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Veterinary phytotherapy, the history of (herbal) veterinary medicinal law, the recent legal situation in Switzerland and some aspects of former German law

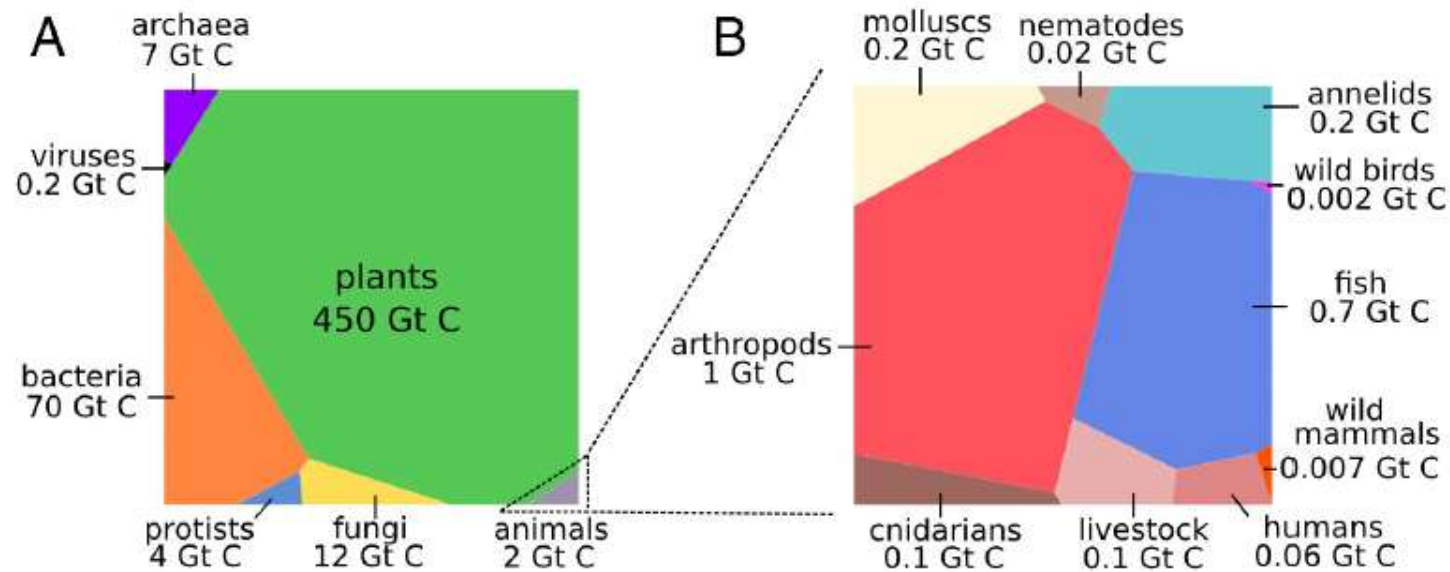
Michael Walkenhorst, 2nd MedPlants4Vet –Training – School,
Santarem, 10.-12. December 2025

**Welcome to the world of herbs, spices, medicinal plants,
herbal drugs, herbal medicines, VMP, HVMP, etc. ...**

- ... but first of all some overall aspects and a «warming up» in our training school.

Live weight mass of all human, livestock and companion animals compared to all other landliving vertebrates inclusive birds, reptiles and amphibians

World's biomass (in Gt C)

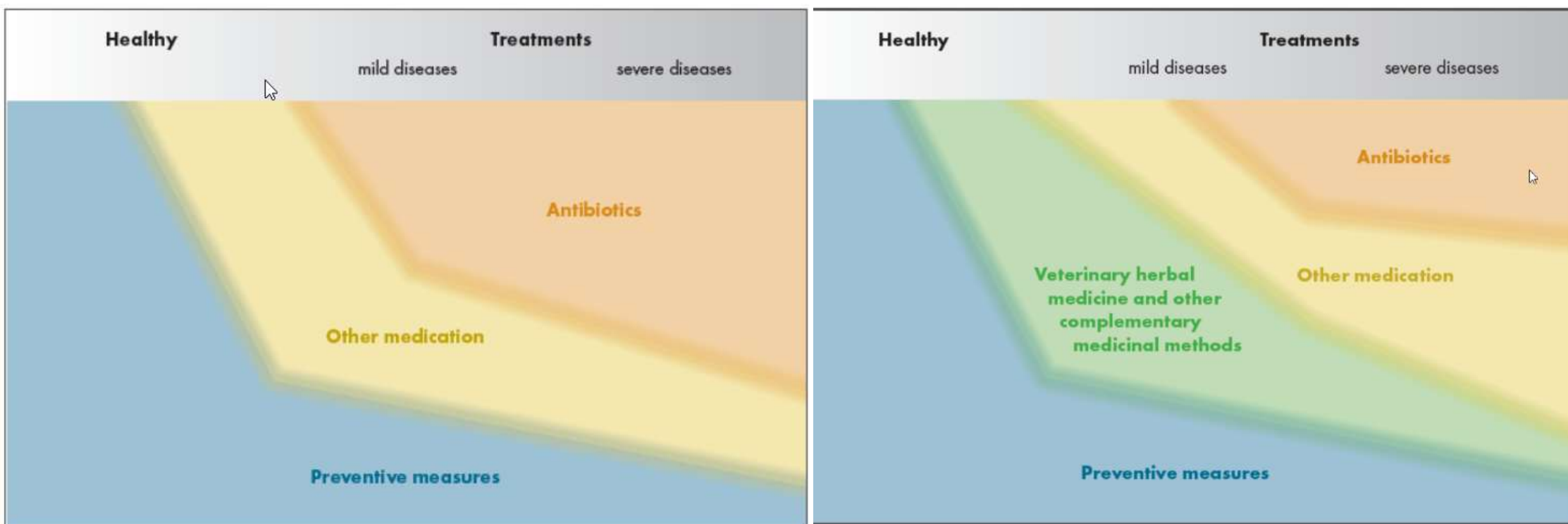


Bar-On et al. 2018

Recent challenges in the animal sector

- sustainable and productive livestock
- healthy and safe companion animals
- antimicrobial resistance
- anti-parasitological resistance

Herbal veterinary medicine as a first line treatment bear the potential to reduce the use of antimicrobials and other animal treatment related xenobiotics



Organic farming regulations

REGULATIONS

Council Regulation (EC) No 834/2007

of 28 June 2007

on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91

REGULATIONS

COMMISSION REGULATION (EC) No 889/2008

of 5 September 2008

laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control

Organic livestock production rules ...

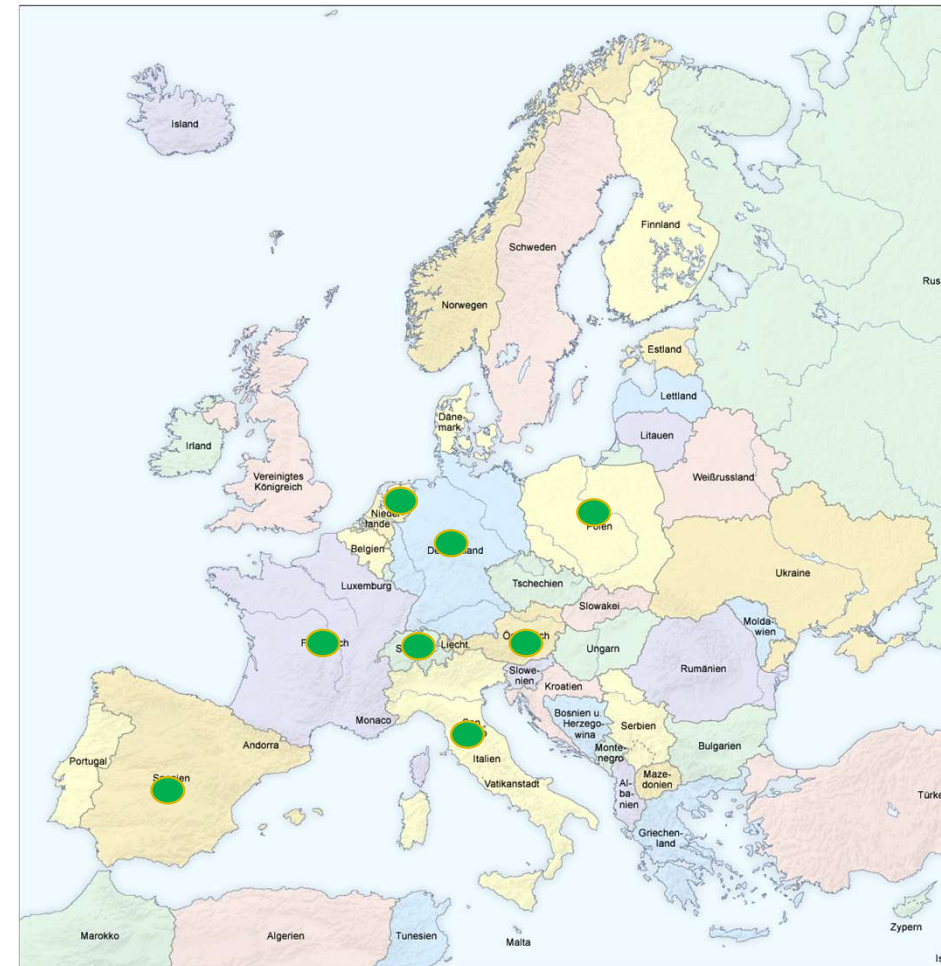
(e) with regard to disease prevention and veterinary treatment:

(i) disease prevention shall be based on breed and strain selection, husbandry management practices, high quality feed and exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions;

(ii) disease shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined;

There is (still rising) interest of veterinarians in the use of medicinal plants to treat animal diseases

- officially recognised further education title for veterinary herbal medicine in Austria, Germany and Switzerland
- a professional master programme in veterinary phytotherapy exists in Italy, University of Bologna
- research about the veterinary pharmacology of medicinal plants in Poland (University of Warsaw), The Netherlands (University of Utrecht) and Switzerland (University of Bern)



There is an active international scientific network about Medicinal Plants and Natural Products in Animal Healthcare and Veterinary Medicine under the umbrella of the Society for Medicinal Plants and Natural Product Research

<https://ga-society.org/activities/animal-health-network/>

Society for Medicinal Plant and
Natural Product Research



Gesellschaft für Arzneipflanzen-
und Naturstoff-Forschung e.V.

GA-networking group on Medicinal Plants and Natural Products in Animal Healthcare and Veterinary Medicine

We are a worldwide group of scientists interested in the use of medicinal plants and natural products in animal healthcare and veterinary medicine.

We represent diverse professions, such as veterinarians, pharmacists, agronomists, biologists etc., and we have diverse backgrounds, like research, practice or industry. By now we have members from five continents.

Get in touch

ga-animalhealth@ga-online.org

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Herbal veterinary medicinal products are:

- Sustainable
- Renewable raw materials
- Easily and completely biodegradable
- Local available
- Diverse



**= A UNIQUE
SELLING POINT**



- Creative tool for innovative products based on a long tradition
- High demand from veterinarians, (especially organic) livestock breeders, companion animal owners, society
- potential to reduce the use of antimicrobials and other xenobiotics



Plant ingredients

- **Primary plant ingredients:**
 - fat
 - protein
 - carbohydrates
- storage of energy – constructive substances for plants
- feeding

Plant ingredients

- Plant secondary metabolites
- Substances in small amounts which fulfill specific and very diverse „jobs“ for the plants
- Why do they do this?

Plant ingredients

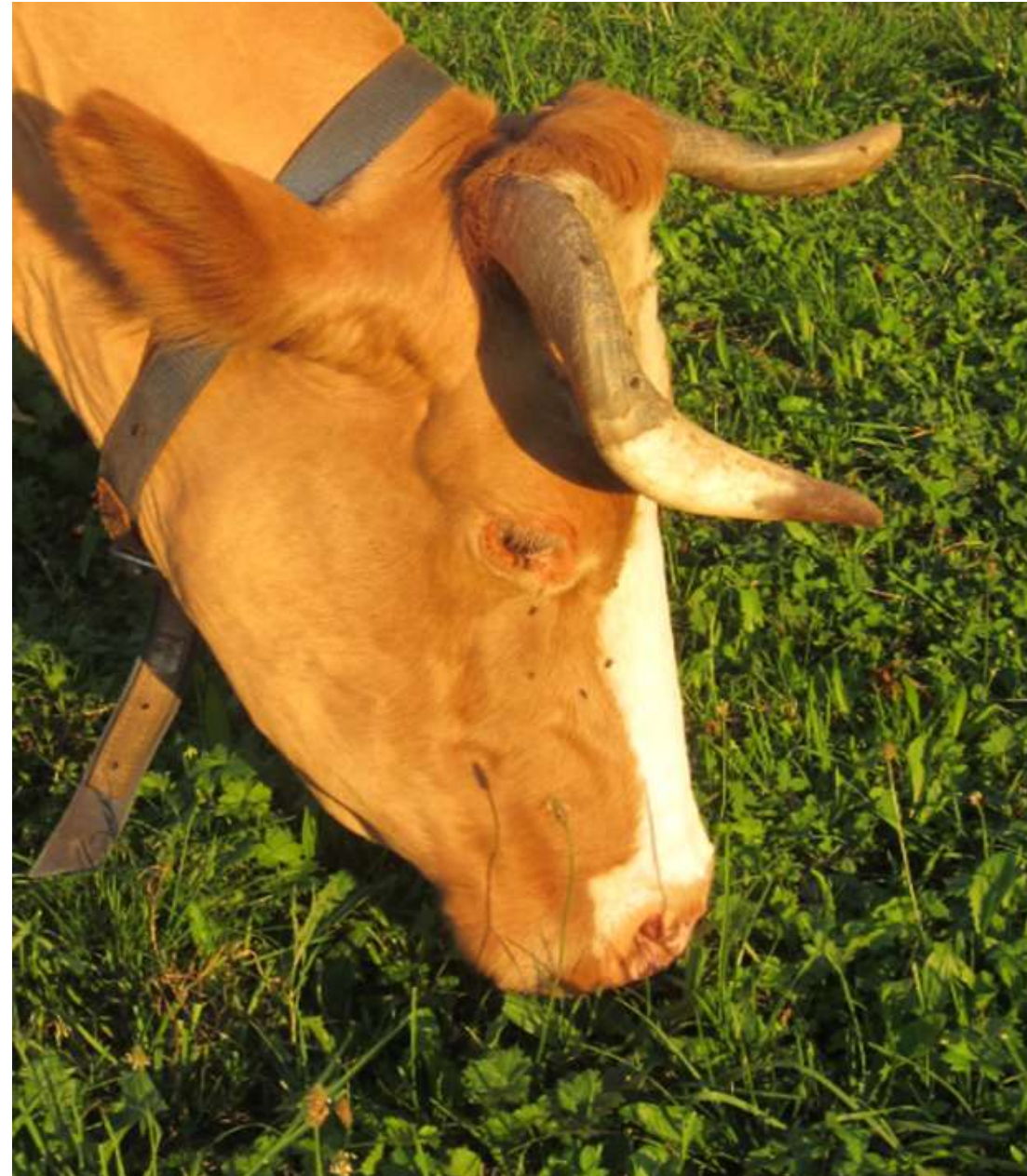
- **Plant secondary metabolites**
- Substances in small amounts which fulfill specific and very diverse „jobs“ for the plants
- Why do they do this?
- Plants cannot run (away)!
 - Protection against diseases (bacteria, fungi, viruses), insects and other herbivores
 - Communication
 - Sex and multiplication
 - 1'000'000 existent, 100'000 known, only 10'000 well analysed

