



The classification of drug and food products

Legal and regulatory aspects

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Content



- **Part 1: Legal aspects**

- Thesis
- Partial harmonization
- Full harmonization
- Thesis: Consequences

- **Part 2: Regulatory aspects**

- Comparison
- Risks for consumer health
- Drug regulation in the borderline area:
Traditional herbal medicinal products

- **Conclusion**

Thesis



Partial harmonization

§ 2 German Drug Act, former version (AMG a.F.) -
§ 1 Foodstuffs and Commodities Act (LMBG)



Full harmonization

§ 2 German Drug Act, current version (AMG n.F.) -
§ 2 German Food and Feed Code (LFGB)



Thesis:
Broadening the term 'food',
curtailing the term 'medicinal product'

Partial harmonization



- § 2 AMG a.F.

“Medicinal products (...) intended (...)
diseases, pains, physical injuries or pathologic complaints to heal, to
alleviate or to prevent(...).“

- Rule-Exception-Relationship of LMBG § 1

“Foodstuffs (...) intended (...) to be consumed (...);
with the exception of substances that are chiefly intended for
other purposes **than for consumption as food for nourishment**
and pleasure.“

Demarcation – Partial harmonization



Predominant purpose of a product
To be consumed as food for nourishment and pleasure
to heal, alleviate or prevent diseases ↔

General opinion of the consumer

Subjective criteria

- Presentation
- Information on packing, package leaflet or advertising e.g., indication, dosage, distribution channel

Objective criteria

- Already existing view of the purpose of comparable products and their usage
 - Possible usage according to their nature (pharmaceutical, medical literature, expert reports, reports by institutes)

Full harmonization



- § 2 AMG n.F.

“**Medicinal products** (...),

1. which (...) presented as having properties for treating, alleviating or preventing (...) diseases or pathological complaints or

2. which (...) may **be used or (...) administered** to (...)

a) (...) restore, correct or modify the physiological functions by exerting a **pharmacological, immunological or metabolic action** (...).“

- § 2 LFGB - Reference to Regulation (EC) 178/2002, Art. 2

“(...) **food**, (...) **intended** to be, or **reasonably expected** to be **ingested** by humans.“

Demarcation – Full harmonization



Subjective criteria	Objective criteria
Presentation drug product	Functional drug product
<ul style="list-style-type: none">• A product which is explicitly described or recommended as such• A product which gives the consumer the conclusive but certain impression that it must have the properties as drug <p>The purpose by the manufacturer, which is recognizable for the consumer should be taken into consideration.</p>	<p>Consideration of all the characteristics of the product</p> <p>especially :</p> <ul style="list-style-type: none">• the composition• the pharmacological properties• the risks• the modalities for its usage• the extent of the distribution• familiarity among the consumer

Thesis: Consequences



- Thesis

- Consequences

Broadening
the term 'food'

Curtailing
the term 'medicinal
product'

Opening
the food sector for drug
products

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Increase
in ambivalent substances

Content



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Regulatory aspects



- Comparison

Parameter		Medicinal product	Food product
Pre-market control	Quality control	Yes	No
	Efficacy control	Yes	Yes ¹⁾
	Safety control	Yes	No
Post-market control	Pharmacovigilance-system	Yes	No

¹⁾ Applies to: Claims in the scope of Regulation (EC) No. 1924/2006: Nutrition and health claims made on foods.

Regulatory aspects



- Risks for consumer health:

Medicinal product	Pharmacovigilance-system	<p>Kava Kava- / Kavain- containing drugs: BfArM³⁾ 2002:</p> <p>39 spontaneously reported undesirable effects 18 spontaneously reported serious side effects</p> <p>↓</p> <p>Withdrawal of marketing authorisations</p>
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Food product	<p>Kava Kava-containing food products: BgVV⁴⁾ 2002 – based on the BfArM-decision:</p> <p>↓</p> <p>BgVV warned of such food products and declared that they are no longer to be marketed in Germany as food</p>
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³⁾BfArM: Federal Institute for Drugs and Medical Devices

⁴⁾BgVV: Federal Institute of Consumer Protection and Veterinary Medicine

Regulation of THMP's



- Directive 2004/24/EC:
Traditional herbal medicinal products (THMP)

Aims

- Health protection, free movement of goods
 - Elimination of national differences and uncertainties concerning THMP's
 - Creation of a harmonized legal framework for THMP's

