alliance for natural health

"Good Science, Good Law"

ANH INNOVATORS CLUB BULLETIN

June/July 2006

News

European Union

MHRA Warn of Link between Herbal Medicine Ingredient and Liver Disorders

The Medicines and Healthcare products Regulatory Agency (MHRA) today said it was concerned about links between black cohosh, an ingredient of herbal products commonly used to treat menopausal symptoms, and the risk of liver disorders.

Professor Philip Routledge, Chair of the Herbal Medicines Advisory Committee, stressed: 'After reviewing all available data, the Herbal Medicines Advisory Committee has come to the conclusion that black cohosh may be associated with liver disorders. This is rare, but can be serious.'

This link has been confirmed by the Commission on Human Medicines and the Herbal Medicines Advisory Committee. Both committees have reviewed all available data and concluded that the data underlines an association between black cohosh and risk of liver disorders.

Following advice from both committees, warnings are now to be added to the labels of black cohosh products and the MHRA is working with the herbal sector to ensure the public is fully informed about this potential risk.

Professor Philip Routledge, Chair of the Herbal Medicines Advisory Committee, emphasised: "After reviewing all available data, the Herbal Medicines Advisory Committee has come to the conclusion that black cohosh may be associated with liver disorders. This is rare, but can be serious."

Professor Kent Woods, MHRA Chief Executive, said: "In the light of this advice, the MHRA is working with the herbal sector to ensure that labels of black cohosh products carry updated safety warnings. The labels will point out the possible symptoms so that appropriate action can be taken without delay."

ANH Comment: This is a little reminiscent of the recent ephedra issue in the US and kava kava in Europe. Very rare incidences of liver disorders, most likely initiated in persons whose livers are already heavily stressed by alcohol or substance abuse, are being used to cast a negative light on herbal products. In Europe, this is at the time when the Traditional Herbal Medicinal Products Directive is increasingly seen as the 'correct' way of getting herbs to market, albeit via a simplified medicinal licensing route. The media has picked this up and used it as way of bashing the natural product sector – yet again. ANH is working closely with a range of herbal product associations to create a meaningful way forward for the regulation of herbs and botanical products generally, particularly while the botanical category within the EU Food Supplements Directive is still up for negotiation, and will be an extremely important safe-harbour for non-medicinal herbal and botanical products.

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European Commission - H5N1 confirmed in wild duck in Spain

Avian influenza H5N1 confirmed in a wild bird in Spain: authorities applying precautionary measures

The Spanish authorities have informed the European Commission this afternoon that tests have confirmed the presence of the highly pathogenic avian influenza virus H5N1 in a wild duck (of the pociceps species), found dead in a wetland in the province of Alava in the Basque Country. Samples will be sent to the Community Reference Laboratory for avian influenza in Weybridge for further tests to determine if this is the H5N1 strain of the virus found in Asia.

The Spanish authorities are applying the precautionary measures set out in Commission Decision 2006/115 on certain protection measures in relation to highly pathogenic avian influenza in wild birds in the Community. The Decision sets out the measures to be applied in any EU Member State which has a case of suspected or confirmed highly pathogenic avian influenza H5N1 virus in wild birds.

The measures consist of the establishment of a high risk area (a 3 km protection zone) and a surrounding surveillance zone of 10 km (which includes the protection zone), to be defined taking into account the specific conditions of the wetland. In the protection zone, poultry must be kept indoors, movement of poultry is banned except directly to the slaughterhouse and the dispatch of meat outside the zone is forbidden except where products have undergone the controls provided for in EU food controls legislation (i.e. meat sourced from healthy animals in registered farms, subject to ante and post mortem checks by vets in the slaughterhouse). In both the protection zone and the surveillance zone, on-farm biosecurity measures must be strengthened, hunting of wild birds is banned and disease awareness of poultry owners and their families must be carried out.

Spain is the fourteenth EU Member State to report a case of highly pathogenic avian influenza H5N1 in wild birds. The other countries are Greece, Italy, Slovenia, Hungary, Austria, Germany, France, Slovakia, Sweden, Poland, Denmark, Czech Republic and UK. Avian influenza H5N1 was confirmed in poultry in 5 EU Member States - France, Sweden, Germany, Denmark and Hungary.

ANH Comment: Intelligence to ANH suggest that the risk of an avian influenza pandemic will increase again as of September this year, particularly when migratory birds return to Qinhai Lake in western China. It was revealed at the Lancet Medical Forum held in Singapore in May that that these birds already contain the necessary genes to propagate sustainable human to human transmission of the virus. In addition, *The Alternative* practitioner magazine, published in the UK by Parkview Media (approx 13,000 circulation), has published this month the second of a three part article on the role of natural products in the event of an avian influenza pandemic. The report picks up some of the points made in ANH's ground-breaking report submitted to the World Health Organization in April (see ANH website).

