DEMARCATION BETWEEN PHYTOPHARMACEUTICS AND NEIGHBORING PRODUCT CATEGORIES IN THE EU

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Topics

- Demarcation criteria between different product types
- Regulatory differences between product categories
- Consequences for product-related marketing
Medicinal products – Legal Definition

- Legal definition:

  • Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by *exerting a pharmacological, immunological or metabolic action*, or to making a medical diagnosis

    → Pharmaceutical as a result of product’s mode of action:

    Therapeutic means *and*

    Pharmacological, immunological or metabolic function

    or

  • Any substance or combination of substances presented as having properties for treating or preventing disease in human beings

    → Pharmaceutical as a result of product presentation
### Medicinal product – characteristics (Medical Devices Guidance Document 2.1/3)

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Pharmacological means</td>
<td>Interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-response correlation is indicative of a pharmacological effect.</td>
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<tr>
<td>Immunological means</td>
<td>Action in or on the body by stimulation and/or mobilisation of cells and/or products involved in a specific immune reaction.</td>
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<tr>
<td>Metabolic means</td>
<td>Action which involves an alteration, including stopping, starting or changing the speed of the normal chemical processes participating in, and available for, normal body function.</td>
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Medicinal Products – Authorization Procedures and Consequences for Marketing

- Regulatory Requirements for traditional herbal medicines in order to obtain marketing authorization:
  - marketing authorization procedure proving efficacy, safety and quality to regulative authorities
  - alternatively: Registration procedure for herbal medicines if
    - Traditional use for at least 30 years, with at least 15 of them in the EU
    - Based on this use
      - sufficient evidence for safety of product
      - Efficacy is plausible
    - Restrictions in marketing (mandatory information has to include clarification that indication is based solely on traditional use)
  - alternatively: Registration procedure for homeopathics, if corresponding requirements are met
    - No test of efficacy; safety can be proven based on dilution of substance
    - Restrictions in marketing (no marketing related to specific indications, as efficacy has not been proven)
Substance-based Medical Devices – Legal Definition

- Legal definition:
  - Therapeutic use
  - Absence of pharmacological, immunological or metabolic action, which would be characteristic for a medicinal product
  - Typically a strictly chemical or physical mode of action
    → rarely met in phytopharmaceutics
Medical Devices – Authorization Procedures and Consequences for Marketing

- Regulatory Requirements for Medical Devices:
  - Conformity assessment procedure under consultation of a Notified Body
  - Market access procedure without involvement of competent authorities
    - Consequence: Different from medicinal products, product classification and merchantability can be legally challenged by Competitors
  - Health advertisement law does apply
    - Less restriction than for medicinal products
Food and adjacent product categories – Legal Definition

- Legal definition:
  - **Food and Novel Food** serves primarily nutritional purposes, but can have certain desirable health effects
  - **Foods for particular nutritional uses (dietetic foods)**, specially manufactured to satisfy the particular nutritional requirements of specific groups of people
  - **Nutritional supplements**, typically presented in dosed forms similar to pharmaceuticals but serving the purpose to maintain general nutrition demands

→ Specifically hard to differentiate from medicinal products

→ Dosage of substance is frequently relevant to determine, whether a product has a nutritional or therapeutic purpose (Garlic capsules, etc.)

→ Rule of thumb: Would one plausibly consume the recommended dosage by generals consumption of food
Food Supplements, etc. – Authorization Procedures and Consequences for Marketing

- Regulatory requirements for food and adjacent product categories:
  - Generally no marketing authorization procedure required
    - Consequence: Different from medicinal products, product classification and merchantability can be legally challenged by Competitors
  - Restricted options regarding health-related marketing
    - Not allowed to promote products with disease-related claims (some exemptions for dietetic food)
    - Health-related claims need sufficiently significant and valid proof and in many cases comply with formal requirements (list of formally accepted health claims in the EU)
    - Differentiation between health-related and disease-related claims oftentimes subject to legal disputes and ultimately subjective (“strengthening the immune system” versus “preventing a cold”)
Cosmetics – Legal Definition

- Legal definition:
  - Cosmetics are intended, exclusively or mainly, for cleaning, perfuming, protecting purposes
  - Similar demarcation problems as with food / nutritional supplements and medicinal products:
    → Dosage of substance oftentimes relevant to determine whether product is a cosmetic or a pharmaceutical
Cosmetics – Authorization Procedures and Consequences for Marketing

- Regulatory Requirements for Cosmetics:
  - Generally no marketing authorization procedure required
    - Consequence: Different from medicinal products, product classification and merchantability can be legally challenged by Competitors
  - Restricted options regarding health-related marketing
    - Not allowed to promote products with disease-related claims (some exemptions for dietetic food)
    - Health-related claims need sufficiently significant and valid proof and in many cases comply with formal requirements (list of formally accepted health claims in the EU)
    - Differentiation between health-related and disease-related claims oftentimes subject to legal disputes and ultimately subjective ("preserving a healthy skin" versus "restoring a healthy skin"?)
Conclusion

- Relevant aspects to consider before determining route for market entry for borderline products:
  - Regarding borderline products, legal classification can frequently be determined by product design, product formula or product presentation.
  - Distributing a product as a pharmaceutical generally results in higher requirements regarding market entry and promotion of the product.
  - However, distributing a product as a pharmaceutical holds significant advantages compared to other product categories:
    - Product status cannot be contested
    - Option to promote product with disease-related claims
    - ...
  - Where a product character can be influenced by product design, product formula or product presentation, an reflected individual economic decision on how to introduce the product to the market is required:
    - shall product be part of reimbursement regime of SHI?
    - shall product be sold in pharmacies?
    - shall product be promoted with disease-related claims?
    - ...
ANNEX
Market access - comparison for medical devices and medicinal products

Medical Devices
- Conformity Assessment under consultation of Notified Body
- Market access could be cheaper and quicker
- After Assessment marketable in all member states
- Product character can be contested
- Specific reimbursement regime

Pharmaceuticals
- Marketing authorization procedure
- Market access potentially more expensive and time consuming
- Not necessarily marketable in all member states depending on chosen authorization procedure
- After Authorization product character cannot be contested
- Specific reimbursement regime
Pharmaceuticals – related product types

- **Pharmaceuticals**
  - Therapeutic use and pharmacological, immunological or metabolic function or
  - Claim of such use and functions

- **Medical Devices**
  - Therapeutic use
  - Physical mode of action, no pharmacological, immunological or metabolic function

- **Cosmetics**
  - No therapeutic use

- **Food/Supplements**
  - No therapeutic use in the strict sense
  - Health-preserving character