International Association
of
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Guiding Principle for Regulatory Practise
For the development of the regulatory practise we think that "proportionality/balance" will be a pragmatic guiding principle.
Here follow 2 examples:

Fees:
Mostly homeopathic medicinal products and anthroposophic medicinal products manufactured according to homeopathic pharmacopoeial procedures do not yield a very high turnover. They are part of a range of products for prescribers/users. Too high fees will make it impossible for applicants to register the products in MRP/DcP or will tend to create a monopole.

Safety data:
A *well known* homeopathic stock in a concentration of 1:10 000 is present in an amount that is comparable to the allowed range of unidentified impurities in *new* drug substances.
Safety requirements of well known homeopathic stocks should not be overproportionate.

Further Legal Development for Homeopathic Medicinal Products
(including anthroposophic medicinal products manufactured by a homeopathic pharmacopoeial procedure)

We think, that the implementation of article 16.2 of Directive 2001/83 should be made mandatory for Member States. To be really helpful, the implementation must take place according to the needs of the stakeholders in the particular Member State.

A 16.2 procedure without proof of efficacy, as already practised in CH and NL may be a good option for a part of the concerning products.
The concerning medicinal products, e.g. injectables for subcutaneous use, could in that case be on prescription.

Further Legal Development for Anthroposophic Medicinal Products not Manufactured by Homeopathic Procedures

The IAAP strongly supports the setting up of special adequate rules for these medicinal products as these are still not ruled by 2001/83 as amended.
The concerning products are comparable to homeopathic medicinal products, because they are most particularly characterised by their manufacturing procedure and they are not meant to act within the pharmacological model "molecule on a receptor". As homeopathic medicinal products they are mostly prepared from natural raw materials (e.g. minerals, plants).
The Competent Authorities are the Officials that are dealing with the assessment of this kind of medicines.

The "Anthroposophic Pharmaceutical Codex" APC that can be downloaded from the internet at www.iaap.org.uk contains all relevant definitions/information to make the implementation into the Law possible.