Secondary plant metabolites

- Chemically very diverse
- Plants and their extracts are always complex mixtures of substances of diverse chemical structure
- But these complex mixtures are in advantage for many aspects for example regarding the development of antimicrobial resistance.
- „Multi Target Drugs“

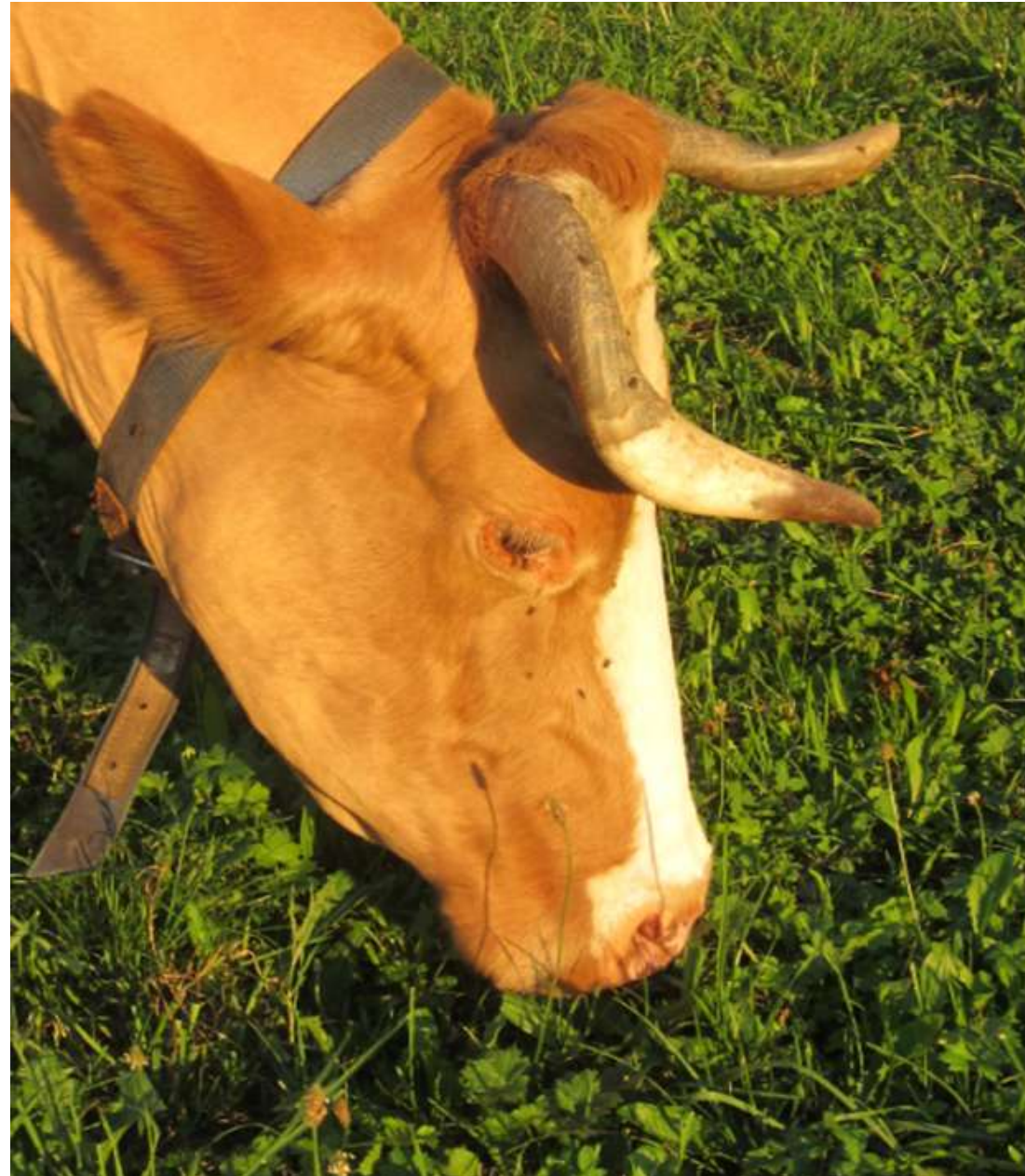
Phytochemicals in feed and food

- Out of the approximately 1 Mio **phytochemical substances** 10-20% are known and of 1-2% at least some aspects of their bioactivity is studied
- Having in mind the high plant variety of the diverse European **pasture agro-ecosystems** we can assume the intake of an incalculable amount of known or unknown phytochemical substances (including toxic ones) via pasturing or outdoor running livestock
- Herbivores and Omnivores developed effective detoxifying systems through **co-evolution with plants**



Phytochemicals in feed and food

- The natural intake of phytochemicals comprises always a **broad spectrum** of different substances at the same time.
- The intake of one single phytochemical substance in high amounts in an otherwise poor-in-phytochemicals-diet is highly uncertain (apart from toxicological studies)
- **Human's diet** is based on wild or domesticated pasturing animals since the very beginning of human being
- There is a rising evidence that meat and milk produced based on biodiverse pastures is **healthier** than beef from feedlots



... after warming up – let's go into detail.

Overview

- Medicinal plants in animal health
- About markets and regulations
- Some aspects of medicinal plants and herbal drugs in veterinary medicinal products law
- The German and Swiss example

Overview

- **Medicinal plants in animal health**
- About markets and regulations
- Some aspects of medicinal plants and herbal drugs in veterinary medicinal products law
- The German and Swiss example

Medicinal plants in animal health – sources of knowledge

- **Animal self medication**
- Historical and recent experience of animal owners, animal care taker and veterinarians - Ethnoveterinary research
- Modern pharmacognostic, in vitro, in vivo, and (human and animal) clinical research regarding

There is evidence that animals self medicate with plants

scientific reports

OPEN **Active self-treatment of a facial wound with a biologically active plant by a male Sumatran orangutan**

Isabelle B. Laumer^{1,2}, Arif Rahman², Tri Rahmaeti², Ulil Azhari³, Hermansyah⁴, Sri Suci Utami Atmoko⁵ & Caroline Schuppli¹



Figure 1. Process of wound healing. Rakus fed on and later applied the masticated leaves of *Fibraurea tinctoria* to his facial wound on June 25. On June 26 he was again observed feeding on *Fibraurea tinctoria* leaves (see photo). By June 30 the wound was closed and by August 25 was barely visible anymore.

Laumer et al., 2024

There is evidence that animals self medicate with plants

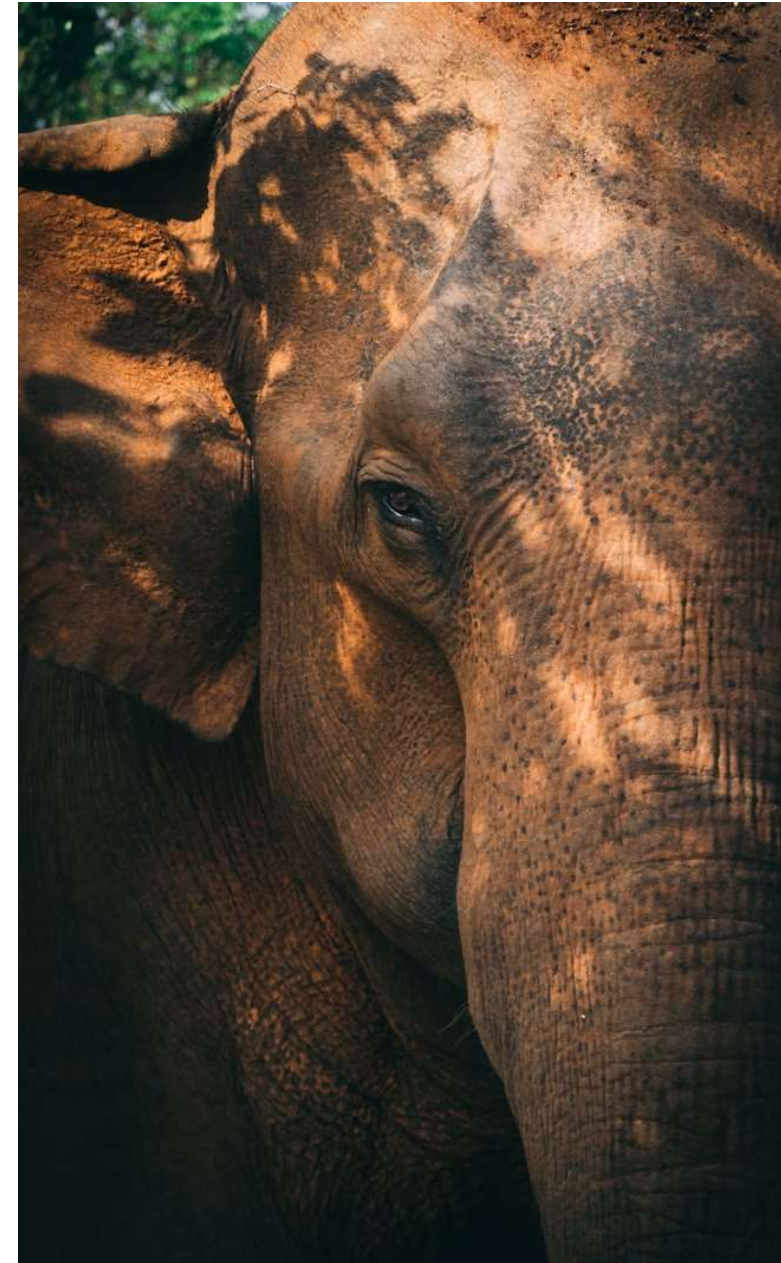
Table 1. Studies showing evidence of self-selection of plant secondary compounds (PSC) aimed at improving health

Animal	PSC	Effect	Reference
Primates			
Chimpanzee (<i>Pan troglodytes schweinfurthii</i>)	Sesquiterpene lactones and steroid glucosides	Antiparasitic, antiamoebic, antibacterial, antifungal, antitumour	Huffman & Seifu ⁽⁵⁴⁾ ; Ohigashi <i>et al.</i> ⁽⁵⁵⁾
Insects			
Monarch butterflies (<i>Danaus plexippus</i>)	Cardenolides	Antiparasitic	Lefèvre <i>et al.</i> ⁽⁸⁹⁾
Woolly bear caterpillars (<i>Grammia incorrupta</i>)	Pyrrolizidine alkaloids	Antiparasitic	Singer <i>et al.</i> ⁽³⁰⁾
Tiger moths caterpillars (<i>Grammia geneura</i>)	Pyrrolizidine alkaloids	Antiparasitic	Bernays & Singer ⁽⁹⁰⁾
Birds			
Blackcaps (<i>Sylvia atricapilla</i>)	Flavonoids	Antioxidant, antiinflammatory, immunomodulatory	Catoni <i>et al.</i> ⁽⁹⁾ ; Beaulieu <i>et al.</i> ⁽⁶³⁾
Gouldian finch (<i>Erythrura gouldiae</i>)	Polyphenols	Antioxidant	Catoni <i>et al.</i> ⁽⁶²⁾
Ruminants			
Sheep (<i>Ovis aries</i>)	Condensed tannins	Antiparasitic	Villalba <i>et al.</i> ⁽³²⁾ ; Juhnke <i>et al.</i> ⁽³³⁾ ; Copani <i>et al.</i> ⁽⁵⁹⁾
Goats (<i>Capra hircus</i>)	Condensed tannins	Antiparasitic	Amit <i>et al.</i> ⁽³⁴⁾



There is evidence that human learned from animals self medication to treat themselves or their animals with plants

