

**CROSS-SECTOR INNOVATIONS
&
LEGAL LOOPHOLES**

Agenda

- Warming-up: testing your knowledge on product qualification
- Legal framework for distinction between various types of life sciences products
- Legal consequences on product qualification
- Take home



Product qualification (1)



Product qualification (2)

Forse btw-verlaging voor tandpasta en zonnebrandcrème

Veruit de meeste tandpasta's en zonnebrandmiddelen zijn aan te merken als geneesmiddelen en vallen als zodanig onder het verlaagde btw-tarief van 6% in plaats van het algemene btw-tarief van 21%. Dat heeft de Hoge Raad vrijdag geoordeeld in een zaak die een ondernemer met twee winkelketens aanspande tegen de btw-afdracht volgens het hoge tarief.

Decision of Dutch Supreme Court 11 November 2016
ECLI:NL:HR:2016:2560

Product qualification (3)

Lucovitaal puur en groen

“Improves the digestion of food containing gluten and lactose”



Product qualification (4)



NutriBullet blender

“Pulverizes food at cell level, enabling the body to easily absorb nutrients such as vitamins, mineral and fibers”

Testimonial as to positive effects by former cancer patient

Product qualification (5)

XL-S Medical aangeprezen door René Froger



XLS-Challenge.nl

Legal framework (1)

Product definitions

Medicinal product: any product aimed at curing, preventing or diagnosing a disease

- Article 1.2 Medicinal Products Directive 2001/83
- Article 1.1 (b) Dutch Medicinal Product Act

Food product: any product intended to be ingested by humans

- Article 2 General Food Law Regulation 178/2002
- Article 1 (b) Dutch Commodities Act

Legal framework (2)

Interpretation of product definitions

As to medicinal products, the following criteria were developed in case law as of the '80-ies and are still applied nowadays:

- **Distinction between medicinal products *by presentation* or *by function*** (*aandieningscriterium* vs. *toedieningscriterium*)

As to the distinction between medicinal product and any other product, art. 2.2 Medicinal Products Directive and art. 1 (6) Dutch Act on Medicinal Products provide:

- **When in doubt, rules relating to medicinal products shall prevail**

Legal framework (3)

How about advertising?

It is prohibited to advertise medicinal products without having a market authorization

- Article 6 Medicinal Products Directive
- Article 84 Dutch Medicinal Product Act
- Article 4 Dutch Advertising Code Medicinal Products

For advertising food products, it is permitted to use authorized nutrition & health claims, but it is prohibited to use medical claims

- Recital 3 Claims Regulation 1924/2006 + NVWA guidance # 79
- Article 7.1 (b) Labelling Regulation 1169/2011

Legal framework (4)

What are medical claims exactly?

- *Chardonnay grape seeds offer inflammation mitigating advantages*
- *Aloë Vera benefits digestion or to calm down the bowl system*
- *Black cumic seeds boost the immune system*

Dutch Advertising Code Committee 23 August 2016 ruling on Rain Core and Rain Soul seed mixes.

Bottom line: communications claiming that advertised products improve health problems imply that these products have a medical effect.

Thin line between non-authorized medical claims and authorized disease reduction claims!

Legal framework (5)

What should be understood by “advertising”?

- Depending on source, notion can be pretty broad and not only factual.
- According to Dutch Advertising Code advertising covers *any public and /or systematic direct or indirect recommendation of goods, services or views for the benefit of an advertiser, whether or not using third parties*
- Covers so-called “influencers” → Social Media Code (1 January 2014)
- Can cover client reviews when circulated systematically

Case law (1)



Medicinal product *by presentation* ECJ van Bennekom (227/82)

Facts

- Large quantity of (multi) vitamin preparations traded by Dutch national van Bennekom was seized > Medicinal Products Supply Act.
- Preparations in pharmaceutical form and highly concentrated.
- Van Bennekom did not meet registrations & authorization requirements.
- According to him, products were foodstuffs, not medicinal products.

Ruling

- Concept of “presentation” broadly construed > consumer protection.
- No benchmark for vitamins to qualify as a medicinal product > evaluation on case-by-case basis.
- As long as there is no full harmonization in place, MS may apply their national legislation requiring market authorisation for such products.

Case law (2)



Medicinal product *by function* (ECJ Hecht-Pharma, case C-140/07)

Facts

- Hecht Pharma was marketing a fermented red rice product in the form of capsules presented as food supplements.
- Further marketing in Germany was prohibited, as it contained significant levels of monalin k > inhibitor of cholesterol synthesis.
- In sum, the product was considered to be a medicinal product *by function*, for which no marketing authorisation had been obtained.

Ruling

- Regarding a medicinal product by function, it should be scientifically established that it is capable of restoring / correcting / modifying physiological functions of the human body → assessment case-by-case!

Case law (3)



Food Health Legal
legal and regulatory blog

Melatonine based food supplements (The Hague Court 1 June 2016)

Facts

- Dutch Health Inspectorate (IGZ) had announced enforcement measures regarding various melatonin based food supplement containing > 0,3 mg melatonin marketed by different manufacturers.
- Central announcement of enforcement action via health products association NPN.

Ruling

- Prior to enforcement measures, IGZ should motivate why a particular product qualifies as a medicinal product.
- Each product should be assessed on an individual basis, applying the criteria developed in standing EU case law (Van Bennekom, Hecht i.a.).

Case law (4)



What are *functional foods*? Appeal Court The Hague 7 June 2016

Facts

- Both Unilever and Ablynx had obtained a license from Brussels University (VUB) under certain antibodies patents owned by VUB.
- License Unilever → food products, license Ablynx → medicinal products.
- Under its license, Unilever developed so-called functional foods having certain beneficial effects against infections caused by the rota-virus.
- Ablynx claimed Unilever thereby had operated outside its licensed field.

Ruling

- Unilever's license was directed at non-pharmaceutical products.
- It can target general health benefits but not specific pathogens.

Case law (5)



Food product = medical device Dutch Advertising Code Cie. 2 June 2016

Facts

- Dutch singer René Froger claims he lost 8 kg. thanks to XL-S Medical.
- According to claimant, such claims for food products are prohibited according to art. 12.b Claims Regulation 1924/2006.
- Based on NVWA website info, testimonials re. “before” and “after” are prohibited.

Ruling

- XL-S is medical device → food law not applicable.
- Applicable framework is Medical Device Code (MDC).
- Art. 7.2 MDC prohibits stating the amount of weight loss / time unit, but allows stating achieved results.

Take home (1)

How to obtain pre-market clearance for communication on health products?

- Take guidance from Advertising Code Health Products (*Code Aanprijzing gezondheidsproducten*), applicable to products having a pharmaceutical form and a health related primary function, however without being medicinal products → Commodities Act (*Warenwet*)
- Obtain approval from KOAG / KAG Keuringsraad, whom actively evaluates claims and provides endorsements



Take home (2)



How to deal with enforcement measures?

- In case of violation of applicable laws, usually IGZ and NVWA do not fine immediately, but initially share their intention to do so and offer the opportunity to respond.
- Buy some time by claiming an extension for response.
- Carefully consider if claims made by enforcement authorities are factually & scientifically correct and legally enforceable.



Conclusions



- Begin with the end in mind: what type of product will you be marketing?
- Prevention is better than curing: know the rules!
- Pay careful attention to the grey area of borderline products.
- If and when confronted with enforcement measures.....





KEEP
CALM
AND
CALL
AXON