Regulation of THMP's



- 3-Stage model: Influence on harmonization

Type of reference	Directive 2004/24/EC
Product specific	THMP registrations granted by other Member States shall to be taken into account, further data may be required
	The MRP ⁵⁾ / DCP ⁶⁾ does not apply
Community monograph	Shall be taken into account, further data may be required
	The MRP ⁵⁾ / DCP ⁶⁾ shall apply
List position	Additional data to assess the safety and the traditional use of the product must not be provided Refusals due to the safety and traditional use do not apply
	The MRP ⁵⁾ / DCP ⁶⁾ shall apply

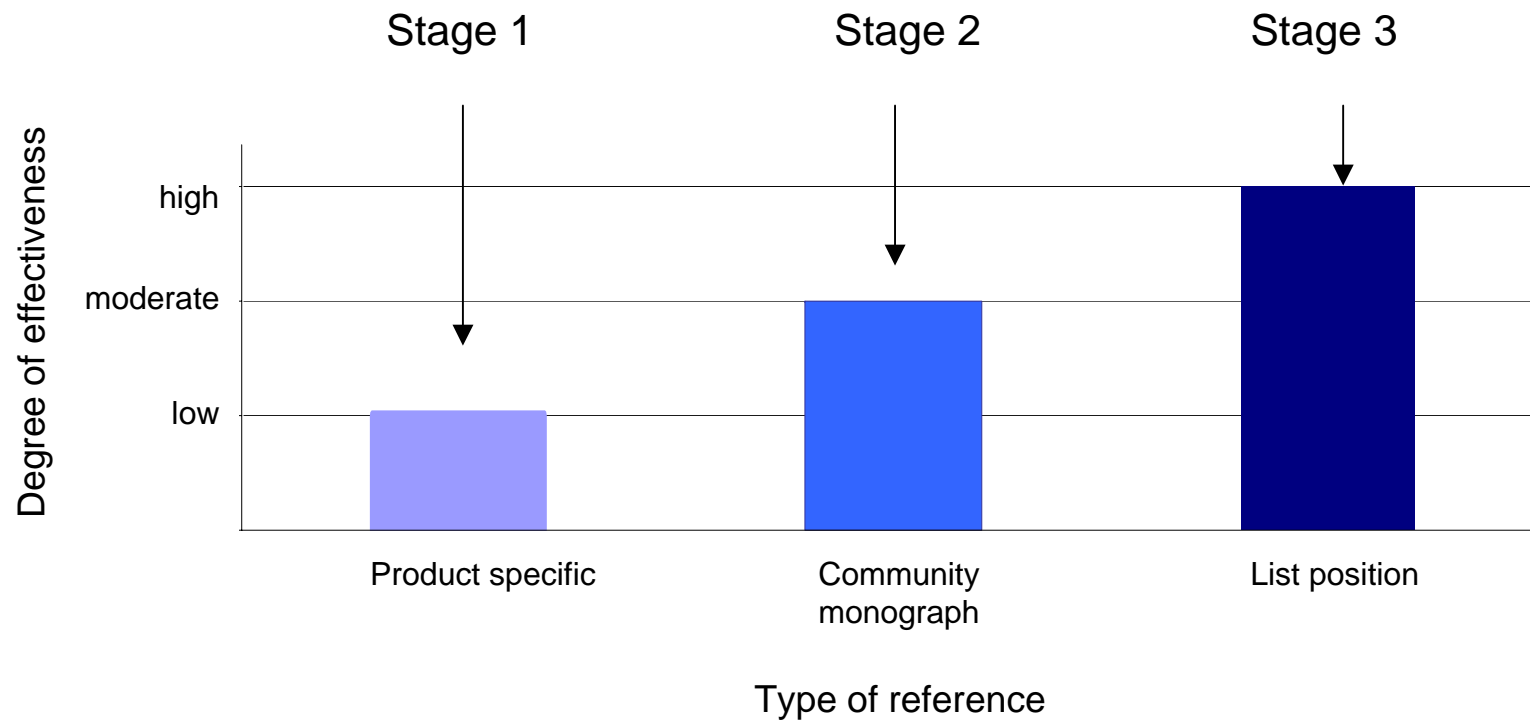
⁵⁾MRP: Mutual Recognition Procedure

⁶⁾DCP: Decentralized Procedure

Regulation of THMP's



- 3-Stage model: Influence on harmonization



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Conclusion



- Current regulatory situation in the food sector acc. to EU law

- EU-wide approval of nutrition and health claims
- No control of adverse reactions
- No quality control

- Recommendation to strengthen the regulatory system of THMP's

Increase of attractiveness in the regulation of THMP's, e.g.

- Community monographs should become legally binding
- Community monographs / List positions should be created and adopted in shorter periods of time
- Indications should clearly differ from health-related claims for food, means a clear disease-relation should be established



**Thank you
very much for your attention!**