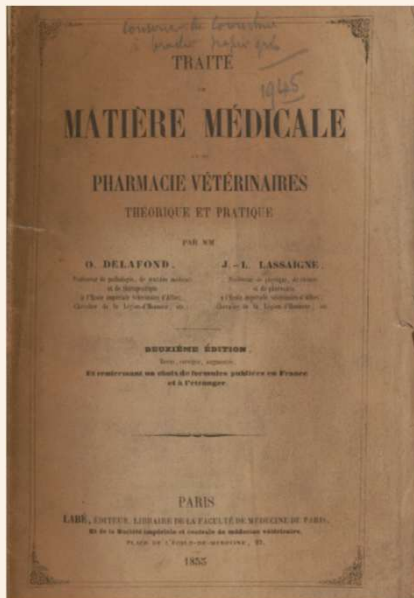
- Interviews with mahouts
- Report of 114 plant species
- → clear convergences between the observations interpreted by the mahouts as self-medication behaviour from elephants and their own medicinal practices



Medicinal plants in animal health – sources of knowledge

- Animal self medication
- **Historical and recent experience of animal owners, animal care taker and veterinarians - Ethnoveterinary research**
- Modern pharmacognostic, in vitro, in vivo, and (human and animal) clinical research regarding

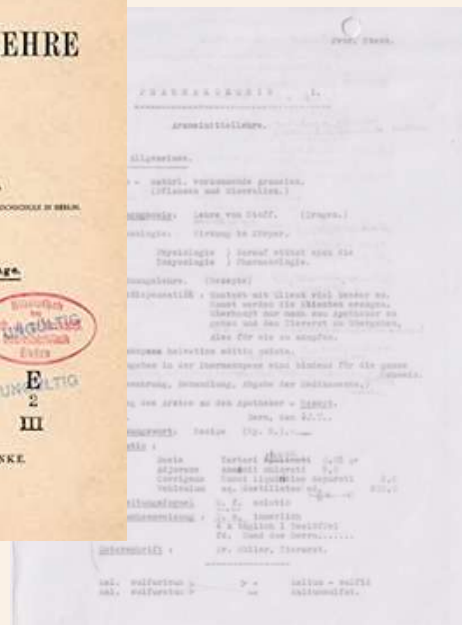
There is a (very) long tradition in using medicinal plants to treat animals



Delafond, 1855



Fröhner, 1900



Steck, 1944



Hippiatrica, 300 AD

There is, scientifically documented, a recent use of > 450 different medicinal plant species by livestock farmers in Europe

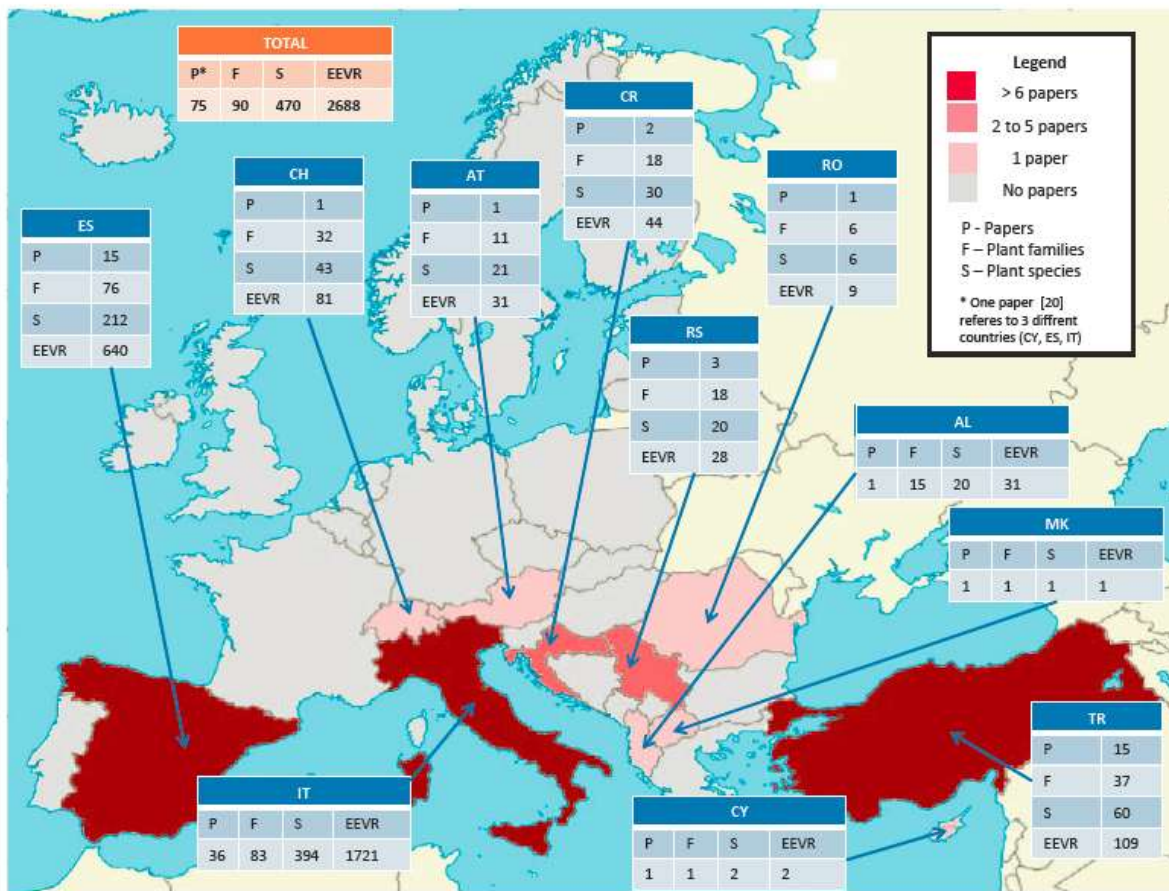
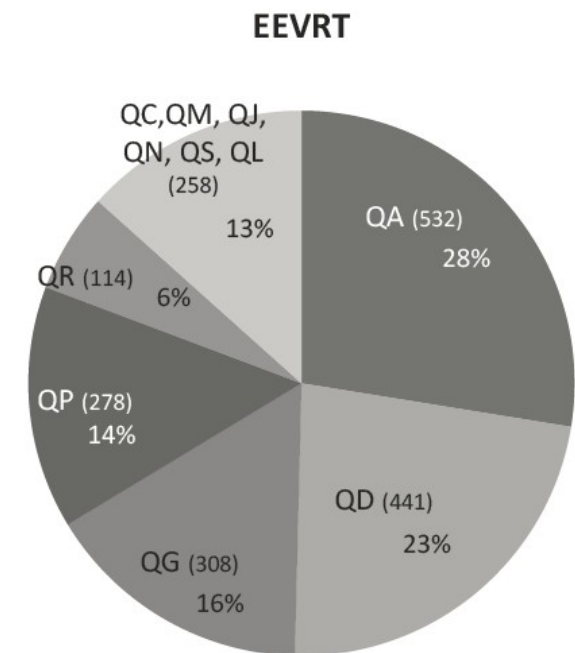
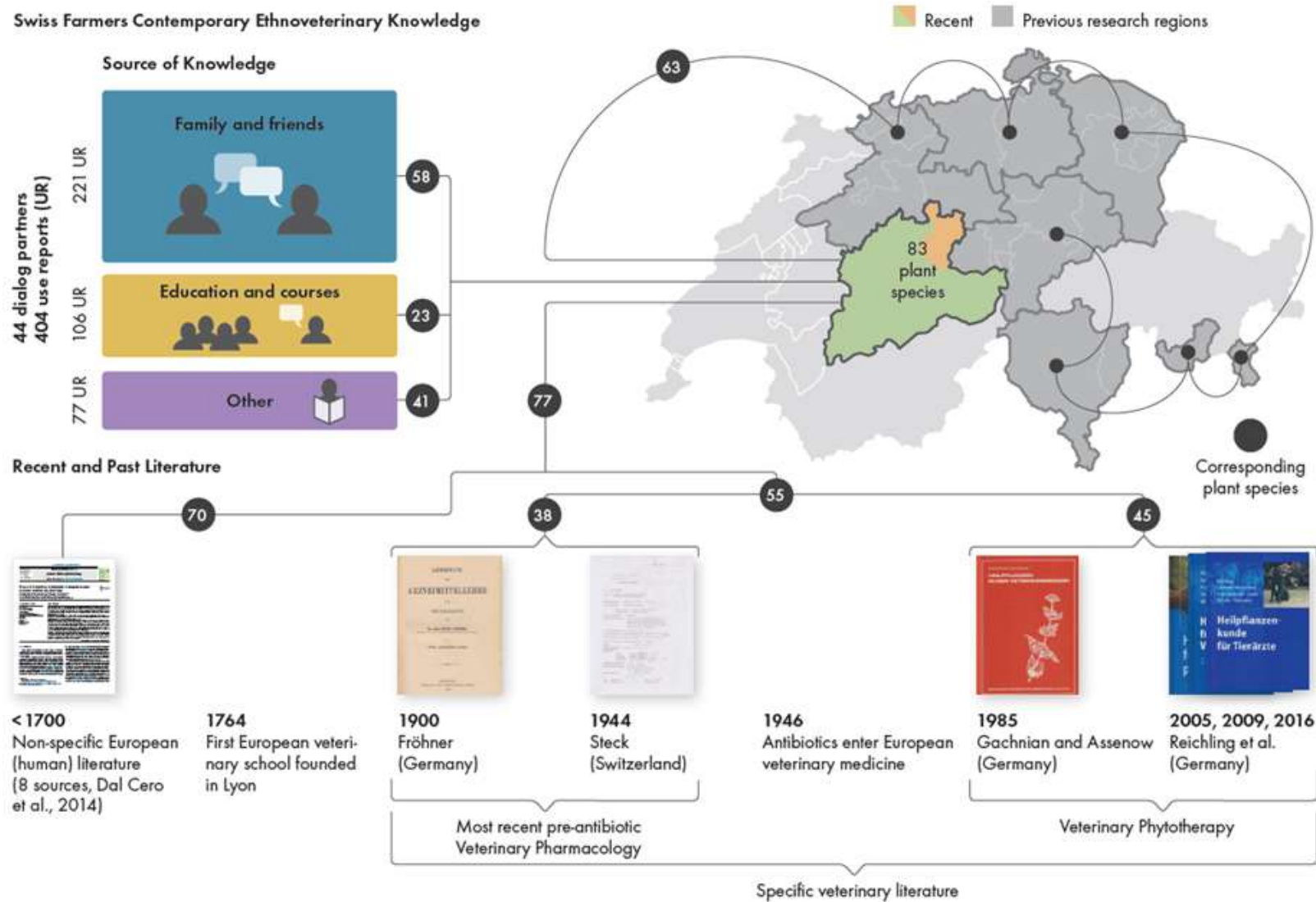


Fig. 2. European map of ethnoveterinary research. AL = Albania; AT = Austria; CH = Switzerland; CR = Croatia; CY = Cyprus; RO = Romania; IT = Italy; MK = Macedonia; RS = Serbia; TR = Turkey.

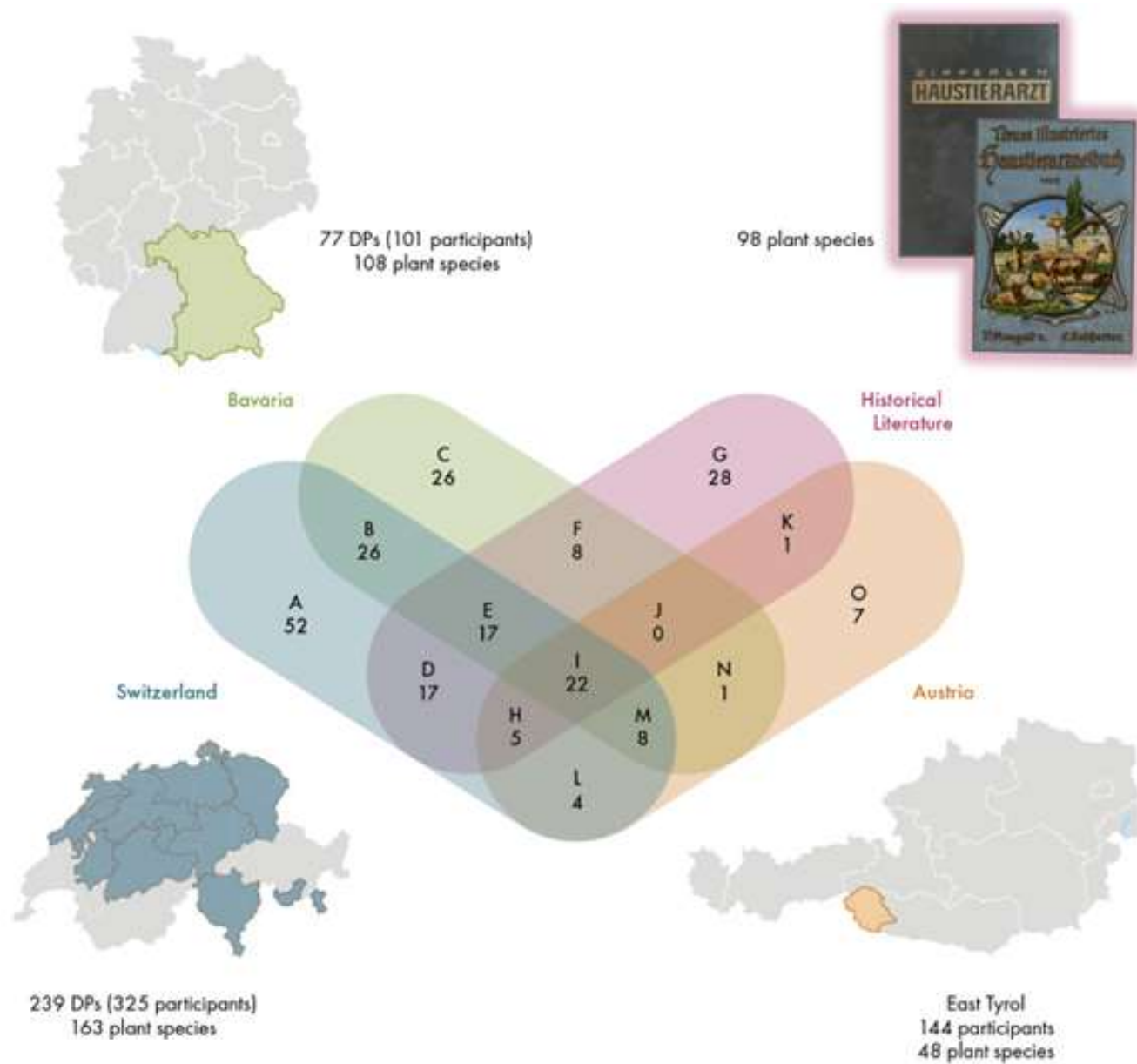


Mayer et al., 2014

There is consistency between recent use and historical literature ...



