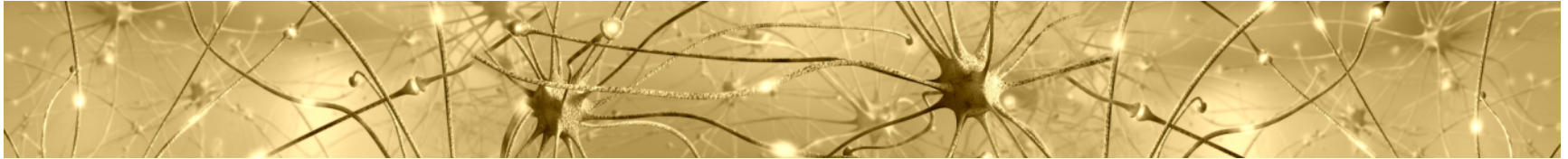


Natural compounds in Animal Health

Nature creates ability; luck provides it with opportunity- Francois De La Rouchefoucauld



1. Overview of where natural compounds are found in Animal Health

2. Veterinary medicines:

- When do you need a Marketing Authorisation?
- What data is required?
- Examples of natural compounds in veterinary medicines
- Case study - new veterinary medicine - use the “cascade” to your advantage

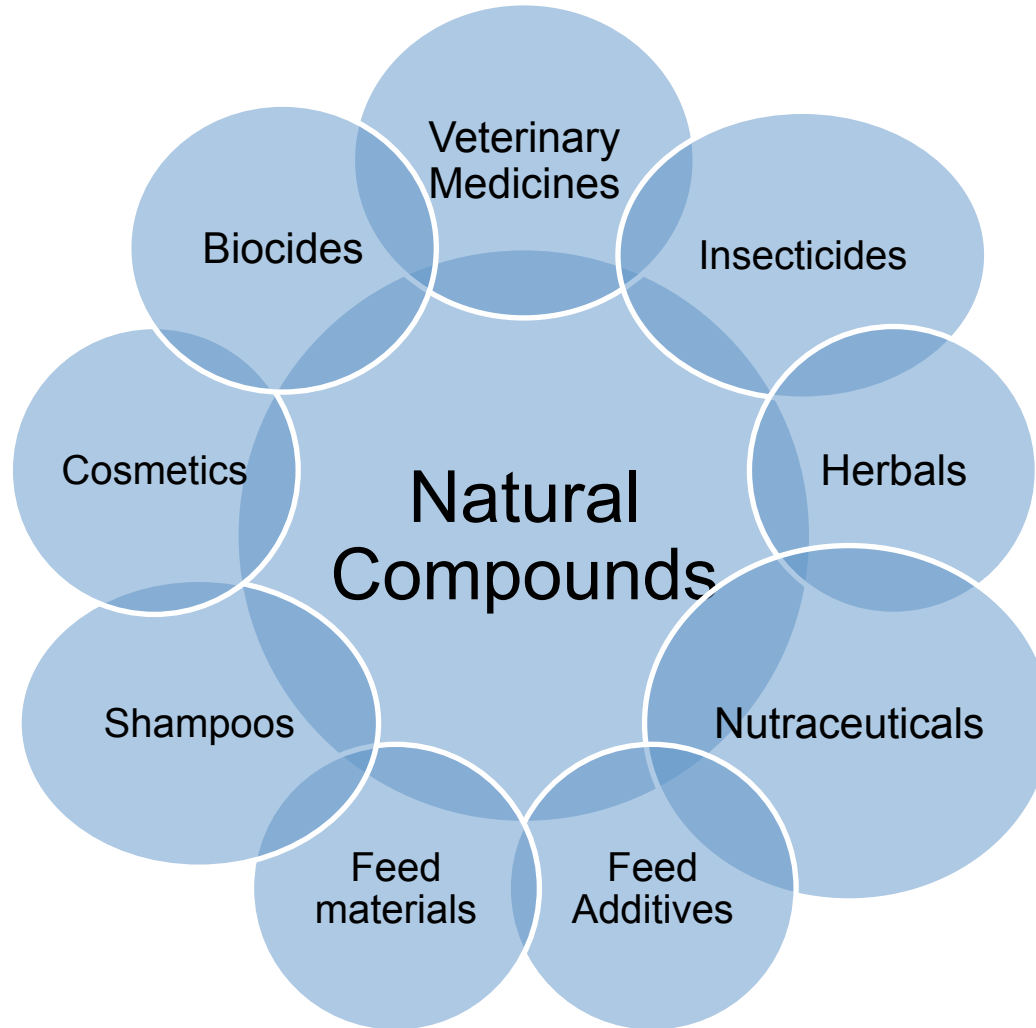
3. Unregulated veterinary products:

- Potential for certain animal products to be less regulated
- Animal skincare products

4. Summary

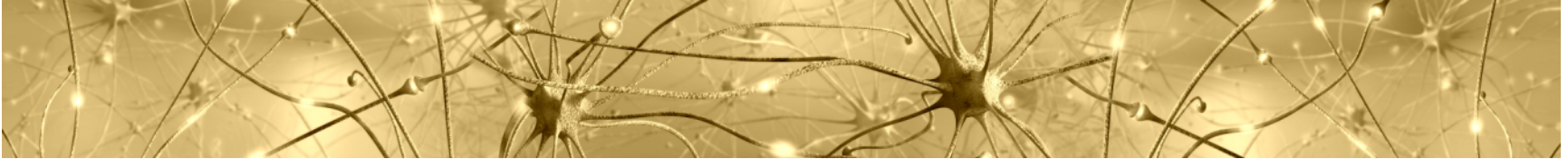
Natural compounds found in all Animal Health areas

An important role



When do you need a Marketing Authorisation?

