MTHF for depression – either as an adjunctive, or especially as a sole therapy;
  - Interests of patient safety need to be considered;
  - Is it a food or a medicine?
    - Neurofolin appears to be a therapeutic good.
    - Subject to the same restrictions as listed complementary medicines.

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Neurofolin

Complaint Outcome & Consultation

- Complaint submitted to TGA on May 2018 alleging a breach of Section 19D(1) of *the Act.*
- Case closed with no detail published.
- Main promotional sites are down but pharmacy websites are still going.

TGA had a public consultation:

- Consultation: Proposed clarification that goods are therapeutic goods - goods containing folate substances in certain circumstances.
- 14 responses including:
  - "Why has it not been possible for the TGA to work with Grünbiotics to amend Neurofolin so it better meets the TGA's own expectations, and unique interpretation, of what an FSMP should be? **Why has the TGA ignored the advice and legal opinion of the eight legal/regulatory consultants and departments provided by Grünbiotics? Many of these were provided at great cost to Grünbiotics and at the request of the TGA. They unanimously expressed the opinion that Neurofolin is an FSMP.** Was it because the opinions provided were not what the TGA wanted to hear?

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Sports Supplements

- Sports supplements can be regulated by either TGA or FSANZ.
- TGA notes that determining whether a sport supplement is a food or medicine can be complex.
  - FSANZ standard 2.9.4 (Formulate Supplementary Sports Food) under review.
- A 2016 survey, 1 in 5 sports supplements contain 1 or more banned substances.
- Australian Sporting Anti-Doping Authority (ASADA) advises no supplement is safe as it may adulterated with prohibited substances.

- Some supplements are advertising:
  - Schedule 4 (prescription-only) substances
  - Schedule 10 (totally prohibited, substances of such danger to health).
- E.g. Selective androgen receptor modulators (SARMs) are a group of experimental, prescription-only medicines sometimes used illegally by bodybuilders.

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Sports Supplements

TGA achievements in 2019:

- July - $10 million fine awarded by Federal Court against Peptide Clinics Pty Ltd to advertising schedule 4 products.
  - Company was in liquidation and did not pay
- September – Redback paid dine $15,210 for advertising of schedule 4 substances
- September - Pharmacare paid fine of $12,600 for advertising a therapeutic good cancelled from the ARTG.

- Key points:
  - Many companies complained about are still promoting illegal products.
  - Are the fines enough for companies that have a revenue of over $5 million per year?

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Questions for the panel

1. How are TGA and FSANZ working together on products that fall within the 'food-medicine' interface?
   a. Particularly in cases where similar products are regulated;
   b. Specifically for food with special medical purposes.
2. How can we help support the important work of the TGA, ACCC and FSANZ when it comes to regulation and misleading claims?

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