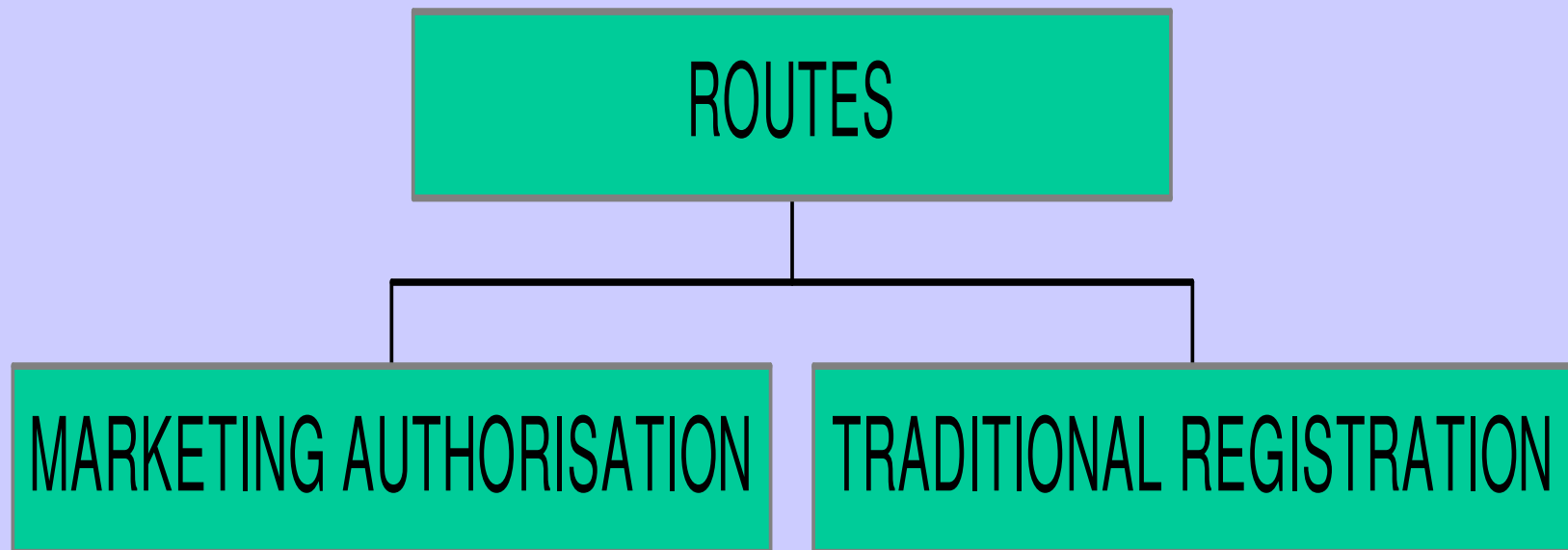


**REGULATORY REQUIREMENTS
FOR MARKETING OF
AYURVEDIC PRODUCTS (herbal)
in EUROPE**

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TWO ROUTES TO MARKET



MARKETING AUTHORISATION

- To market a product as a licensed medicine with approved indications

Requirements ---

- Product quality
- Product safety
- Product efficacy (clinical studies) of international standards .

TRADITIONAL REGISTRATION under THMPD

To market a product under the EU Directive on Traditional herbal medicines that came into force on 30th April '04

Requirements -

- Product quality
- Product safety
- Evidence of traditional use

EU REGULATIONS ON AYURVEDIC PRODUCTS

KEY DATES

DATE A ---APRIL 2004 (new directive on THMP comes into force)

DATE B ---OCTOBER 2005 (all member states start to comply with the new directive --- MHRA ready for licensing)

DATE C ---APRIL 2011(all products must comply - --7 years transitional period for our existing products).

THMPD

- Simplified registration procedure for herbal products which fulfil the following criteria
 - use without supervision of medical practitioners
 - specified strength
 - oral/external or inhalation only
 - Evidence of Traditional use
 - Traditional use shows not harmful .