USA

The Washington Post Strikes Again...

On 20th of June consumers were once again treated to a dose of what amounts to little more than press releases from pharmaceutical companies, the government, and big trade associations. Even worse is that Big Pharma-funded educational institutions with "new" studies showing the "dangers" or "ineffectiveness" of therapies and supplements that are commonly accepted in the "alternative" world as safe and effective are given a platform such as this. If you didn't catch the full story in all its glory, read it here.

The interesting news is that consumers have obviously had their fill and the Washington Post has received 3000 letters to date.

Regulatory Developments

European Union

Risk (and Benefit) Assessment

Risk assessment methodologies will increasingly be used, globally, to determine maximum safe or permitted levels of nutrients and provide justification for bans. Risk assessment data, including dose-response data where these are available, will also increasingly replace the RDAs which have been set in the USA at two standard deviations above the Estimated Average Requirement (EAR).

Although most of the work has focused to-date on risk assessment of vitamins and minerals, these methods will increasingly be applied to other nutrient groups including essential fatty acids, amino acids, phytonutrients, other botanicals, etc.

The Institute of Medicine (IoM) in the US and the European Food Safety Authority (EFSA) in Europe are among the leading bodies worldwide assessing the safety of nutrients. Risk assessment has also become a major issue for the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), which expects to finalise global guidelines for vitamins and minerals in about 2012. Dr Robert Verkerk of the ANH is directly involved with scientific inputs to EFSA, as well as being a member of the risk assessment Electronic Working Group in the CCNFSDU.

ANH identified in its major submission to the FAO/WHO nutrient risk assessment project in 2003[1] major flaws with existing methodologies used by the IoM, the UK Expert Group on Vitamins and Minerals, including:

- The lack of consideration of benefit in assessments
- The excessive focus on vulnerable groups
- Misuse of the precautionary principle
- The lack of consideration of differences in risk/benefit between different forms of nutrients
- Absent published data in assessments
- The exclusion of observational and clinical data
- Lack of a tiered or prioritised approach to assessments

The EFSA organised a scientific colloquium on risk /benefit assessment of foods and nutrients in Tabiano, northern Italy, close to its HQ in Parma, on 13-14 July. Rob Verkerk was among 80 scientists, mainly from Europe, in attendance. US participants included Dr John Hathcock of CRN and Dr Beth Yetley of the NIH. This colloquium potentially represents a landmark event, signalling the future shift away from just assessment of risk in isolation, but rather the consideration of risk and benefit, possibly using a common 'currency'.

The meeting, proceedings from which are expected to be available in March 2007, was intended primarily as a brainstorming exercise to help develop risk/benefit assessment approaches and methodologies for foods, nutrients and functional foods. Following introductory lectures, the meeting focused on developing approaches within individual discussion groups, of which there were four, the most relevant one (including Rob Verkerk, John Hathcock and Beth Yetley) pertaining to nutrients and functional foods. This particular discussion group was chaired by Professor Albert Flynn (Cork University, Ireland) and the Rapporteur was Dr Alan Boobis (Imperial College London, School of Medicine).

Key, relevant summary points emerging from the meeting are as follows:

- The EFSA must be congratulated for putting on a major colloquium which included benefit assessment rather than just risk assessment. There was no doubt that EFSA takes the issue seriously, but it remains to be seen how political processes will be enacted to slow the finalisation of EFSA-approved methodologies.

- The importance attributed to the German Federal Institute for Risk Assessment (BfR) methodologies was clear, the key proponent in Tabiano being Professor Hildegard Przyrembel, of the BfR, who has been used as key spokesperson on risk assessment put forward by major trade associations such as

[1] ANH website: http://www.alliance-natural-health.org/_docs/ANHwebsiteDoc_121.pdf.

the IADSA since 2004. In the view of the ANH and numerous other scientists, Professor Przyrembel's views are flawed. She has great difficulty considering that benefit is anything other than the reduction or absence of risk, whereas benefit associated with nutrient intakes can often be a discrete property that is independent of risk and refers to health gains above a pre-determined baseline. It should be recognised that while Professor Przyrembel appears to wish to play a major role in EFSA, her colleague at the BfR, Professor Rolf Grossklaus, chairs the CCFNSDU in Codex.

- Dr Alan Boobis, a highly eminent scientist with Imperial College emerged as a new ally given his agreement and support for the principles in ANH's programme to establish a good and proper scientific basis in risk (and benefit) assessment.

- Rob Verkerk was able to integrate all of ANH's concerns about existing risk assessment methodologies and these were presented to the main plenary session by Prof Boobis. The only objections came from Prof Przyrembel and during discussion, Prof Boobis asked Rob Verkerk to intervene on the subject of misapplication of the precautionary principle (a key area of research in the HAN Foundation project) to which Prof Przyrembel was unable to (or chose not to) respond.

