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HMPC COMMUNITY MONOGRAPHS AND LIST ENTRIES: NATIONAL REGULATOR'S PERSPECTIVE ON IMPLEMENTATION

Heribert PITTNER

AGES PharmMed, Austria

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Directive 2004/24

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- Issued on 31 March 2004
- Member States should comply with this directive by 30 October 2005
- As of 30 June 2007, three Member States had not yet implemented Directive 2004/24 into national law

THMP applications and registrations as of 30 June 2007

	Applications	Registrations
Austria	6	1
Belgium	5	-
Czech Republic	1	-
Denmark	2	-
Germany	27	4
Spain	6	-
Finland	1	-
France	4	-
Greece	12	-
Italy	4	-
Latvia	1	-
Lithuania	4	-
Netherlands	2	2
Poland	2	-
Sweden	7	-
Slovenia	3	2
Slovakia	1	-
United Kingdom	26	4
Total	**114**	**13**

HMPC Meetings 2004 - 2007

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September 2004 – August 2007:

18 HMPC Meetings

8 Meetings of the HMPC Drafting Group on Lists and Monographs (November 2004 – January 2006)

9 Meetings of the MLWP

(Since March 2006)

Why so few THMPs until now?

Although HMPC has created several guidelines on THMPs during the last years, there is still a lot of uncertainty both in industry and among regulators.

“Well established use“ or “Traditional use“?

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- When a monograph / list entry is available, this will help to decide on the adequate procedure
- When no monograph is available:

  - Extent and quality of the clinical documentation?

  - Indications (Prescription only or OTC?)

What to do?

- Request for registration as THMP for which a full marketing authorisation has been given previously
- A full authorisation was granted for a HMP in one MS, while in another MS a request for registration as THMP is submitted.

What to do? (Contd.)

- The traditional use for 30 years has been demonstrated for two single herbal preparations, but not for the combination.
- Implementation of Directive 2004 to “old“ HMPs until 2011: Immediate action or “Wait and see?“

Queries

- “It is both too difficult and too expensive to submit the results of the pharmaceutical tests in full length“
- Request for mutagenicity data for THMPs

Queries (contd.)

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- Safety data for herbal medicinal products with a tradition outside Europe (e.g. TCM, Ayurvedic Medicine)?
- Are indications such as “prostatic hypertrophy“ or „diabetes mellitus“ possible for registrations as THMPs?

Advantages of List Entries for THMPs:

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When a list entry has been finalised:

- Safety has to be accepted by all national authorities
- Plausibility of traditional use has to be accepted by all national authorities
- Possibility of community procedures

Advantages of Monographs for HMPs with Well-established use

- Although HMPC monographs are not legally binding to national authorities, by the time existing monographs will harmonise the requirements for authorisation / registration and the different product informations
- In case of a referral, HMPC (and CHMP) will decide in line with the content of the monographs adopted by HMPC

Theoretical risks for registrations of THMPs:

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Until now:

- No request to HMPC on the adequacy of long-standing use
- Not one MRP for any THMP
- Not one referral to EMEA in relation to a THMP
- Not one referral to EMEA in relation to other products containing herbal substances

Conclusions:

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1. HMPC monographs and list entries are of importance and of value for the authorisation / registration and harmonisation of HMPs in Europe.
2. It is essential that more regulatory experience is gained with THMPs.
3. Member States should encourage their HMPC / MLWP delegates to take over rapporteurships for herbal monographs and list entries.

Conclusions (contd.)

4. Regulators in the NCAs should handle applications for authorisation of HMPs with well-established use and for registration of THMPs in a pragmatic and flexible way
5. Applicants should not only consider the risks, but also the chances given by Directive 2004/24.

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