



Why urgent regulatory change is needed in Europe to safeguard Ayurveda

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3+ millennia of healthcare

Plant-based medicine



Mineral-based medicine



Energy-based medicine



Homeopathy

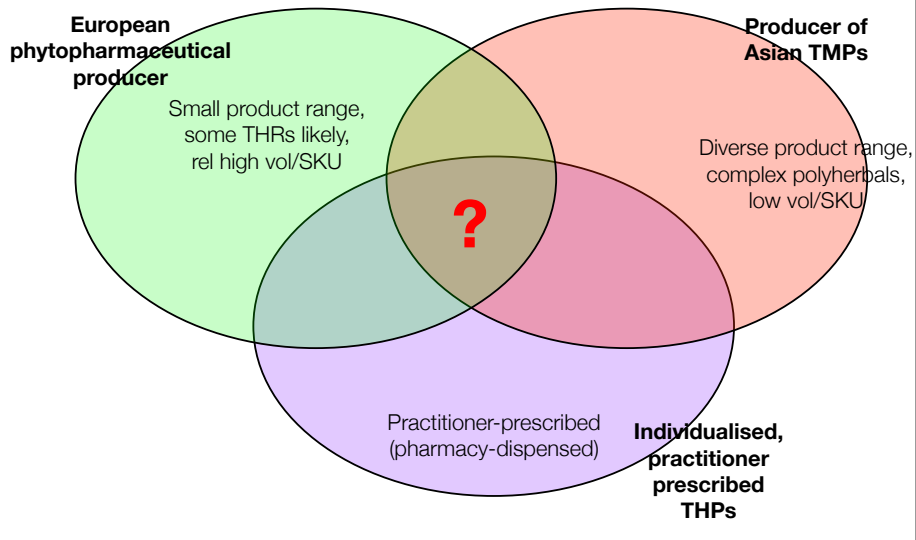


New-to-nature pharmaceutical-based medicine

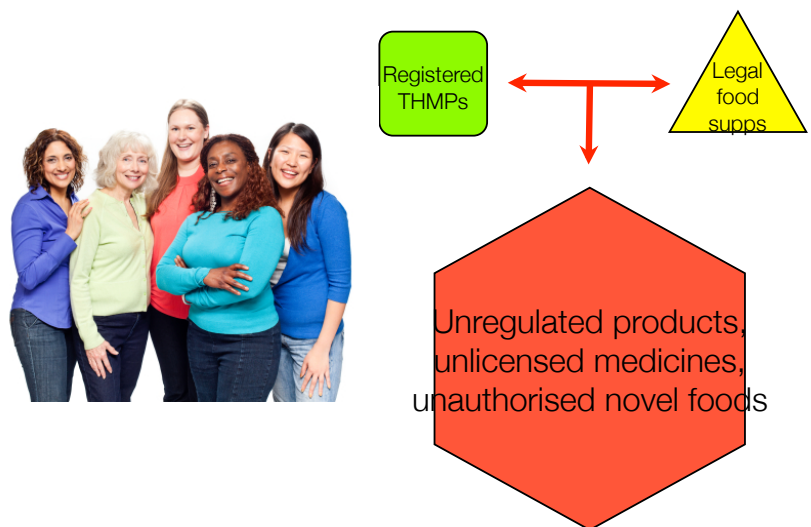


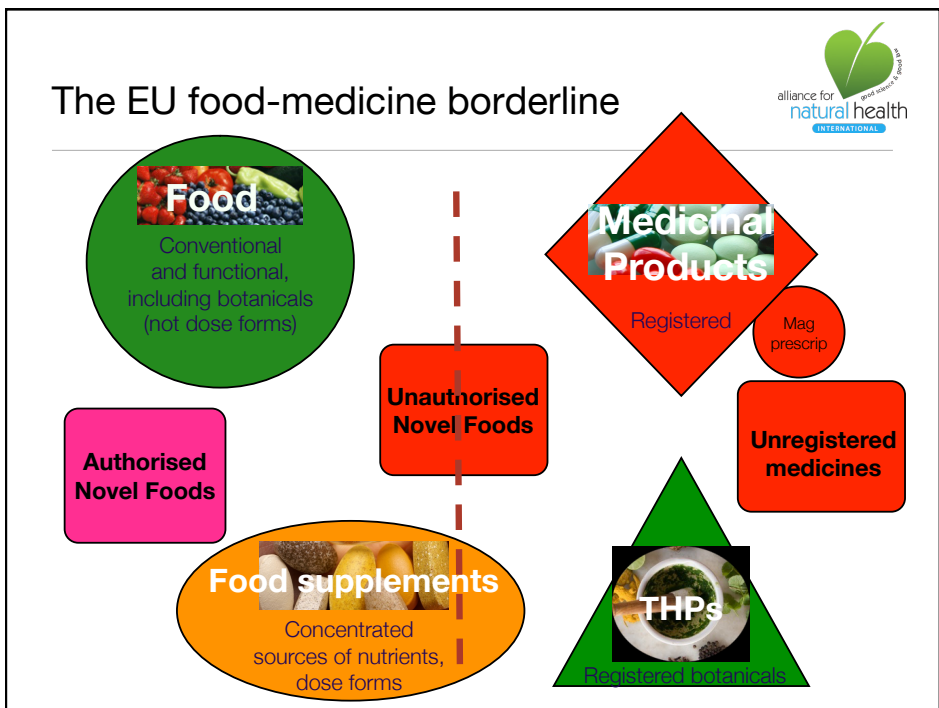
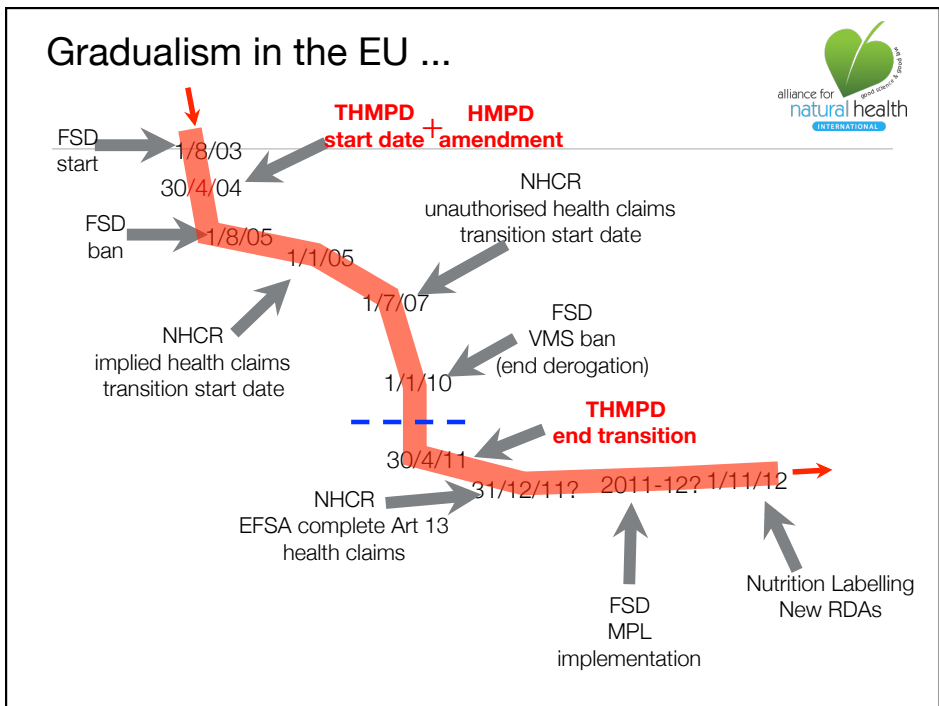
3,000 BC 2,000 BC 1,000 BC 0 AD 1,000 AD 2,000 AD

Different challenges, different sectors



Consumer safety: The risk of falling between 2 'stools'





General regulatory challenges

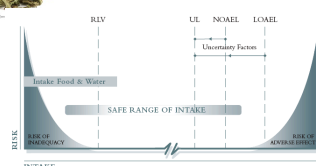
1

Which herb(s)?



2

How much?



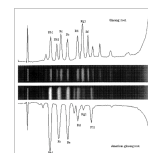
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Claims?

4

QC?

- Only ~200 registrations in 27 MSs
- Only ~30 herb species



Specific challenges for Asian products

- Practice and self-care with indigenous and traditional systems of Asian medicine deeply threatened after 30 April 2011
- THMPD fails to meet originally conceived objective of providing appropriate regulatory regime for diverse range of THMPs
- Regime inaccessible for Asian THPs: disproportionate and discriminatory
- THMPD recognised by EC as “inappropriate” for holistic traditions such as TCM and Ayurveda
- Many Asian products may be excluded from food supplement regime
- Many herbs regarded by CAs as novel foods or medicinal



Specific challenges of THMPD