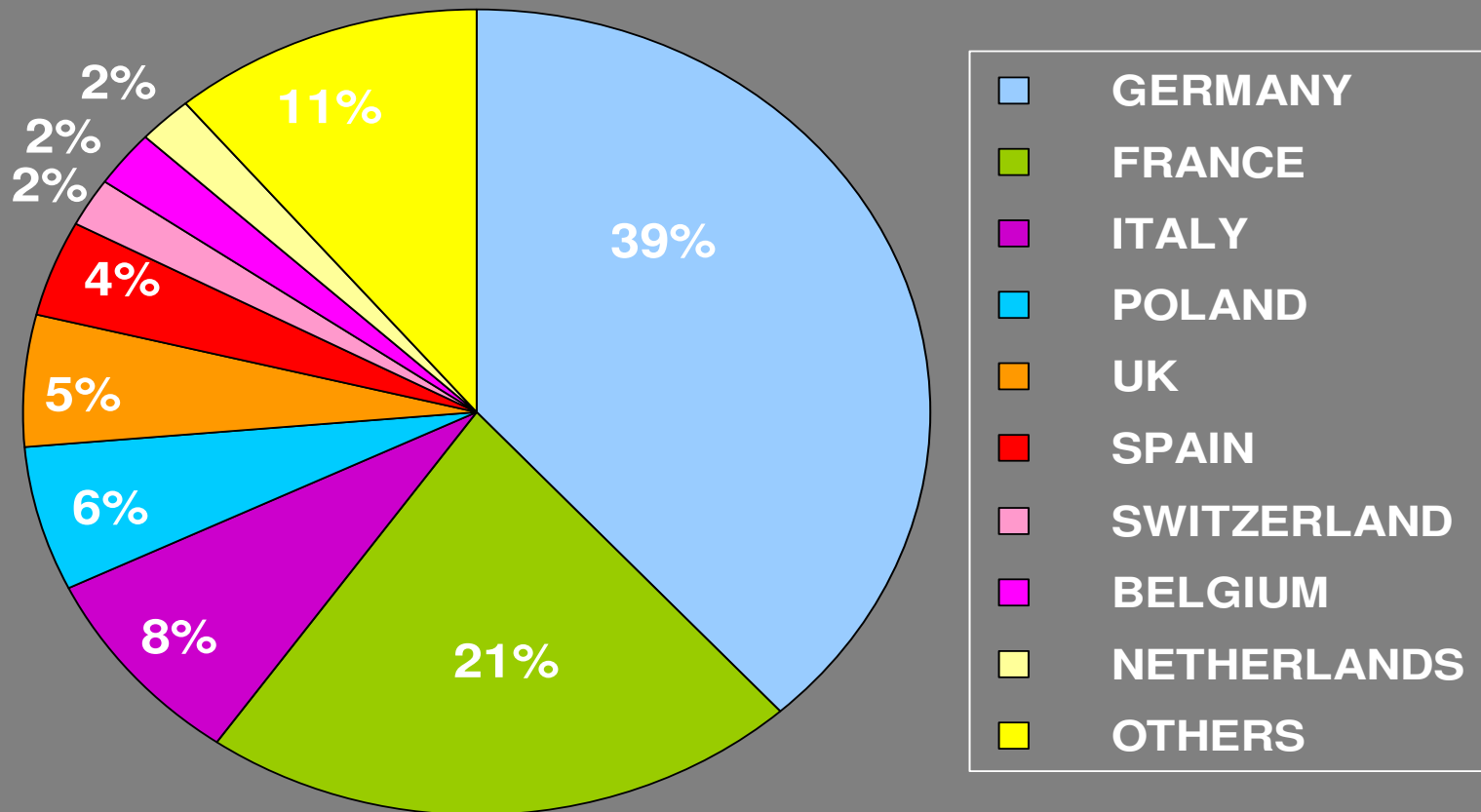
In brief the QUALITY parameters for all herbal products will be more or less the same in both the Marketing Authorisation and THMPD registration with the exception of demonstrating efficacy as this is replaced by the historical / traditional use of the products in THMPD.

Timelimits for licensing/registration

2011

Germany & France dominate on the European herbal market

Total Market 09/2003-09/2004: ~ 3.7 billion € ex-factory



Source: IMS 2005

CHALLENGES FOR AYURVEDIC PRODUCTS

- Important ayurvedic formulations like Chyawanprash are a complex combinations of ingredients /constituents .
- Constituents vary with source and environmental factors
- No single active ingredient responsible for the broad therapeutic effects associated with the complex formulations .

CHALLENGES FOR AYURVEDIC PRODUCTS

- Standardisation of individual herbs to give a defined constituent quite difficult to achieve in every batch manufactured .
- Safety studies needed to establish any interactions with conventional drugs.
- Last but not the least scarcity of clinical data of international standard (though this is replaced in the herbals directive by the bibliographic reference of safe use) .

WAY FORWARD

- Compliance on quality (GACP and GMP)
- Compliance on safety
- Documentation of bibliographic evidence of safe use with reference to ayurvedic pharmacopoea ,text books and available scientific literature .

Thank you