... at least
in **Germany**,
Austria and
Switzerland



Medicinal plants in animal health – sources of knowledge

- Animal self medication
- Historical and recent experience of animal owners, animal care taker and veterinarians - Ethnoveterinary research
- **Modern pharmacognostic, in vitro, in vivo, and (human and animal) clinical research regarding**

RESEARCH ARTICLE

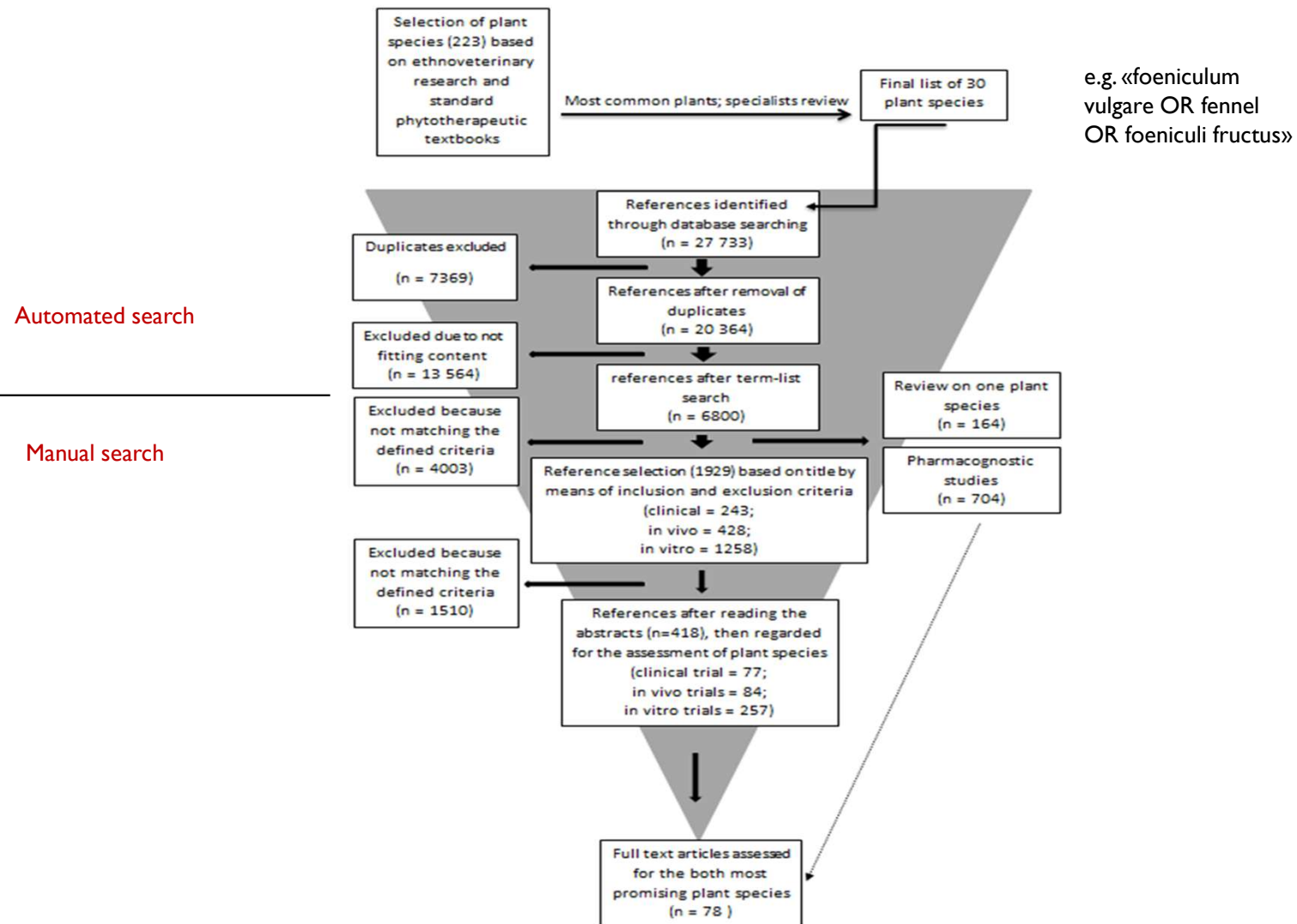
Open Access



Medicinal plants – prophylactic and therapeutic options for gastrointestinal and respiratory diseases in calves and piglets? A systematic review

Hannah Ayrle^{1,2*}, Meike Mevissen², Martin Kaske³, Heiko Nathues⁴, Niels Gruetzner⁴, Matthias Melzig⁵ and Michael Walkenhorst¹

Procedure of literature search

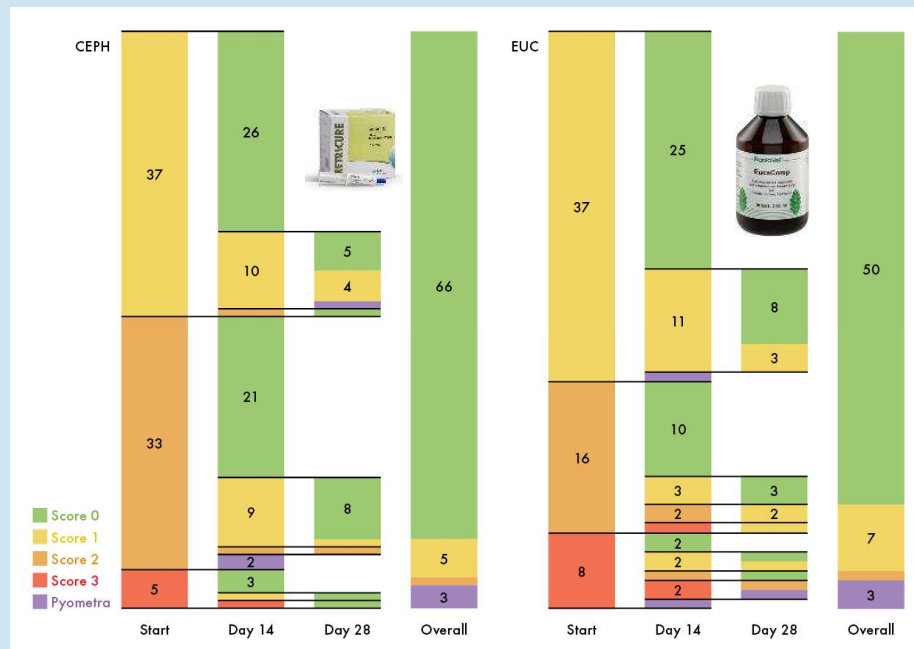


Most promising plant species from the review

gastrointestinal tract	respiratory tract	modulation of the immune system and inflammation
<p><i>Allium sativum</i> L. (garlic, Knoblauch)</p> <p>antibacterial, synergism with antibiotics, antiprotozoal, antidiarrheic, Immuno stimulative, anti-inflammatory</p>	<p><i>Echinacea purpurea</i> (L.) MOENCH (purple coneflower, Purpur-Sonnenhut)</p> <p>antibacterial, antiviral, immuno stimulative, anti-inflammatory</p>	<p><i>Echinacea purpurea</i> (L.) MOENCH (purple coneflower, Purpur-Sonnenhut)</p> <p>immuno stimulative, anti-inflammatory</p>
<p><i>Mentha x piperita</i> L. (peppermint, Pfefferminze)</p> <p>antibacterial, synergism with antibiotics, spasmolytic, antidiarrheic</p>	<p><i>Thymus vulgaris</i> L. (thyme, Thymian)</p> <p>antibacterial, bronchospasmolytic</p>	<p><i>Camellia sinensis</i> (L.) KUNTZE (green/black tea, Schwarz/Grüntee)</p> <p>immuno stimulative, anti-inflammatory</p>
<p><i>Salvia officinalis</i> L. (sage, Salbei)</p> <p>antibacterial, antiprotozoal, antidiarrheic, spasmolytic, immuno stimulative</p>	<p><i>Althaea officinalis</i> L. (marshmallow, Eibisch)</p> <p>antitussive</p>	<p><i>Glycyrrhiza glabra</i> L. (licorice, Süßholz)</p> <p>immuno stimulative, anti-inflammatory</p>

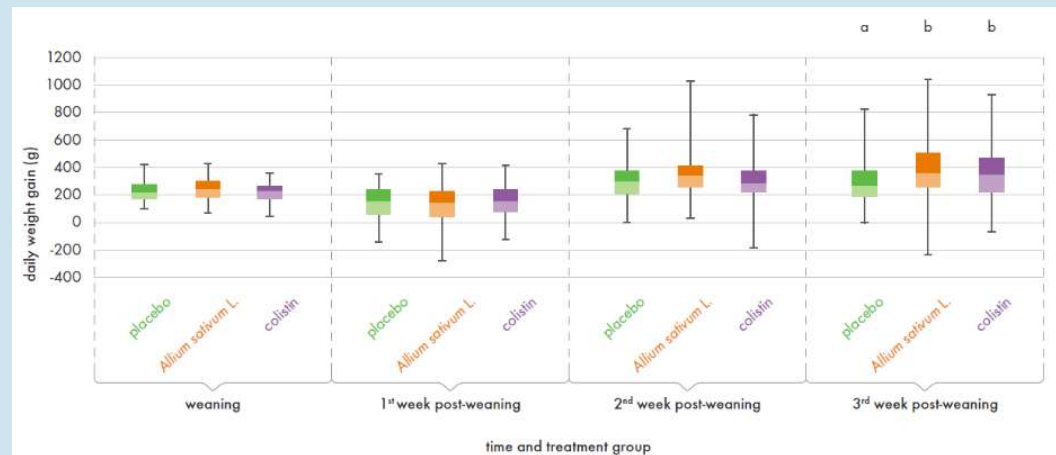
There is recent clinical research showing the potential of medicinal plants and herbal veterinary medicinal products to reduce the use of antibiotics

Clinical trial comparing a HVMP with a standard antibiotic in the treatment of clinical endometritis in dairy cows



Menoud et al., 2024

Clinical trial “KnobiPorc” (*Allium sativum* L. for postweaning piglets)



Ayrle et al., 2019

Overview

- Medicinal plants in animal health
- **About products, markets and regulations**
- aspects of medicinal plants and herbal drugs in veterinary medicinal products law
- The German and Swiss example

About products, markets and regulations

maybe play the short theatre with a goat, a farmer, a vet, a pharmacist, a feed producer and thyme etc. ...

Herbal veterinary medicinal products a special case within the broad field of phytogenic products for animals.

Plant based products for animals (health and welfare) could be:

- homemade feed or herbal remedies (animal owners responsibility, in livestock specific responsibility of farmers for the safety of products)
- feed, feed material, feed additive in the frame of feed law
- biocide in the frame of chemicals law
- food, cosmetics, care products in the frame of food law
- animal healthcare/skincare products in the frame of chemicals law

... and herbal veterinary medicinal products in the frame of veterinary medicinal products law (2019/6)?

About products, markets and regulations

- As soon as you buy something ... be sure, the market access is regulated somewhere
- It is also allways a question of responsibility.

... but, is there a future for veterinary phytotherapy in Europe?