Natural compounds in Veterinary Medicinal Products



A Marketing Authorisation is required if:

- medicinal claims are made
- the product contains certain ingredients that exert a pharmacological effect



“Herbals” and “Nutraceuticals” require authorisation if medicinal claims are made... UK enforcement agency is kept very busy...

Exemption for small pet animals

- Aquarium fish, cage birds, homing pigeons, small rodents, ferrets and rabbits
- Oral or topical, manufactured to GMP
- Active ingredient must be on “approved list”

Data required for authorisation of veterinary medicines

In comparison with human medicines



Administrative

Vet PV requirements less stringent

No PIL user-testing for vet package leaflet

CMC

Almost identical

Efficacy

Overlap with pre-clinical data requirements

Differences in clinical requirements

Safety

Vet safety has multiple aspects

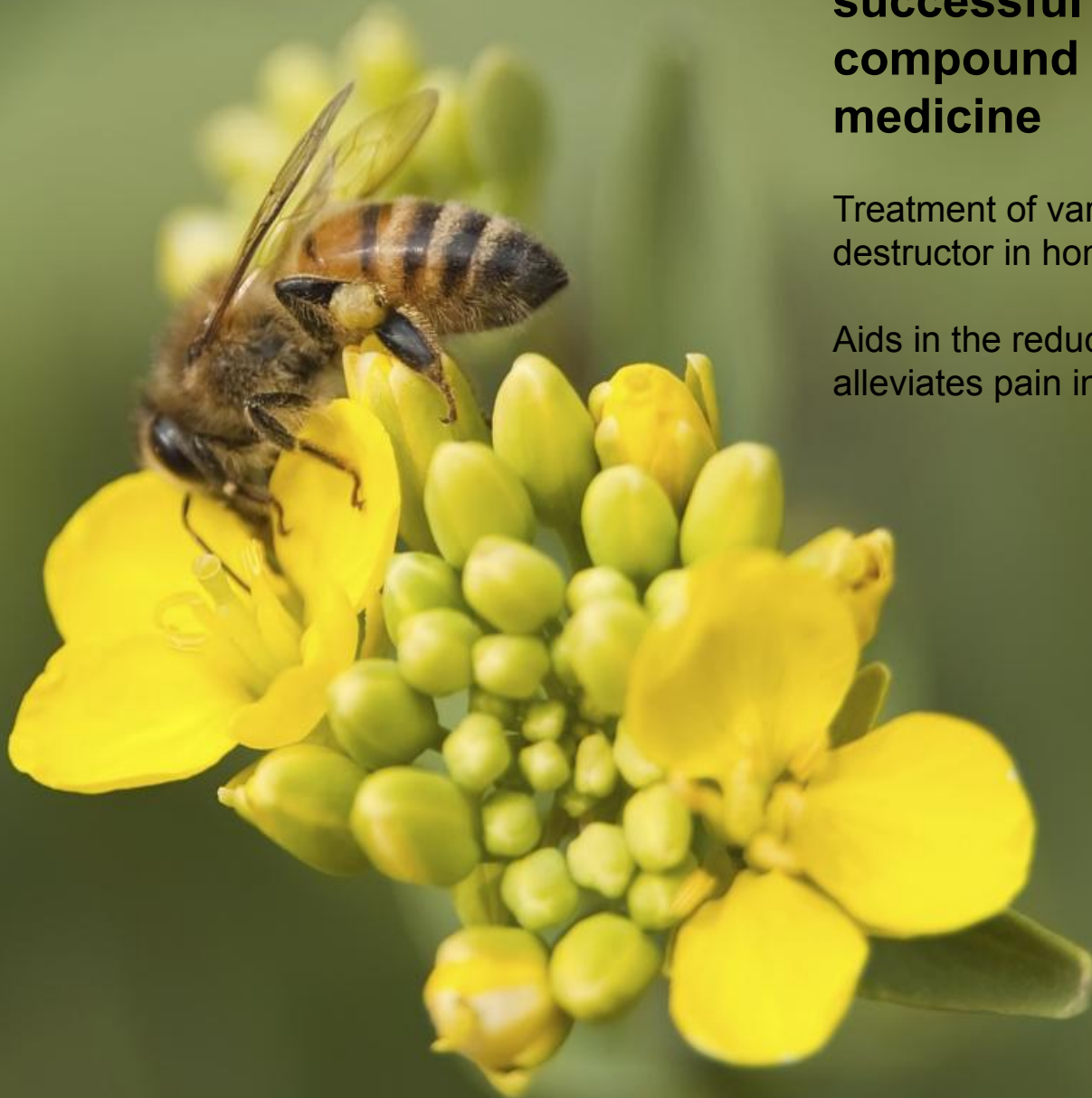
User, consumer (food producing species, MRL) and environment (food producing species, ERA)

