

Fixed combination herbal medicinal products from non-European traditions provide solutions for multi-factorial diseases – the example of Tibetan Medicine

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Objective

Provide a contribution to the discussion why fixed combination herbal medicinal products from non-European Medical Traditions should have a rightful place in the regulatory landscape in Europe.

Materials and Methods

Background to the origin of the formula Padma 28 and an introduction to the rational principles of Tibetan medicine - an example of a non-European Medical Tradition – are presented.

Tibetan herbal medicinal products are fixed combinations of many mainly herbal powdered drugs. Based on logical and rational principles, the compounding process leads de facto to a “new herb” designed to optimise efficacy and minimise side effects.

Data from studies with the formula Padma 28 are used as an example.

Results

Data from double blind randomised clinical studies with Padma 28 in Arterial Occlusive Disease (AOD, intermittent claudication) attribute a high level of efficacy to Padma 28 (evidence level 1b). Further in-vitro and ex-vivo data support the clinical data on a biochemical and immunological level (effects on currently accepted risk factors and mechanisms leading to AOD).

Conclusion

These findings suggest that fixed combination herbal medicinal products may be particularly well suited to act on multi-factorial diseases and seem to confirm the rationality of the traditional method of compounding.

We propose that these products are to be judged on their efficacy and that the compounding principles of the medicinal system of their origin are to be acknowledged as justification of their combination.