EU-Regulation (EU) 2019/6



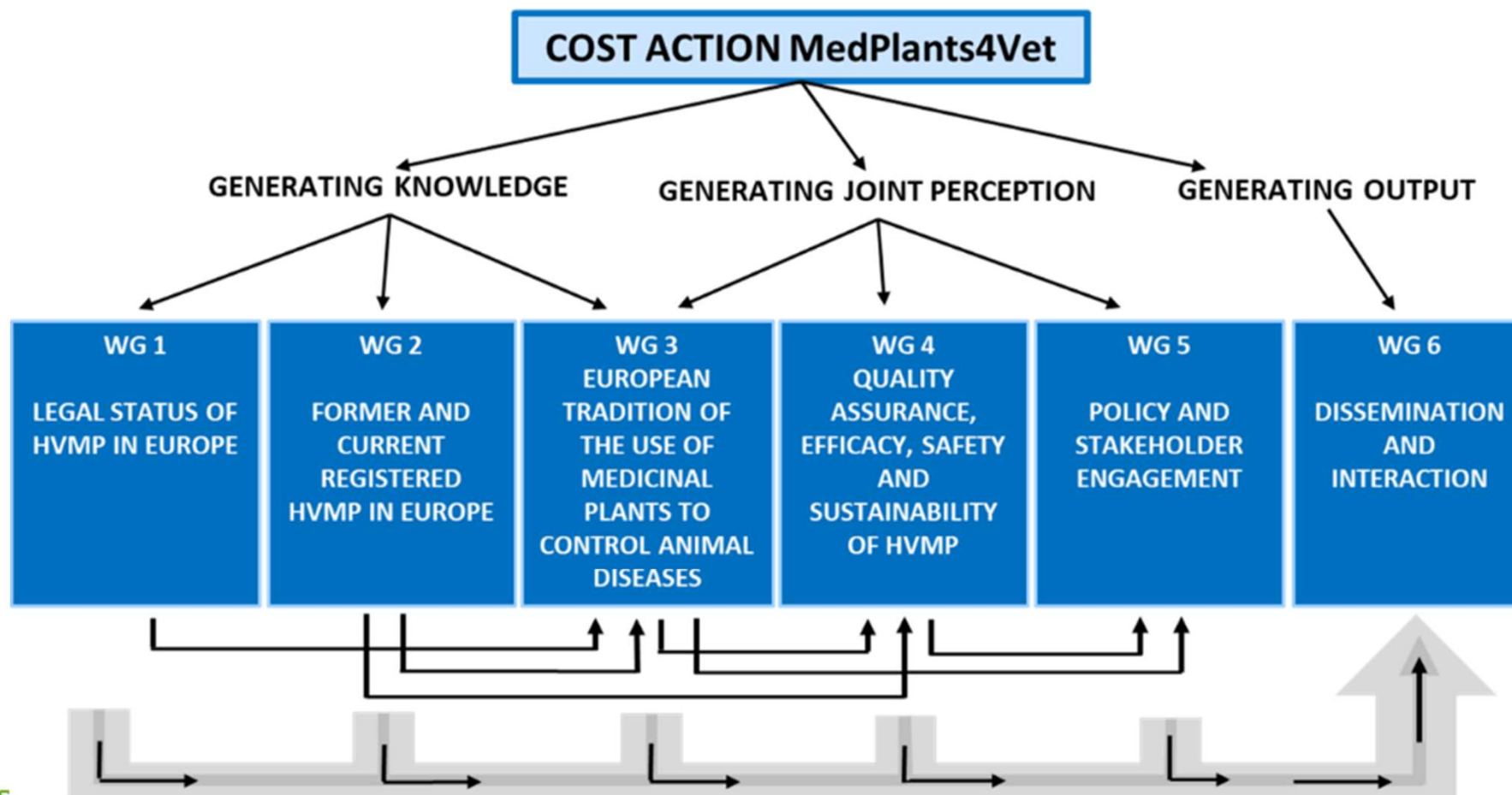
Article 157:

Commission report on traditional herbal products used to treat animals

The Commission shall report to the European Parliament and to the Council by 29 January 2027, on traditional herbal products used to treat animals in the Union. If appropriate, the Commission shall make a legislative proposal in order to **introduce a simplified system for registering** traditional herbal products used to treat animals.

The Member States shall provide information to the Commission on such traditional herbal products within their territories.

Network of the COST-Action MedPlants4Vet



Overview

- Medicinal plants in animal health
- About markets and regulations
- **Some aspects of medicinal plants and herbal drugs in veterinary medicinal products law**
- The German and Swiss example

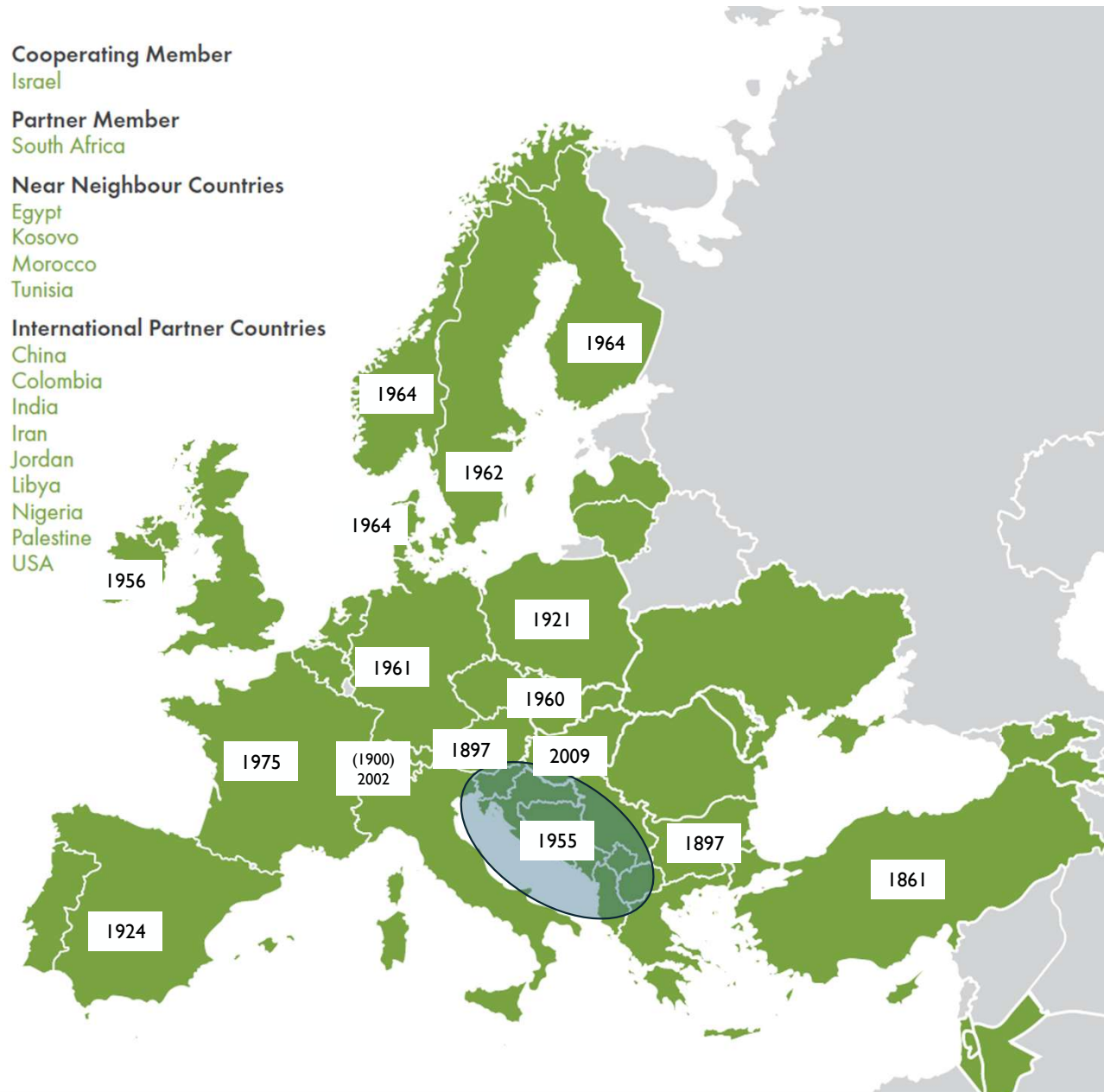
- Albania
- Armenia
- Austria
- Belgium
- Bosnia & Herzegovina
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Finland
- France
- Georgia
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Latvia
- Lithuania
- Republic of Moldova
- Montenegro
- Netherlands
- Norway
- Republic of North Macedonia
- Poland
- Portugal
- Romania
- Serbia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- Ukraine
- United Kingdom

Israel

South Africa

Egypt
Kosovo
Morocco
Tunisia

China
Colombia
India
Iran
Jordan
Libya
Nigeria
Palestine
USA



- Some early
- some later
- Some in common with human MP
- Some separate
- switching responsible national authorities (human health / agriculture)...

sometimes several times during the last 100 years;

COST ACTION MedPlants4Vet

GENERATING KNOWLEDGE

GENERATING JOINT PERCEPTION

GENERATING OUTPUT

WG 1

LEGAL STATUS OF
HVMP IN EUROPE

WG 2

FORMER AND
CURRENT
REGISTERED
HVMP IN EUROPE

WG 3

EUROPEAN
TRADITION OF
THE USE OF
MEDICINAL
PLANTS TO
CONTROL ANIMAL
DISEASES

WG 4

QUALITY
ASSURANCE,
EFFICACY, SAFETY
AND
SUSTAINABILITY
OF HVMP

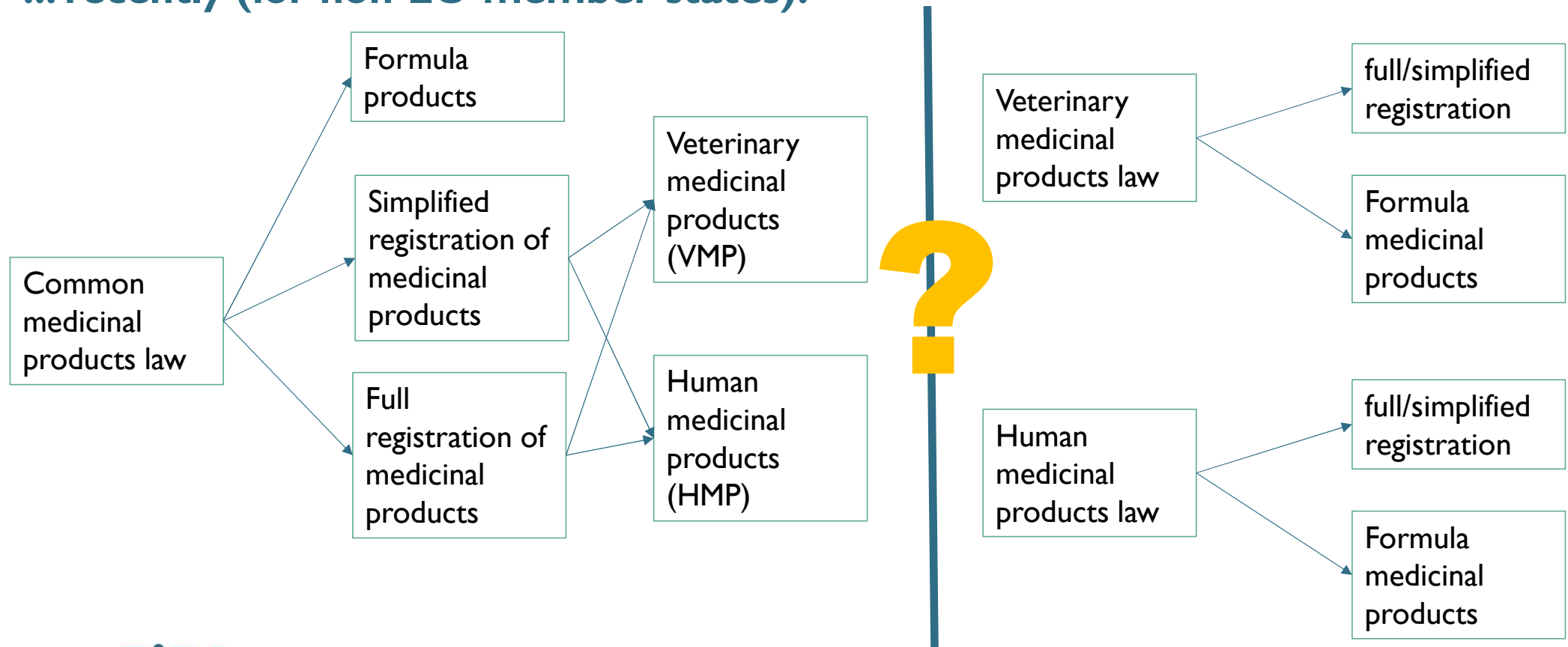
WG 5

POLICY AND
STAKEHOLDER
ENGAGEMENT

WG 6

DISSEMINATION
AND
INTERACTION

How was/is the structure of **VMP** registration law in your country...
... in the beginning?
... before the new **European VMP** law comes into force (for **EU** member states)? or
... recently (for non-**EU**-member states)?

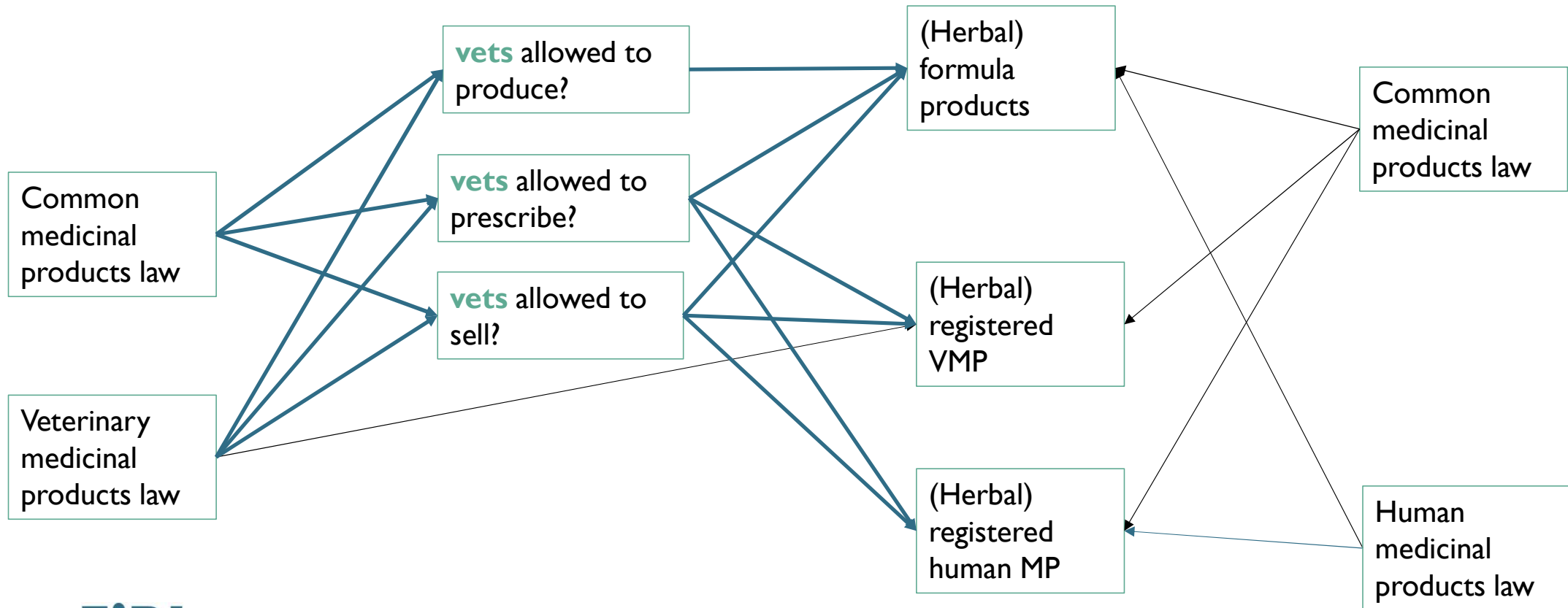


What are/have been veterinarians allowed to do in your country...