MRL and ERA for natural compounds

MRL data package could be significantly reduced

ERA would stop in Phase I without the need for any testing or calculations

} Depending on compound



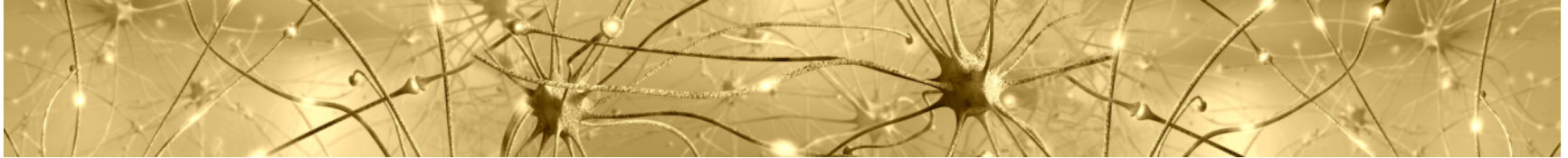
Thymol: Example of successful natural compound in veterinary medicine

Treatment of varroosis due to *Varroa destructor* in honeybees

Aids in the reduction of inflammation and alleviates pain in horses

Battle against anti-microbial resistance

Natural extract from pineapple stem



- Medical and veterinary communities share concerns over the development of microbial resistance
- Anti-microbial use in animals is being highly monitored
- Policies must focus on *Responsible Use*

- Vet pharma companies are unlikely to invest in new anti-microbials in the near future

- New alternative to antibiotic (to be authorised in 2017)
- Non-antibiotic, anti-infective for use in diarrhoea in pigs
- Recently awarded US sponsor fee waiver



Natural compounds under the cascade

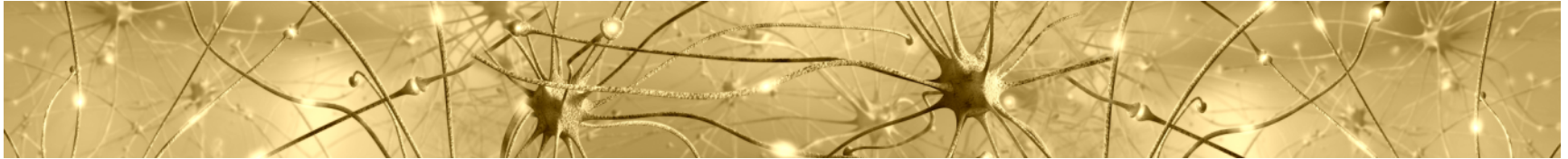
Case study company strategy



- Equine health has a historical high “off label” use of human medicinal products
- An opportunity to be the first to authorise a Veterinary Medicinal Product
- Initial complete market share

Potential for natural compounds to be less regulated

Not without complications



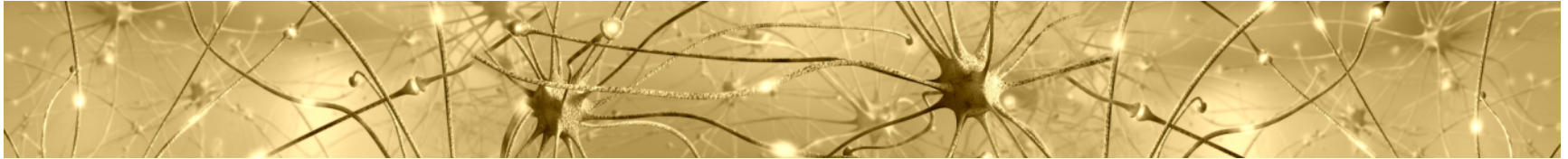
Product type	Human	Vet
Medicinal	✓	✓
Homeopathic	✓	✓
Herbal	✓	x
Cosmetic	✓	x
Medical device	✓	x

} Medicinal herbal falls under vet medicine scope (Dir. 2001/82)

} Less regulated area

Animal skincare products, no specific EU regulations

Often include natural compounds



- Skincare products, used by 127 million dogs & cats
- Annual turnover €70 million
- 15% growth during the last 24 months
- Shampoos, sprays, lotions, wipes, soaps, foams
- These products make no *medicinal* claims (revitalise coat, add shine, soften dry skin, control perspiration...)
 - Not under the scope of veterinary medicines directive (2001/82/EC)
 - There is no veterinary cosmetics regulation
- The complication is regulatory uncertainty: **Individual EU Member States can interpret legislation differently**

Natural compounds in Animal Health

Summary



Natural compounds are found across all aspects of Animal Health

For regulated medicinal products, there is the potential for a reduced data set for natural compounds

There are significant opportunities to market natural compounds in unregulated areas