Eligibility challenges

- '30-year rule'; 15 year EU usage
- Not intended for use by practitioners
- Claims limited e.g. minor ailments only
- Non-herbal ingredients excluded
- Innovative combinations excluded

Technical challenges

- Pharmaceutical standards derived for use with synthetic drugs
- Stability testing for complex formulae
- Insufficient monographs
- Insufficiently transparent

Financial challenges

- Cost per registration



Major challenges of THMPD



- '30-year rule'; 15 year EU usage
- Pharmaceutical standards (including stability and genotoxicity testing) derived from allopathic models
- Stability testing for complex formulae
- Not intended for use by practitioners
- Claims limited e.g. minor ailments only
- Non-herbal ingredients excluded
- Innovative combinations
- Cost per registration



= disproportionate, non-transparent and discriminatory

Where do we go from here?



Position paper released 31/8/10

How quickly do we need to act?



Short-term actions

- a. Improvement of the food supplements regime EU-wide
- b. Judicial review of the THMPD



Longer-term action

- c. Facilitation of a new regulatory framework for traditional medicinal products

Key immediate requirements



- Funding
- Critical path approach
- Peer-review science publications
- Effective lobbying
- Consistent communications (unified voice)
- 'Support' from parliamentarians, governments, trade associations
- Networking



Getting the word out to elected representatives in the EU