... in the beginning of VMP regulation?

... before the new European VMP law comes into force (for EU member states)? or

... recently (for non-EU-member states)?



European Members

Albania
Armenia
Austria
Belgium
Bosnia & Herzegovina
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Finland
France
Georgia
Germany
Greece
Hungary
Iceland
Ireland
Italy
Latvia
Lithuania
Republic of Moldova
Montenegro
Netherlands
Norway
Republic of North Macedonia
Poland
Portugal
Romania
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
Turkey
Ukraine
United Kingdom

Cooperating Member

Israel

Partner Member

South Africa

Near Neighbour Countries

Egypt
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Morocco
Tunisia

International Partner Countries

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Colombia
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Iran
Jordan
Libya
Nigeria
Palestine
USA

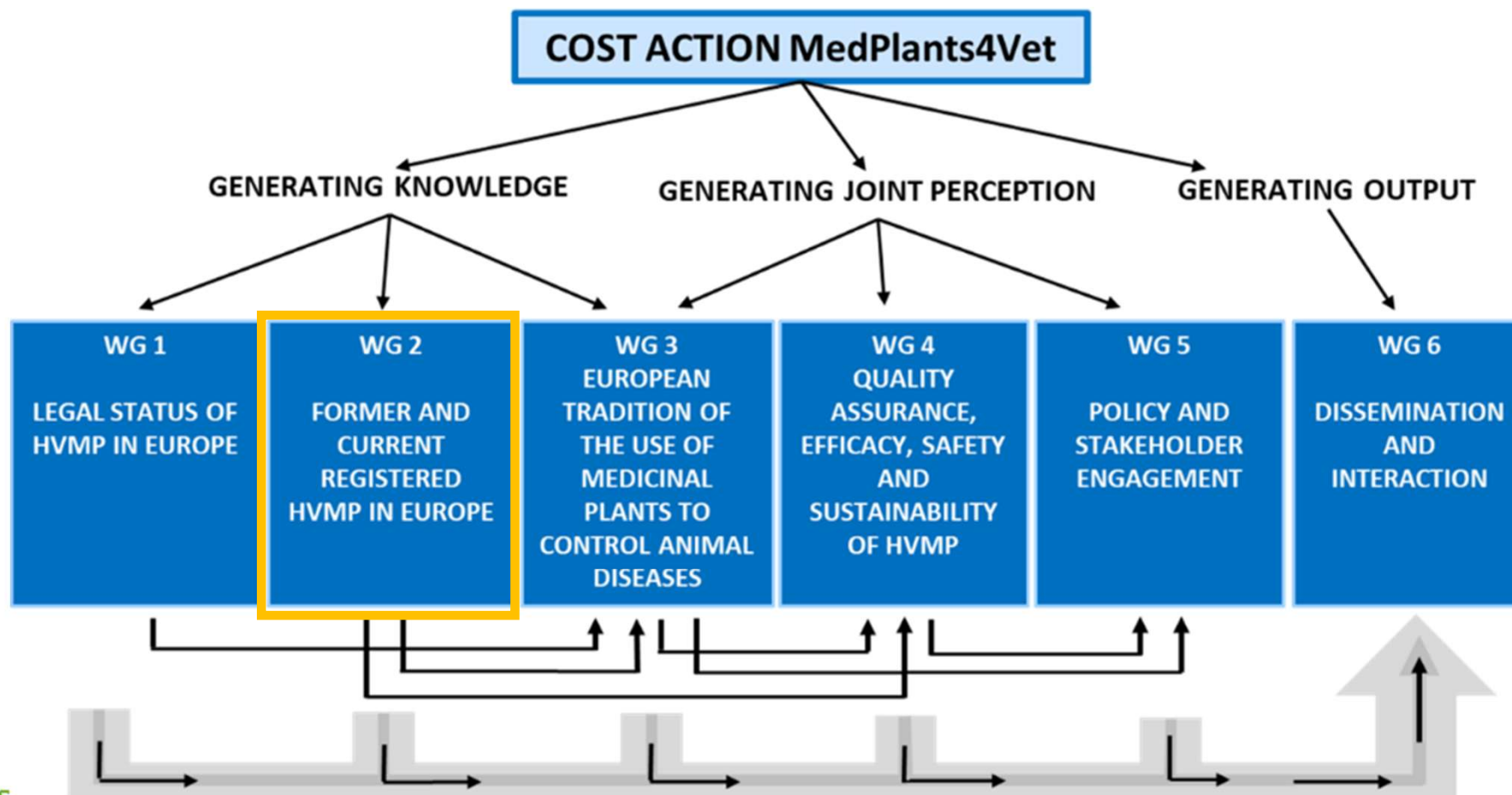


Simplified registration / market authorization

... this is more an aspect of modern “regulatory history”, mainly based on the human medicinal law specifically facing on this based on Directive 2004/24/EC

100-50 years ago, the market access (registration/market authorization) of VMP was “simple” and that of HVMP even simpler.

Having a quick look at outcomes of WG2



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China
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Iran
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Nigeria
Palestine
USA



Legend:

- currently registered HVMPs
- formerly registered HVMPs
- no registered HVMPs found
- WG2 member
- WG2 non member

European Members

Albania
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Croatia
Cyprus
Czech Republic
Denmark
Finland
France
Georgia
Germany
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Hungary
Iceland
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Near Neighbour Countries

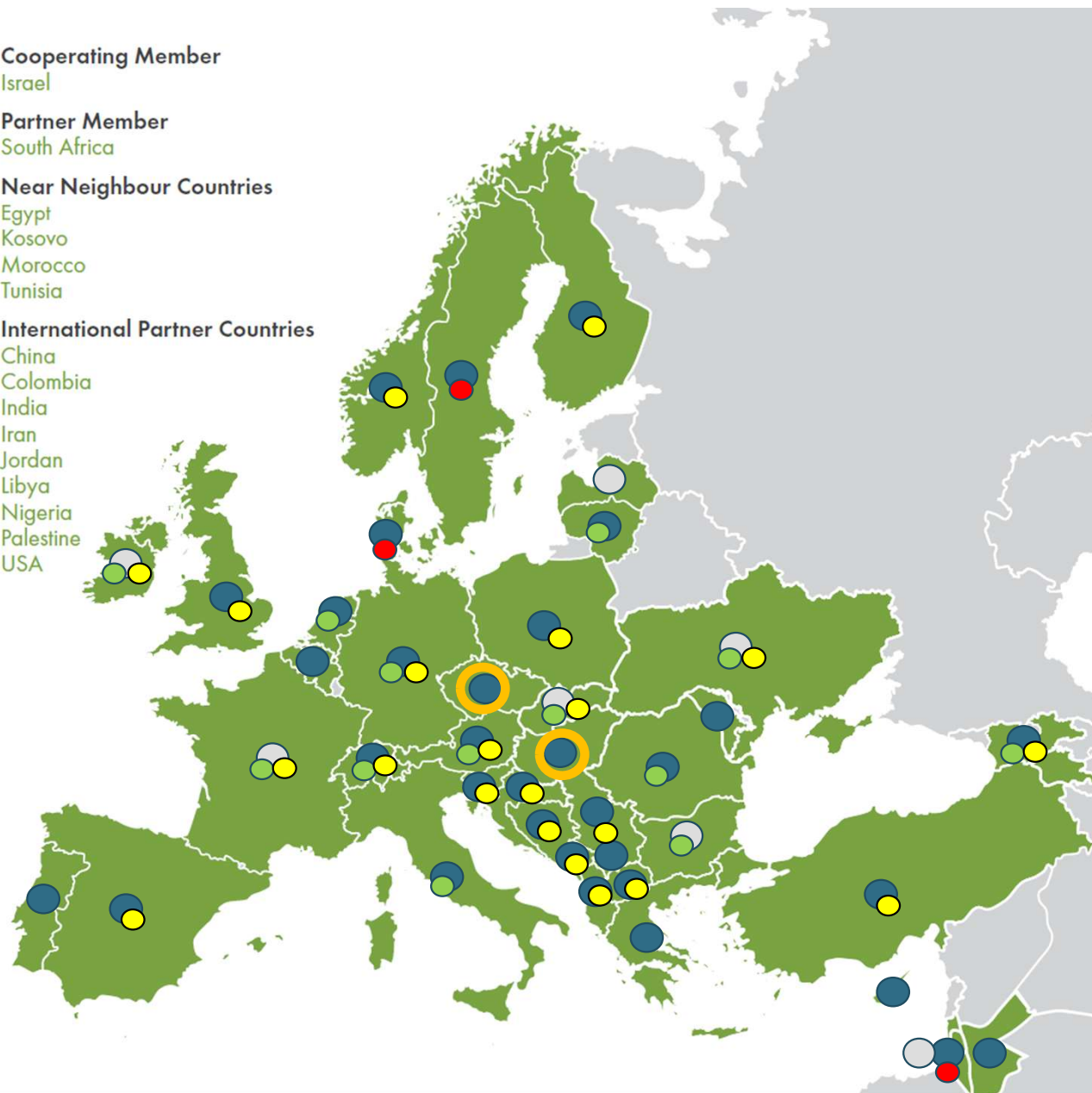
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Kosovo
Morocco
Tunisia

International Partner Countries

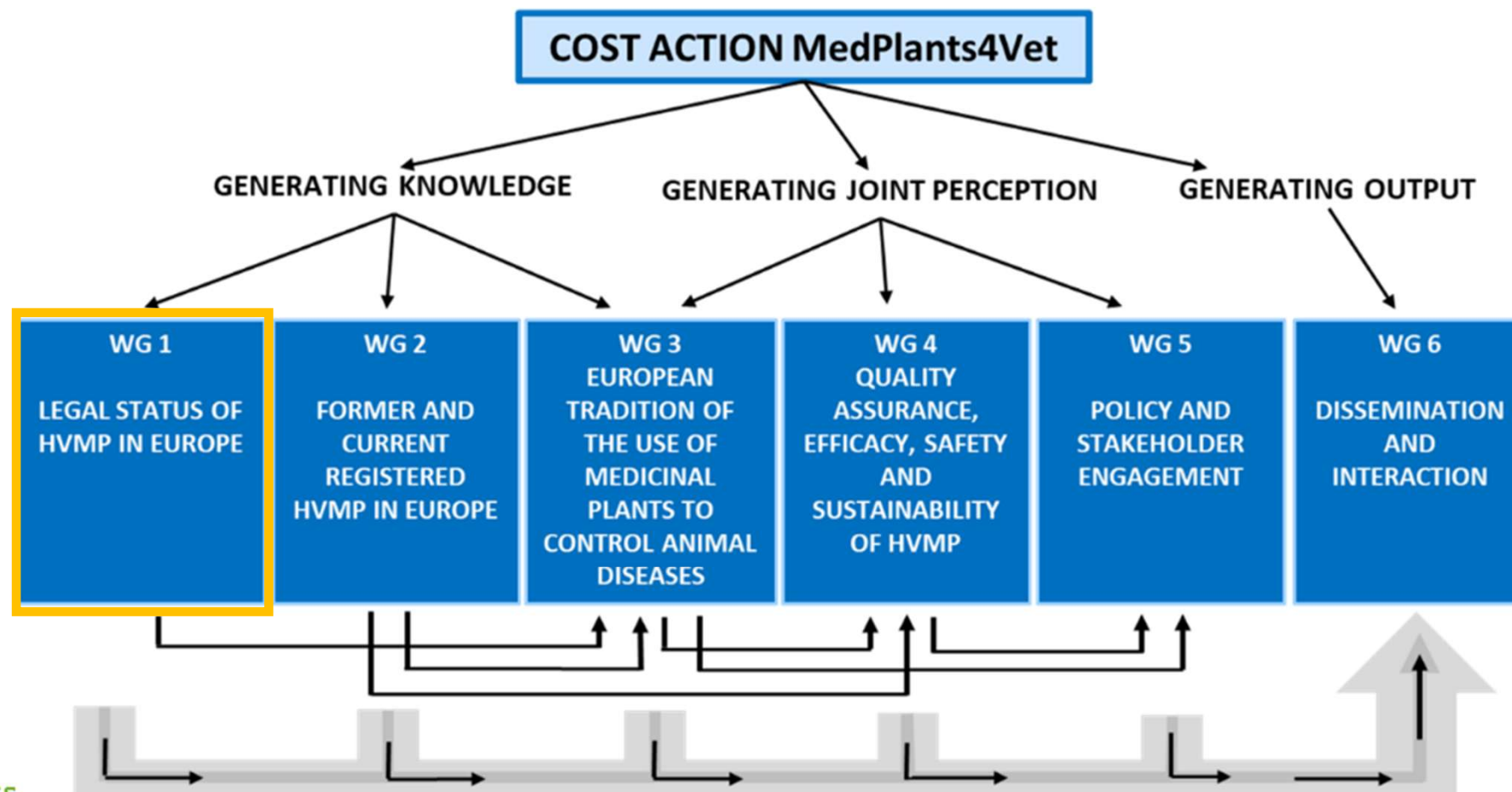
China
Colombia
India
Iran
Jordan
Libya
Nigeria
Palestine
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Legend:

- currently registered HVMPs
- formerly registered HVMPs
- no registered HVMPs found
- WG2 member
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... back to some interesting extra outcomes of **WGI**



European Members

Albania
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Austria
Belgium
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Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Finland
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USA



Non-medicinal veterinary preparations

are products intended for animals that do not fall under the definition of veterinary medicinal products as per Regulation (EU) 2019/6. They do not have pharmacological, immunological, or metabolic actions, but are used for:

- General support and care (e.g., grooming, comfort, stress management)
- Non-therapeutic purposes (e.g., joint mobility, coat health)
- Use as technically defined veterinary products

Typical examples: CBD oils, care gels, plant-based supplements with clearly non-medical claims.

