EU Directive 2004/24/EC

PURPOSE: "Protect public health by requiring specific standards of safety and quality for traditional herbal medicines"

REQUIREMENTS: ALL HERBAL MEDICINE (EXCEPT RAW HERBS) MUST BE LICENSED UNDER THMR (TRADITIONAL HERBAL MEDICINES REGISTRATION)

DIRECTIVE WAS PASSED IN APRIL 2004 BUT ALLOWED FOR A 7 YEAR TRANSITION PERIOD. DIRECTIVE WILL BE ENFORCED APRIL 2011

THMR REQUIREMENTS:

1. PRODUCT DOSSIER

- Prove 30 years traditional use and 15 years use in EU
- Complete product profile including specific labeling requirements
- Pass all EMEA tests – stability, heavy metals, genotoxicity etc
- Expert reports and evidence of safety

2. MANUFACTURERS LICENSE

- All manufacturers must comply with EU standards of GMP
- Regular inspections by EU

3. IMPORT LICENSE

- All importers must have a manufacturers import license
- Meet EU standards of GDP
- Regular inspections by EU

THE NUMBER OF CHINESE HERBAL REMEDIES THAT HAVE BEEN LICENSED SINCE THE BEGINNING OF THE TRANSITION PERIOD: ZERO

WHY NO CHINESE HERBALS ARE BEING LICENSED:

1. GUIDELINES DELAYED

MHRA guidelines have been slowly added to their website and only in the couple of years has a clear picture emerged of what is expected for registration. Not a true 7 year transitional period.

2. COMPLEX HERBAL REMEDIES UNLIKELY TO PASS EMEA TESTS

Chinese herbal remedies often use combinations of herbs. Research and discussion with other herbal groups has shown that with remedies over 2-3 herbs it is impossible for these products to pass the pharmaceutical tests. Natural products do not behave in the same way as synthetics.

3. EXPENSE
There are hundreds of traditional herbal formulae. Good estimates of the cost of registering just 1 product are around £70,000. Herbal sector cannot afford to register all formulations and perhaps will only try to register a handful.

4. TRADITIONAL USE REQUIREMENT
It is difficult for a relatively young herbal sector to prove 15 years use in the EU. This requirement also stops any innovation or development of herbal formulae.

5. FINDING MANUFACTURERS
The Chinese medicine manufacturers are exclusively in China. Their internal market is much bigger than the EU and so finding manufacturers that are prepared to change their procedures, staff and take time and money to change to EU GMP is not a simple process. Most manufacturers seem to prefer to concentrate on producing herbal remedies for China and other parts of the world and cut out the EU public.

RESULT OF THIS LEGISLATION:

1. Number of Chinese herbal remedies available to the public will drop drastically from hundreds to a handful.
2. Chinese herbal practitioners with no medicine to prescribe will go out of business.
3. Public choice and public health will suffer greatly – the opposite of the legislations purported aim.

POINTS TO CONSIDER:

1. IS THIS LEGISLATION PROPORTIONATE TO THE RISKS?
Chinese herbal medicine has been practiced unregulated for decades in the EU with millions of people treated. There have been no proven deaths from properly prescribed, uncontaminated remedies (the highly sited cases of deaths in Belgium involved untrained practitioners and contaminated formulations). So the risks posed to the public justify the severity of this legislation?

2. WILL THIS LEGISLATION MEET ITS AIMS?
We are just over a year away from enforcement and registration of one product is estimated to take about a year. It is clear from the fact that currently there are no Chinese herbal medicines licensed (or in the process of being licensed), that this legislation will take hundreds of Chinese herbal remedies off the shelves of clinics and close down Chinese clinics. Will this ‘protect public health’ or will it be to the detriment of public health?

3. IS THIS LEGISLATION DISCRIMINATORY?

Traditional and ethnic medicines are negatively affected by this legislation which is based on a Western Pharmaceutical framework even though the 2 modalities are very different. Is the removal of the public's right to choose traditional ethnic medicines discriminatory? This legislation also prevents any innovation and development of Chinese herbal medicine (due to the traditional use requirement). Is this discriminatory?

ANOTHER WAY?

It is clearly important that the public are protected from uncontaminated, bad quality herbal remedies and most of the Chinese herbal sector would support some legislative control. It is also clear from decades of unregulated use of Chinese herbals, that they pose an extremely small risk to the public. Would an amended directive that controls quality but is not so severe in terms of cost and requirements be more fair and effective?

This directive takes no notice of the hard work towards statutory regulation. Given the impossibility of licensing the hundreds of Chinese herbal formulations, after SR the practitioners would have no remedies to prescribe meaning that many will go out of business. Would it be more sensible to ensure that Statutory Regulated practitioners could continue to prescribe 'unlicensed' remedies? If so, there would be a legal vacuum between the date of enforcement (April 2011) and the implementation of Statutory Regulation and many practitioners will disappear. Could we bring the 2 regulations into sync so that the date of enforcement is delayed until Statutory Regulation is finalised?

PROPOSALS FOR ACTION

1. Raise awareness of the detrimental effects of this directive on public health, public choice and the herbal remedy sector.

2. Demonstrate to the relevant EU authorities that this directive is unworkable, disproportionate, discriminatory and is at odds with its purported aims.

3. Alter the directive to ensure standards of quality and purity, whilst making the licensing process practical and not a hindrance to herbal remedy innovation. This would involve changing the requirements so that licensing is simpler, cheaper and possible for multi-herbal compounds.

4. Extend the transitional period to give the Herbal sector time to make licensing applications. This would also allow the directive to synchronise with Statutory Regulation.