- The most likely candidates for a common currency between risk and benefits are some form of Quality of Life index, such as Disability Adjusted Life Years (DALYs).

- US participants voiced their view that the nature of the methodologies proposed at the meeting represented a higher level of advancement scientifically than equivalent discussions in the US (e.g. IoM, NIH).

In summary, the development of proper risk/benefit assessment procedures could become one of the most important tools in the development of sensible, scientifically rational regulatory approaches and the EFSA colloquium could represent a landmark event in this respect. The ANH regards this as one of the most important areas in which it can continue to make very significant, constructive input.

USA

Adverse Event Reporting (AER) – making sense of the confusion!

The coming together of Senators Orrin Hatch (R-Utah), Tom Harkin (D-Iowa) and Dick Durbin (D-Ill) to introduce the 'AER Bill' has understandably created considerable controversy. The default health freedom position has been to oppose the bill, whilst the default mainstream industry position has been its support.

The American Association for Health Freedom (AAHF), affiliated with the ANH and based in Washington, provides us with their position:

> **AAHF position**
>
> American Association for Health Freedom would like to thank Senators Hatch and Harkin for their work on S.3546 the Dietary Supplement and Non-Prescription Drug Consumer Protection Act (the "AER bill"). We appreciate their long-time support and belief in the right of the consumer to access dietary supplements. Ultimately, after careful review of the bill, we are unable to support S. 3546.
>
> If S. 3564 becomes law, it will amend the federal Food, Drug and Cosmetic Act to require the reporting of "serious" adverse events for both over the counter (OTC) drugs and dietary supplements to the U.S. Food and Drug Administration.
>
> As the politically active voice of the healthcare practitioner and their patients, AAHF sees S. 3546 as part of a bigger picture that would like to treat dietary supplements more like pharmaceuticals and not as food as it currently stands. We believe that as soon as you accept differential treatment between dietary supplements (as concentrated nutrient forms) and conventional foods, you have given up very valuable ground.

S. 3546 would also discourage consumers from properly submitting their adverse events. Consumers should be discussing their adverse event reactions with their practitioner rather than just sending a complaint to the manufacturer or retailer. There is a serious potential for abuse of the system and supplements could easily be blamed in place of things as divergent as pharmaceutical drugs, recreational drugs, genetic sensitivities, food intolerances, alcohol abuse, etc. A healthcare professional is crucial to determining the adverse event.

Additionally, the FDA is already broken and this bill would just add to its misery. The FDA's own enforcement reports (for drug products) show it to be an agency under increasing pressure to do more with less. The number of warning letters issued to pharmaceutical companies has dropped over the past 10 years even as product recalls have increased. In other words, the agency is allowing more manufacturer product mistakes to reach the market. Adding supplements would reduce enforcement efficiency even more - for both drugs and supplements. This bill is a classic demonstration of the federal government wasting money to protect the public from a relatively small health threat on the part of dietary supplements. In fact, food is actually more dangerous than dietary supplements and cause 5,000 deaths and over 80 million hospitalizations a year in the US, according to the Centers for Disease Control.

We encourage the dietary supplement industry to report their adverse events and we believe that over-the-counter medications should have a mandatory adverse event reporting process but we believe that S.3546 is not what is best for the American public.

July update – 5000 letters have been sent to Congress to date from consumers and practitioners opposing the AER bill.

ANH Comment: In our opinion, the proposed AER Bill cannot be taken at face value. The concept is clearly admirable and, if implemented with good intention across all sectors of the community would be nothing other than beneficial. The industry that supports it wholeheartedly believes that the lack of reported adverse event cases will provide it with much needed ammunition to show the anti-natural product sceptics just how safe natural products are, as well as just how responsible the industry is. They also believe it will help skim off a few of the less responsible operators – something we would all be happy to see.

But, as both ANH and AAHF have previously made clear, this is a slippery slope. In combination with a pre-market authorisation approach which has already been proposed (in 2002) by the Institute of Medicine in its "*Proposed Framework for Evaluating the Safety of Dietary Supplements*", Adverse Event Reporting or 'flagging' could more or less bring the industry to its knees – especially if abused. According to the Bill's current text, there are inadequate safeguards in the text to prevent its abuse, and we believe that this 'after the event' approach to safety evaluation is not the best way to demonstrate the extreme safety of the majority of this industry's products.

A comprehensive, science-based approach to risk/benefit assessment, as developed during the EFSA colloquium on the subject in Tabiano, Italy, last week (see above), is – in our estimation – a much better *a priori* approach for the evaluation of safety – as well as benefits. Of course, only history will show which approach is better…

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