Paramedicinal products:

a product intended for use in animals that is neither classified as a veterinary medicinal product nor as a veterinary biocidal product, and which may be used as a supportive or complementary treatment for animal diseases. Such a product exerts a beneficial biological effect, does not cause harmful effects or side effects when used as directed, and, in the case of food-producing animals, has no required withdrawal period and does not pose any health risk to consumers.

European Members

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Denmark
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France
Georgia
Germany
Greece
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Iceland
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Italy
Latvia
Lithuania
Republic of Moldova
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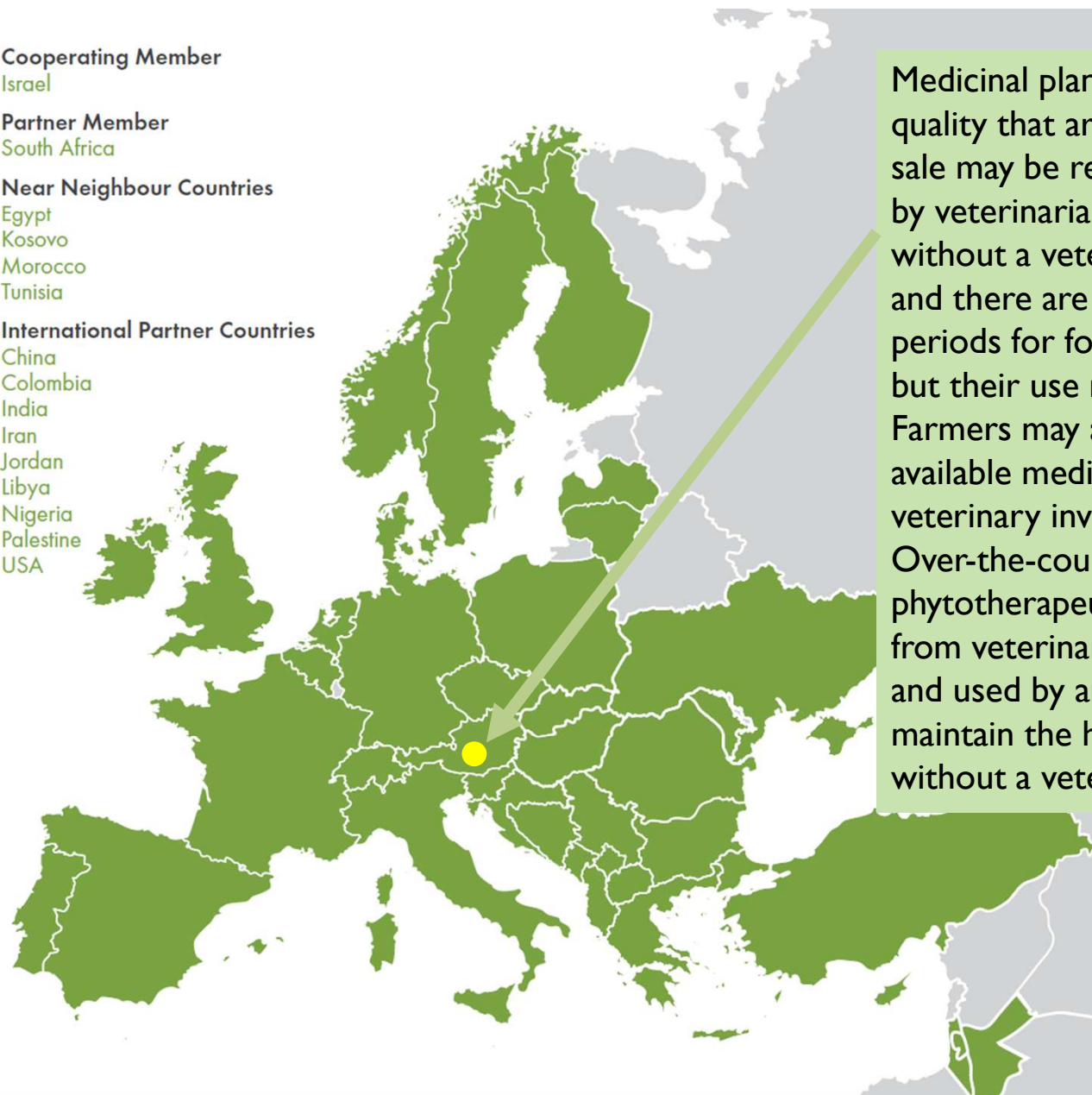
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Palestine
USA



Medicinal plants of pharmacopoeia quality that are freely available for sale may be recommended for use by veterinarians. They are available without a veterinary prescription and there are no withdrawal periods for food-producing animals, but their use must be documented. Farmers may also use freely available medicinal plants without veterinary involvement. Over-the-counter phytotherapeutics may be obtained from veterinarians or pharmacies and used by animal owners to maintain the health of their animals without a veterinary prescription.

European Members

Albania
Armenia
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Belgium
Bosnia & Herzegovina
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Finland
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Georgia
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Greece
Hungary
Iceland
Ireland
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Latvia
Lithuania
Republic of Moldova
Montenegro
Netherlands
Norway
Republic of North Macedonia
Poland
Portugal
Romania
Serbia
Slovakia
Slovenia
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Sweden
Switzerland
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Egypt
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Morocco
Tunisia

International Partner Countries

China
Colombia
India
Iran
Jordan
Libya
Nigeria
Palestine
USA



veterinary surgeons wishing to use phytotherapy are authorized to resort directly to extemporaneous preparations (4th degree of the cascade), without taking account of the intermediate degrees of the cascade.

(CH:

- also all human herbal medicinal products could be used,
- it is tolerated to store and distribute extemporaneous preparations manufactured in pharmacia)

Food Producing animals: only if medicinal plants are named explicitly in the regulation 37/2010

CH: without withdrawal period

FR: withdrawal period of 2 days (?)

Overview

- Medicinal plants in animal health
- About markets and regulations
- Some aspects of medicinal plants and herbal drugs in veterinary medicinal products law
- **The German and Swiss example**

Overview

- Medicinal plants in animal health
- About markets and regulations
- Some aspects of medicinal plants and herbal drugs in veterinary medicinal products law
- The **German** and Swiss **example**

Former legal situation in Germany

Differentiation of medicinal products into different marketing authorization categories:

- over-the-counter
- pharmacy-only
- prescription-only

The majority of herbal veterinary medicinal products in Germany are in the category over-the-counter.





Former legal situation in Germany

According to §13 AMG,
veterinarians are authorized to produce by themselves:
"medicinal products containing substances or preparations of such substances
which are exclusively released for sale outside pharmacies".

furthermore:
"medicinal product consisting of a finished medicinal product
and non-active ingredients".
may be prepared.



Former legal situation in Germany

Regulation on medicinal products which are suitable to be sold in pharmacies and over-the-counter (AMVerkVR):

- = valid for human and **veterinary medicinal products**
- within the meaning of this regulation: The plants and their mixtures contained therein are all medicinal products
- regulates their sale ability outside pharmacies

Former legal situation in Germany

→ in interaction with the TÄHAV and the Animal owner- Medicines- Application- Detection- Prescription, this means a simplified documentation obligation. Neither the veterinarian nor the livestock or pet owner must keep records of these "medicinal products released for circulation outside the pharmacy".



Former legal situation in Germany



When using herbal medicinal products not licensed for the animal species and indication, the **reclassification cascade** must be taken into account (§56a AMG).

For livestock, this has the consequence:

- a minimum of 7 days withdrawal period on milk
- a minimum of 28 days on edible tissues

Exceptions:

(in accordance) with §56a AMG and TÄHV

- mother tinctures
- **over-the-counter veterinary herbal medicinal products**



Former legal situation in Germany

AMG § 39 b: Registration of traditional herbal medicinal products:

"the concerned medicinal product or a corresponding medicinal product has been in medicinal or **veterinary** use for at least 30 years, including at least 15 years in the European Union,

at the time of application, the medicinal product is harmless under the stated conditions of use

and its pharmacological effects or efficacy are plausible on the basis of many years of use and experience,"

Former legal situation in Germany



Conclusion:

- 1) In Germany, veterinarians were allowed to prepare herbal veterinary medicinal products themselves from over-the-counter medicinal plants of pharmacopoeia quality for the animals they care for. (They are allowed to pass these on to the animal owners, without the consequence of a withdrawal period).
- 2) Medicinal plants in veterinary medicinal products has been anchored in law for many decades (AMG – Germany; Article 39a-c).
- 3) Only few Veterinary Herbal Medicinal Products are currently on the market.

Registered herbal medicinal products



Registered herbal medicinal products

February 2025

Medicinal products that have successfully completed an authorisation procedure - GERMANY

Phytopharmaka	zugelassen	nachzugelassen	Summe
Monopräparate	473	217	690
Kombinationspräparate	59	77	136
Summe	532	294	826



Quelle: BfArM - Aktuelles - Statistik

HERBAL VETERINARY MED. PRODUCTS

country	2022	2025
Switzerland	2 from 2 manufacturer	1 from 1 manufacturer
Austria	11 from 6 manufacturer	9 from 4 manufacturer
Germany	20 from 7 manufacturer	17 from 3 manufacturer



Quelle: Vetidata and MedPlants4Vet

There are still registered herbal veterinary medicinal products for livestock and companion animals available on the European market



... but how long?



Registered Herbal Veterinary Medicinal Products in Germany

2022 there have been 20 herbal veterinary medicinal products on the market:

- 15 products: nationally approved according to §39a AMG
- 5 products: exempt (formerly) from compulsory marketing authorization according to §60 AMG:
„Over-the-counter medicinal products for ornamental fish, ornamental or songbirds, carrier pigeons, terrarium animals, small rodents, ferrets or rabbits not intended for the production of food are excluded.“

Source: <https://vetidata.de/>

Registered Herbal Veterinary Medicinal Products in Germany

- A total of 26 different herbal active ingredients are contained in the 20 approved products.

- E.g.:

Herbal agent	Herbal Veterinary Medicinal Product
Absinthium-Extrakt	Herbi Colan
Anisi aetheroleum	ColoSan®
Arnica montana	BenAcet aethericum Euterbalsam Dr. Schaette
Calendula officinalis	EucaComp® PhlogAsept®
Carvi aetheroleum	ColoSan® Herbi Colan

Registered Herbal Veterinary Medicinal Products in Germany

Manufacturers

2020 there have been 10 companies in Germany producing HVMP:

- Agraria Pharm GmbH
- Alvetra GmbH
- Chevita GmbH
- DHU Arzneimittel GmbH & Co. KG
- Intervet (Pharma Stulln) (belongs to MSD Tiergesundheit)
- LIVISTO c/o aniMedica GmbH
- Serumwerk Bernburg AG (including MEDISTAR)
- SaluVet GmbH
- WDT GmbH & Co. KG
- Preis Aquaristik KG

Overview

- Medicinal plants in animal health
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- **The** German and **Swiss example**

Swiss recent law with regard to the veterinary use and (simplified) registration of (traditional) herbal veterinary medicinal products:

- Swiss veterinarians are (in contrast to German veterinarians) not allowed to prepare or dispense but to sell prepackadged veterinary medicinal products.
- There are still 2 pure herbal veterinary medicinal products available on the Swiss market (one of them is the oldest registered veterinary medicinal product of Switzerland)
- Furthermore Swiss veterinarians are allowed to prescribe medicinal products for animals. Such products are produced in a pharmacy and do not require a registration («Formula magistralis»).
- Formual magistralis is clearly restricted for livestock.

Swiss regulation on veterinary medicinal products (“Tierarzneimittelverordnung”; TAMV):

- Regulates not the registration but the professional use of veterinary medicinal products.

Reclassification of authorised medicinal products Swiss TAMV – Art. 6:

- If no veterinary medicinal product is registered for the treatment of a disease, the veterinarian is authorised to prescribe or dispense a veterinary medicinal product registered for the same target species but for a different indication, in the same dosage as for the registered indication. If no such veterinary medicinal product is available either, she or he may prescribe or dispense in the following order:
 - a. a veterinary medicinal product registered by the Swiss Agency for Therapeutic Products (Institute) for another target species;
 - b. a human medicinal product registered by the Institute;
- registered homeopathic, anthroposophic and phytotherapeutic medicinal products may also be used if a medicinal product is registered for the indication or target species to be treated.
- ...
- Article 12 remains reserved.

