# Complementary and alternative therapies for patients today and tomorrow

## *The legal and policy framework of CAM in Europe*

Workshop at the European Parliament
16 October 2017- European Parliament, Brussels

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Sante B4: Medical products: quality, safety, innovation

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# Background

- *Products used in complementary and alternative medicine, if they are medicinal products as defined in Community law, must comply with the strict requirements regarding quality, safety and efficacy laid down in that law.*
- *Medicines have to fulfil strict requirements regarding quality, safety and efficacy laid down in Community law*

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# Background

- *In order to enable certain of these products to be placed on the market, the Community adopted two directives regarding **homeopathic** (Directive 92/73/EC of the Council) and **traditional herbal medicinal products** (Directive 2004/24/EC of the Parliament and the Council) introducing a simplified registration procedure whilst maintaining an adequate level of protection of public health and safety*

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# Traditional herbal medicinal products

- *Traditional Herbal Medicinal products Directive 2004/24/EC*
- *No particulars and documents on tests and trials on safety and efficacy*
- *Plausible level of evidence of the medicinal use throughout a period of at least 30 years including 15 years in the Union*
- *Other routes of autorisation: well-established use or normal procedure for medicinal products*

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# State of play

- *Products can be marketed either as food or as pharmaceutical products*

- *Member States responsibility to classify on a case by case basis depending of the presentation and claimed effect*

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# State of play

- *Between Dec 15 and today, 2629 applications have been received*

- *at least 1577 traditional use registrations granted*

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# State of play

- *Commission Decision 2008/911/EC of 21 November 2008 establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products.*
- *Examples: Melaleuca alternifolia, … ongoing adoption for Sideritis herba and Valerianae radix*

- *After a scientific assessment by EMA*

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# Challenge

- *REFIT Platform Opinion on the submission by businesses on the Traditional Herbal Medicinal Products Directive: adoption: 07/06/2017*
- *Divergence in implementation and difference in uptake of THMP across Europe, possible simplification*
- *Conclusion: waiting the results of the Refit evaluation of the Regulation on health claims prior to taking any decision on the herbal legislation*

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# Homeopathics medicinal products

- *simplified registration procedure applies to homeopathic medicinal products that are administered orally or externally, that have no specific indication on the labelling and that are sufficiently diluted to guarantee the safety of the product*
- *main focus for the application for registration is the quality of the homeopathic medicinal product*

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*Thank you for your attention*

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