

PRESS RELEASE

For Immediate release

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UK Herbal Quality Campaign misguided ANH-Intl queries UK campaign targeting politicians and bureaucrats

The Alliance for Natural Health International (ANH-Intl), representing natural health consumers, practitioners and suppliers, has today said that most of the concerns expressed by the British Herbal Medicine Association's (BHMA's) Herbal Quality Campaign (HQC) are 'bogus'. The HQC, launched on 24th January in Westminster, claims that the UK government is not doing enough to fully implement the EU's Traditional Herbal Medicinal Products Directive (THMPD), and that public safety is endangered by inadequately regulated herbal products.

Responding to the HQC initiative, ANH-Intl's Dr Robert Verkerk said:

"The EU herbal directive is an optional scheme that only applies to those products that meet its restrictive requirements. Many are not, and will never be, eligible to the THMPD scheme without a major change to the rules. The BHMA must accept that one size does not fit all when it comes to regulating herbal products, and that there are several different regulatory regimes that allow legal sale of herbal products in the EU, including food supplement legislation."

ANH-Intl also argues that there is no evidence that the BHMA's favoured THMPD will do anything to improve consumer safety, particularly since the herbal food supplement sector that is particularly being targeted by the HQC has an exemplary public safety record.

It would appear that the HQC's main reasoning for targeting herbal products sold as food supplements is they pose competition to herbal remedies that have been successfully licensed under the THMPD scheme. Responding to this, Dr Verkerk said:

"The BHMA has not produced any substantive evidence of any health concerns posed by botanical food supplements, other than referencing St John's wort (Hypericum perforatum) food supplements. The risk of Hypericum possibly interfering with the effectiveness of the contraceptive pill is well known, and appropriate warnings are usually clearly stated on food supplement labels."

ANH-Intl says that the EU's THMPD misrepresents the issue of herbal quality. Of particular concern is that herbal products containing a full spectrum of active ingredients tend to be considered as lower quality, compared with highly purified herbal extracts, and are ineligible to the Directive's scheme. Such a view is incorrect, according to ANH-Intl, since many polyherbal products containing diverse active constituents are not only more effective than such extracts, but also extremely safe.

To bring clarity to some of the confusion that has been generated by the Herbal Quality Campaign, ANH-Intl has answered some Frequently Asked Questions (FAQs), which are accessible via the link below this press release.

Ends.

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NOTES TO THE EDITORS

1. Frequently asked questions about the quality of herbal products

These can be found at <http://anh-europe.org/news/frequently-asked-questions-about-quality-and-regulation-of-herbal-products>

2. UK competent authorities

While the Medicines and Healthcare products Regulatory Agency (MHRA) oversees compliance with medicinal laws, including the THMPD, food supplement laws are overseen by the Department of Health.

MHRA “Guide to What is a Medicinal Product”:

<http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con007544.pdf>

UK Department of Health. Food Supplements: Guidance and FAQs:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_130237

3. THMPD significantly flawed

ANH-Intl further proposes that, if the THMPD were doing the job for which it was originally designed, manufacturers would be perfectly willing and able to obtain THRs for large numbers of their herbal products. Unfortunately, the THMPD as currently formulated, contains multiple problems that put the THR scheme effectively out of reach of most manufacturers of herbal products. These problems include, but are not limited to:

1. The THMPD is only open to herbal products that have been on sale in the EU for at least 15 years, out of a total of at least 30 years’ safe use worldwide
2. The THMPD regime favours single-herb products, stabilised in a pharmaceutical-style base containing artificial polymers – very unlike what most herbalists, or users of herbal medicine, would consider true herbal products

3. Manufacturers wishing to apply for THRs must spend large amounts of money to support the application – often upwards of £50,000 and sometimes even more than £150,000 per product. This is out of the reach of most of the small- and medium-sized enterprises (SMEs) that comprise the majority of the UK herbals sector
4. As a result of the above, not a single herbal product has been registered, anywhere in the EU, that is exclusively designed for use by the great traditions of Ayurveda or traditional Chinese medicine (TCM), the Asian traditions that acted as initial drivers for the EU Directive

Together toward a better THMPD!

<http://www.anh-europe.org/news/together-toward-a-better-thmpd>

4. Herbal Quality Campaign: bid for reduced competition?

ANH-Intl believes that further enforcement of this highly flawed European Directive will suit only one group of companies: namely, the large phytopharmaceutical companies that have succeeded in obtaining significant numbers of THRs for their products. It is these very companies who are members of the BHMA, the drivers of the HQC. As it states on the BHMA website, *“Members of the BHMA include companies involved in the manufacture or supply of herbal medicines”*. At the end of 2011, an investigation by ANH-Intl revealed that the HQC’s predecessor, the Herbal Medicine Safety Campaign (HMSC), was being organised by the UK arm of German phytopharmaceutical company, Schwabe Pharma. The HMSC has since been renamed the HQC, with Schwabe taking a back seat to the BHMA in the Campaign’s organisation.

ANH Feature: ANH-Leaks again! The invisible campaign to restrict UK herbal products

<http://www.anh-europe.org/news/anh-feature-anh-leaks-again-the-invisible-campaign-to-restrict-uk-herbal-medicines>

Transparency 1-0 Schwabe. Success for ANH-Leaks:

<http://www.anh-europe.org/news/transparency-1-0-schwabe-success-for-anh-leaks>

5. THMPD unpopular with UK public

ANH-Intl believes that the evidence available to date shows clearly that further enforcement of the THMPD in the manner envisaged by the HQC would be highly unpopular with the UK public. In the case of Healthspan, which is based in Guernsey and sells primarily to the UK, replacement of some of its popular

and long-standing products with new, THMPD-compliant formulations has caused many customers to look elsewhere [<http://www.anh-europe.org/news/eu-herbal-directive-forces-predictable-price-rises-and-customer-discontent>]. Top of the consumers' complaints were high price rises and labeling requirements that make it impossible to tell how much active ingredient is contained the product. And, although the situation is beyond Healthspan's control, any attempt by them to explain the situation is met with accusations of profiteering.

Should the HQC's demands be met, says ANH-Intl, UK consumers will lose out further. Not only will there be further significant, overnight price hikes as occurred with Healthspan, but consumer choice will be further restricted as SMEs are forced out of business. The only winners in this situation will be the large phytopharmaceutical companies – who are directly involved with the HQC as members of the BHMA.

EU herbal directive forces predictable price rises and customer discontent:

<http://www.anh-europe.org/news/eu-herbal-directive-forces-predictable-price-rises-and-customer-discontent>

ANH-Intl news stories related to the topic of this press release

ANH-Intl feature – Frequently Asked Questions about EU herbal registrations and bans:

<http://www.anh-europe.org/news/frequently-asked-questions-about-eu-herbal-registrations-and-bans>

Shoddy study casts doubt on herbal products' safety information:

<http://www.anh-europe.org/news/shoddy-study-casts-doubt-on-herbal-products-safety-information>

Natural healthcare proven amazingly safe – once again:

<http://www.anh-europe.org/news/natural-healthcare-proven-amazingly-safe—once-again>