Reclassification of authorised medicinal products Swiss TAMV– Art. 12 (livestock):

- 1 Only medicinal products may be reclassified for livestock:
 - a. which contain only active substances for which the FDHA, on the basis of Article 10 paragraph 4 letter (e) LGV, has established a maximum permissible concentration for residues of pharmacologically active substances or has not considered it necessary to establish maximum concentrations;
- ...
- 2 Prohibited substances and preparations (Art. 10c) are excluded from reclassification.
- LGV leads to the Ordinance of the FDHA on Residues of Pharmacologically Active Substances and Feed Additives in Food of Animal Origin (VRLtH) which contains beside a lot of other substances **all medicinal plants of the EU Regulation 37/2010. These medicinal plants (and some few more) are also listed in the Annex 2 of the Swiss TAMV.**

- Formular-Arzneimittel in der tierärztlichen Hausapotheke – **NEU** seit Ende 2022



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra


Eidgenössisches Departement des Innern EDI
Bundesamt für Lebensmittelsicherheit und
Veterinärwesen BLV
Tiergesundheit

Merkblatt: Formula-Präparate in der Tierarztpraxis

- In Fällen, wo kein zugelassenes Arzneimittel als Alternative zur Verfügung steht und in Abweichung zur Vorgabe, dass die Abgabe von Formula-Präparaten auf die eigene Kundschaft der Apotheke beschränkt ist, toleriert der Veterinärdienst, dass Tierarztpraxen mit einer Detailhandelsbewilligung solche Präparate in kleinen Mengen für die Behandlung der eigenen Patienten lagern.
- Formula-Präparate dürfen in der Tierarztpraxis weder präsentiert noch beworben werden. Gemäss [Art. 14 ff Arzneimittel-Werbeverordnung](#)³ ist Publikumswerbung nur für Tierarzneimittel der Abgabekategorien D und E erlaubt. Formula-Präparate fallen nicht unter diese Kategorie.

<https://www.blv.admin.ch/blv/de/home/tiere/tierarzneimittel/fachgerechter-umgang-mit-tierarzneimitteln.html>

Andere Tierarzneimittel

 [Merkblatt: Formula-Präparate in der Tierarztpraxis](#) (PDF, 131 kB, 03.11.2022)

Withdrawal periods for reclassified medicinal products Swiss TAMV– Art. 13 (livestock):

- **2.** Veterinary medicinal products authorised for another target species and medicinal products for human use may only be administered in accordance with the authorisation. The following withdrawal periods apply to these medicinal products:
 - a. If the active substances contained in the medicinal product are listed in Annex 2, no withdrawal period is necessary.
- **5.** Withdrawal periods may be waived for authorised homeopathic, anthroposophic and phytotherapeutic medicinal products if the medicinal products contain only active substances:
 - a. for which the FDHA has not considered it necessary to specify maximum concentrations ...

... the same is true for Formula magistralis products (Art. 14), even no obligation to keep records (Art. 26, c)

Swiss Complementary and Phyto Medicinal Products Regulation (“Komplementär- und Phytoarzneimittelverordnung”; KPAV)

- “Regulation of the Swiss Agency for Therapeutic Products on the Simplified Authorisation and Notification Procedure for complementary and herbal medicinal products”
- Includes also main aspects of the **Directive 2004/24/EC** ... “amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use” ...
- ... but Swiss KPAV includes also the veterinary use.

Swiss KPAV

- Art. I Subject matter
- This Ordinance regulates the requirements that complementary medicinal products and herbal medicinal products for human and veterinary use must fulfil and lays down the conditions for their simplified authorisation and authorisation under the notification procedure.

Swiss KPAV

- Art. 4 Terms
- For the purposes of Chapter 2 of this Ordinance, the following are considered to be:
 - a. herbal substances: whole, crushed or cut plants, parts of plants, algae, fungi, lichens in an unprocessed, dried or fresh state and fresh form, and exudates thereof, which have not undergone any special treatment;
 - b. herbal preparations: Preparations which are obtained by herbal substances undergoing treatments such as extraction, distillation, pressing, fractionation, purification, concentration or fermentation. This includes pulverised or powdered herbal substances, tinctures, extracts, essential oils, pressed juices and processed exudates of herbal substances;

Swiss KPAV

- Art. 4 Terms
- For the purposes of Chapter 2 of this Ordinance, the following are considered to be:
 - c. "well established use": at least ten years of medicinal use of a phytopharmaceutical as a medicinal product in the indication applied for and use in at least one country of the EU or EFTA with sufficient bibliographic documentation;
 - d. traditional use: at least 30 years of medicinal use of a herbal medicinal product, including at least 15 years in an EU or EFTA country.

Swiss KPAV

- 2. Chapter: herbal medicinal products
- Section I: Simplified authorisation of herbal medicinal products
- Art. 8 Application for admission
- Art.9 Analytical, chemical and pharmaceutical documentation
- Art.10 Toxicological and pharmacological documentation

Swiss KPAV

- Art. 11 Clinical documentation
- In the clinical documentation on herbal active substances for which a recognised monograph with sufficient information on efficacy and tolerability in the claimed indication and dosage is available, reference may be made to this monograph.
- For traditionally used herbal medicinal products, the following simplifications apply:
 - a. If the efficacy and safety can be plausibly demonstrated, bibliographical documentation may be submitted. bibliographic documentation may be submitted, provided that a traditional field of area of application is claimed.
 - b. In the case of herbal active substances for whose traditional use a recognised monograph exists, this may be monograph exists, this may be claimed as an area of application. may be claimed.
- For herbal medicinal products with "well established use", the indication of the recognised monograph can be claimed.

Swiss KPAV

- Chapter 2: herbal medicinal products
- Section 2: Notification procedure for **teas**
- Art. 12
- Teas may be authorised by Swissmedic on the basis of a notification, provided that:
 - a. they are individual teas whose drug is listed in Annex 4 (List "Tea Drugs");
 - b. they have an indication in accordance with the list of "tea drugs";
 - c. they can be classified in distribution category E.

Swiss KPAV

- Chapter 3: **Cough and throat lozenges and pastilles**
- Art. 13 Cough and throat lozenges and pastilles may be authorised by Swissmedic on the basis of Swissmedic on the basis of a notification, provided that
 - a. they contain only the following ingredients:
 - plants, parts of plants or plant preparations that are listed in Annex 5 (List of "sweets"),
 - flavourings or colourings which are also used for the manufacture of sweets in accordance with food legislation,
 - essential oils with the specified content limits in accordance with Annex 5,
 - synthetically manufactured or chemically defined substances that are included in the list of "sweets" list;
 - b. for which an application is made for an area of use which is included in the list of "sweets list";
 - c. they can be classified in dispensing category E.

Medicinal Plants in the European Regulation 37/2010

20.1.2010

EN

Official Journal of the European Union

L 15/1

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 37/2010

of 22 December 2009

on pharmacologically active substances and their classification regarding maximum residue limits
in foodstuffs of animal origin

(Text with EEA relevance)

Medicinal Plants in the European Regulation 37/2010

20.1.2010

EN

Official Journal of the European Union

L 15/3

ANNEX

Pharmacologically active substances and their classification regarding maximum residue limits (MRL)

Table 1

Allowed substances

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
Abamectin	Avermectin B1a	Bovine	10 µg/kg 20 µg/kg	Fat Liver	NO ENTRY	Antiparasitic agents/Agents acting against endo- and ectoparasites
		Ovine	20 µg/kg 50 µg/kg 25 µg/kg 20 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption.	
Absinthium extract	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY

Medicinal Plants in the European Regulation 37/2010

- about 60 medicinal plants are listed
- all are labelled with “MRL: No MRL required”
- (if no MRL is required ... no withdrawal period as consequence?)

A Swiss example.

des Mittels angenommen hat, als ungeniessbar.

Antrag: Abweisung.

8640. Eucalyptusöl.

Das ätherische Öl des Eucalyptusbaums (ohne besondere Anpreisung gegen Krankheiten).

Antrag: Bewilligung mit Beschränkung des Verkaufs auf die öffentlichen Apotheken.

Nr. 2641.

A.G. vorm. B. Siegfried, Zofingen: Calmitol.

Eine ölige Flüssigkeit, enthaltend

Antrag: Bewilligung des freien

- From the official IKS bulletin of 1924.
- Includes:
 - Eucalyptus essential oil

- From the official IKS bulletin of 1986.
- Product registered at least until 1990.
- Includes:
 - Fennel
 - Gentiana

b) Tierheilmittel

Produits à usage vétérinaire

Electydral ad us. vet., Pulver

45 414

Werner Stricker AG, Alpenblickstrasse 13, 3052 Zollikofen

B

Vétoquinol SA, Magny Vernois, Lure, F

Deklaration:

GLUCOSUM ANHYDRICUM 21,75 g, NATRII CHLORIDUM 2,64 g, KALII CHLORIDUM 2,24 g, MAGNESII CHLORIDUM 0,52 g, NATRII ACETAS ANHYDRICUS 4,92 g, NATRII PROPIONAS 1,44 g, KALII DIHYDROGENOPHOSPHAS 1,02 g, EXCIPIENS AD PULVEREM PRO CHARTA 35 g

Anwendung:

Rehydratation bei Kälberdurchfällen

Code

Verkaufspreis:

6 Beutel Fr. 13.—

45 414 019

Gültig bis:

31. Dezember 1988

IKS, 17. 4. 86

Griseofulvin 10% ufa-med ad us. vet., Medizinalkonzentrat

47 707

Ufa-med AG, 6210 Sursee

B

1: GRISEOFULVINUM 100 g, EXCIPIENS AD PULVEREM PRO 1 kg

2: Dermatomykosen bei Rind und Pferd

Code

3: 1 kg Fr. 73.50

47 707 013

25 kg Fr. 1575.—

47 707 021

31. Dezember 1990

IKS, 24. 3. 86

Medigestin ad us. vet., Pulver

47 493

Medivet AG, 6301 Zug/Steinhausen

C

Deklaration:

CALCII CARBONAS 64 g, NATRII HYDROGENOCARBONAS 46 g, NATRII PROPIONAS 46 g, THIAMINI HYDROCHLORIDUM 0,4 g, CERATONIAE FRUCTUS PULVIS 11,6 g, GENTIANAE RADIX 16 g, ROENICULI FRUCTUS 16 g PRO CHARTA 200 g

Anwendung:

akute Indigestion, Eisenacidose

Code

Verkaufspreis:

200 g Fr. 6.—

47 493 013

Gültig bis:

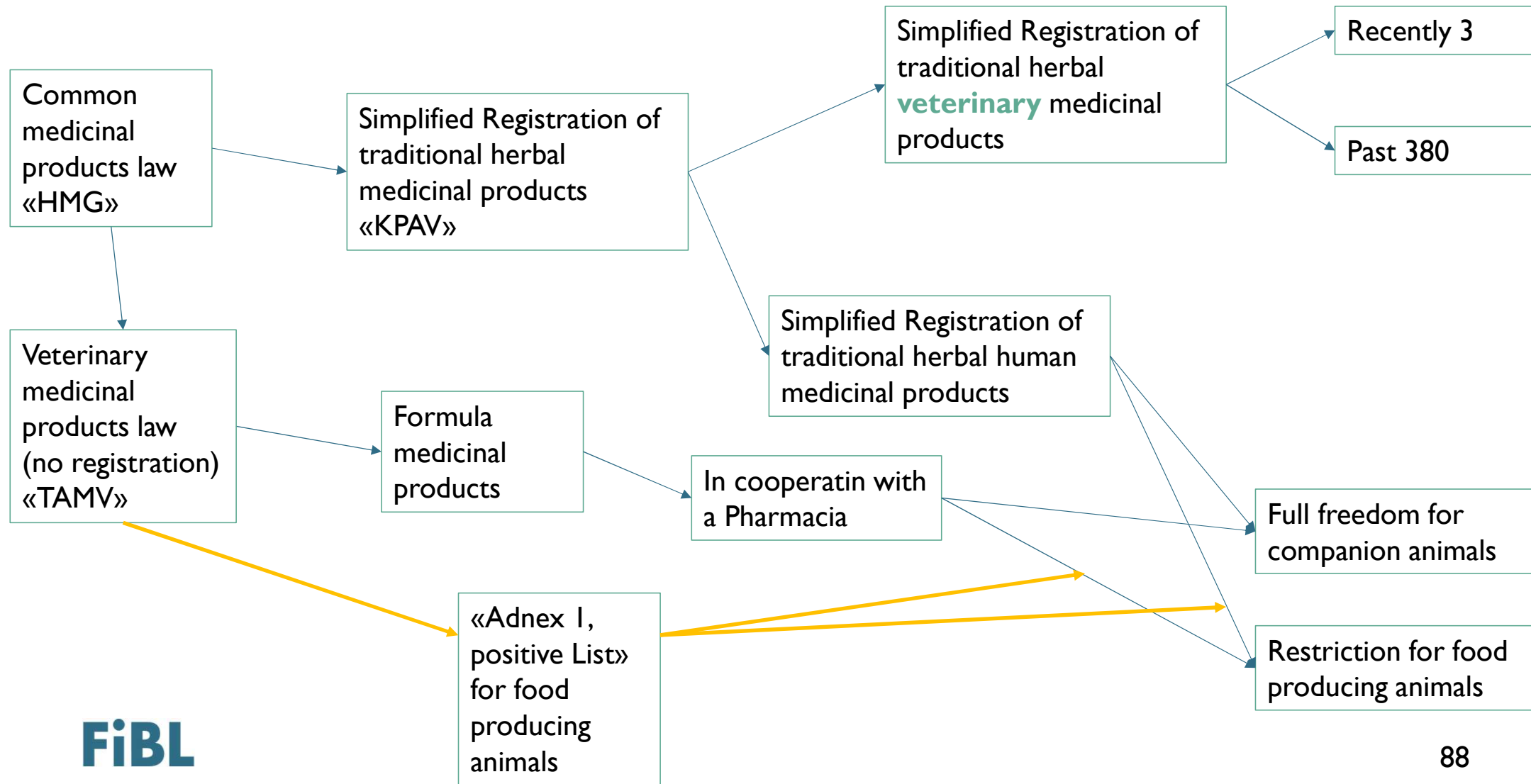
31. Dezember 1990

IKS, 24. 3. 86

IKS Monatsbericht / Bulletin mensuel OICM 4/1986

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Switzerland recently – overall structure of VMP law.



Thank you very much for your attention.