The Authorization and Use of Herbal Medicines in China

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Outline

- Authorization of Herbal Medicines for Animal in China
- Status of using Herbal Medicines in China
Terms of reference

* Traditional Chinese Medicine (TCM): is a medical sciences by using various animal, herb, and mineral material to treat ill, prevent diseases after diagnosed by inspection, auscultation & olfaction, inquiry, and palpation.

* Traditional Chinese Medicines (TCMs): including animal, herb, and mineral material for treating ill and preventing diseases by the principles of TCM theory.
**Natural Medicines**: Those animal, herbal, and mineral materia medica that have been defined its efficacy by modern technics. It’s is actually similar to phytochemical compounds by its major active components was quantified. It differs from TCMs by it not necessary to do compatibility and interaction study.
Herbal Medicines: only those herbal source material of traditional Chinese medicines, including one and/or several herbal medicines combined by formula. These medicines need to be characterized by modern scientific technology to define it’s safety, efficacy, quality; and for those combined herbal medicines need to study compatibility and interaction.
History of TCM

- In ancient time, Shennong Tasted a Hundred Grasses, tried to find herbal medical material.
  - Homology of medicine and food was characterized.
  - In the Western Zhou Dynasty (1046-771 BC), Doctors began to be classified into four categories – dietician, physician, doctor of decoctions and veterinarian.
The first pharmacopoeia, *Compendium of Materia Medica* compiled by Li Shizheng in 1578 (Ming Dynasty), first scientifically categorized medicinal herbs, collected medical material 1892, pictures 1000, empirical formula 10000.
400 years ago, in 1608, *Collection of horse disease therapy* was edited by Yu Benyuan and Yu Benheng (two brothers), famous veterinarian in Ming Dynasty. The book spread to Japan, Korea, Vietnam and Europe.
In 1956, many universities and provinces set up the unit of education and research on traditional veterinary medicines, CAAS specifically set up an institute of traditional veterinary medicines.

From 1960, modern technics were used for studying the efficacy of empirical formula.

Since 1987, new herbal medicines for animal were started to conduct evaluation for purpose of registration.
I. Authorization of Herbal Medicines for Animal in China
In 2004, requirement for registration of herbal medicines for animals were issued.

Docile submitted for registration including:
- Master File, 6 kinds
- Chemistry, Manufacturing and Controls, 12
- Pharmacology and Toxicology, 9
- Effectiveness, 4
- Labeling
Guidelines for registration study of herbal medicines

- 11 guidelines have been issued
  - GL for Pre-prepared
  - GL for extraction and purification
  - GL for preparations
  - GL for medium-scale production
  - GL for stability
  - GL for validation of analytical method
  - GL for clinical trial
Guidelines for registration study of herbal medicines

- GL for general pharmacology
- GL for nomination of drug name
- GL for quality control
Evaluation system on herbal medicines for animal

- Evaluation system for herbal medicines was established basically.
- QC is critical point for herbal medicine, need to pay attention QC based on the different climate, seasons and regions.
- Safety evaluation is based on the chemical pharmaceuticals.
Example of herbal medicines for animal study for registration

* *Macleaya cordata*: active components are Alkaloids, total contents is nearly 5%, belongs to isoquinoline derivatives.
* In the fruit: Sanguinaine, Chelerythine, Protopine, α-Allocryptopine, β-Allocryptpine。
* In the root and above ground parts: Sanguinaine, Chelerythine, Ethoxychelerythrine, Chelilutine, Bocconiue, Chelirubine, Protopine, α-Allocryptopine, Coptisine, Berberine, Corysamine and Bocconine, Dehydrociconthifoline, Dihydrosanguinaine。
Effects of alkaloids from *Macleaya cordata*

1. Antimicrobial effect: Water decoction is effectively inhibit many Gram positive and negative bacteria and leptospira. (Newman et al, 1999).
2. Insecticidal effects: it has strong killing effect on the trichomonas vaginalis.

3. Also has killing effects on the maggot.
Effects of alkaloids from *Macleaya cordata*

* 4. improve hepatic function, stimulate immunity. Stimulate T、B-cell function, improve liver damage, protect hepatic cell membrane and inhibit hepatic fibrosis.
Effects of alkaloids from *Macleaya cordata*

* 5. Antineoplastic effect。
   Alkaloids from *Macleaya cordata* can inhibit KB、P388、W256 neoplastic cell。
Effects of alkaloids from *Macleaya cordata*

6. Other effects

- Relieve cough and asthma, sedation, diuresis.
- Inhibit the adenovirus V and 12, and herpovirus.
Effects of alkaloids from *Macleaya cordata*

- 7. Growth promotion

- Sanguinaine inhibit the aromatic amino acid decarboxylase, modulate the pathway of tryptophan--5-hydroxytryptamine metabolism, so to increase the feed intake of animal.
Application of *Macleaya cordata*

- Injection solution for treatment of piglet white dysentery and yellow dysentery.
- Improve feed conversion.
Study on the extraction process for *Macleaya cordata*
II. Status of using Herbal Medicines in China
Status of using herbal medicines for human in China

- The total production value of human herbal medicines industry is 78.66 billion ¥ RMB in 2015, 1/3 of total medicines industry production value.
- There are 649 standards (products).
The total production value of herbal medicines for animals is 5.5 billion ¥ RMB, is about 15% of total production value of animal drugs industry in 2014.

The increase rate per year of production value is 12.39%, while sale value is 11.35%.
The products type including

- pulvis/powder, occupied 55%
- oral solution, 21%
- injectable solution, 12%
- Granules, 10%
- tablets
- tincture
Veterinary Pharmacopoeia of China 2015 version contains the following herbal medicinal products:

- classification of herbal medicines
  - crude medicinal materials 583 and prepared medicinal slices 397
  - extracts 22
  - historical formula preparations and single preparations 196, including tablets, tincture, pulvis, powder, granules, oral and injectable solution.
Alternatives to Antibiotics from herbal medicines

- **AM effect**: those antipyretic and antidote medicines may show its effect by AM, such as berberine, allicin, cinnamaldehyde, ginger, honeysuckle, fructus, curcuma.
- **immunostimulation**: baicalin, astragalus
- **Coccidiostats**: halofuginone, artemisinin
Challenges

- No herbal medicinal products can completely replace antibiotic’s treatment up till now.
- Resources of medicinal material is limited
  - competitive use by human health
  - endangered species getting more and more, precious medicinal materials becoming less
  - eco-balance destroyed
Challenges

- Wild plants turn to be cultivated
- Good Agriculture Practices for herbal medicinal material is needed
  - geo-authentic crude medicines cultivated in different region.
  - pesticide and fertilizer used in cultivate process.
  - heavy metals contamination in soil of cultivation
- Phytochemical active ingredients to be made industrialized still be a big challenge due its complicated structure.

This report is aimed to reduce the use of AMR and AMU, making great contribution to both human and animal health.

Tu Youyou got Nobel Medical Prize in 2015 by research on artemisinin against malaria.
Thank you for your attention!