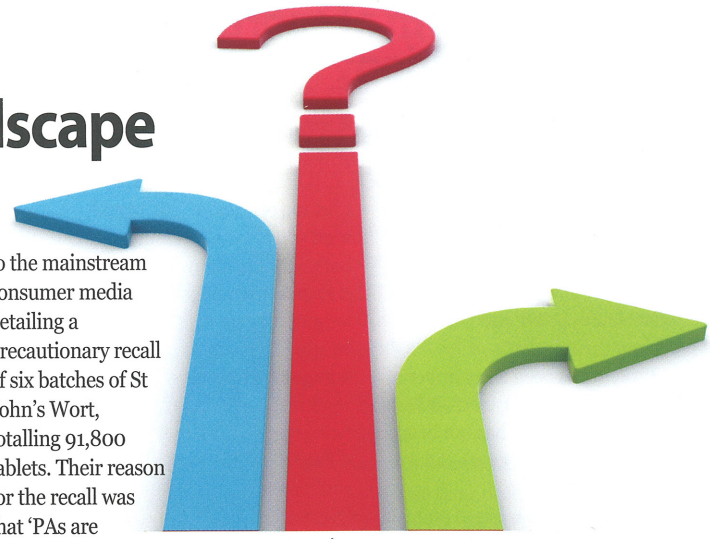
HFMA UPDATE

by Graham Keen, Executive Director

A shifting landscape



I have been saying for some time now that the work of the HFMA is in the process of changing in a fundamental way. Over the last five to 10 years, we have been railing against the EU legislative system, constantly trying to limit the damage caused by an endless succession of new and highly damaging and, ultimately, invariably quite unnecessary new EU Regulations and Directives.

As we come to terms with and learn to work with this new legislation, I believe we will see the work of the next five to 10 years morph into a new dual challenge. One of these will be a 'battle of the borderline', i.e. skirmishes along the borderline between what is a food, and what is a medicine, which I learned recently at a European industry meeting is known in Belgium as the 'grey zone'. This is the reason why the critical work we are doing to support the MHRA in its defence of a legal challenge from a major pharmaceutical company, seeking to require the MHRA to determine that glucosamine containing products, or GCPs, are medicines, is so important.

The other thing we will have to address will be constant challenges to the quality and safety of our products, particularly when it comes to botanical (i.e. plant) substances. It seems that not a month goes by without a new threat emerging, and so it is the case right now. If someone had asked me about pyrrolizidine alkaloids (PAs) before January of this year, I would have probably guessed that they were some form of alien species from the latest new *Star Wars* movie! But this is a real and potentially very challenging issue, and one we are having to take very seriously.

PAs are naturally occurring compounds made by many plant species as a defence mechanism against predators, and can also be toxic to humans. They are found in plants that have been under scrutiny for a while – the European Food Safety Authority (EFSA) has been investigating PAs since 2007 in relation to animal feed and presence in the food chain. EFSA has previously highlighted honey as a particular concern for toddlers as they are high honey consumers.

At a Food Standards Agency (FSA) meeting in mid-January, the results of FSA research were presented on concentrations of PAs in 59 herbal teas, 54 honeys and 46 food supplements. High levels of PAs were found in some honeys and teas, but food supplements were not of particular concern, except one St John's Wort product inadvertently included in the FSA review and later found to be registered as a Traditional Herbal Medicine was passed to MHRA. The BfR has also done some analysis and found high levels in herbal teas in Germany. PAs are not found in St John's Wort itself – the contamination is most probably the result of accidental collection of local weeds, probably ragwort, during harvesting. PA harvesting contamination is unlikely to be confined to St John's Wort though, and other herbs may possibly be affected.

The FSA intends to publish its risk assessment and share the report with stakeholders and product owners. More work is needed for food supplements, and the FSA requested answers to five questions, to which HFMA responded immediately, highlighting weaknesses in the current opportunities for control and the need for a standardised analytical technique. EFSA intends to set MPLs for PAs so the issue will not go away.

The MHRA is also closely tracking the issue, and has asked extract manufacturers to quarantine St John's Wort products until it can be assured that PAs are not a problem. They have also issued a press release to the mainstream consumer media detailing a precautionary recall of six batches of St John's Wort, totalling 91,800 tablets. Their reason for the recall was that 'PAs are known to cause liver problems' and these batches had been found to have levels of a toxic PA above the threshold recommended by the EU Committee on Herbal Medicinal Products. The recall was reported by the BBC, and also the *Daily Mail* and *Independent* newspapers.

We are recommending to our members that they might wish to ask their suppliers if they conduct testing for PAs, and they can contact the HFMA for a list of companies who can carry out this work. Needless to say, we are currently evaluating the implications of this and the HFMA's Technical Committee is monitoring the situation closely. The HFMA and The British Herbal Medicines Association (BHMA) have jointly sought an urgent top level meeting with MHRA to discuss appropriate and achievable PA levels in THR products, and to agree the protocols for the test methods to be used.

So, if PAs were January's emerging issue, what happened in February? Well, sure enough, we were informed by the Department of Health (DH) that the European Commission has received an application from Sweden, Denmark and Norway under Article 8 of Regulation 1925/2006 for green tea extracts and infusions. In case you are not aware, Article 8 is the process whereby substances are added to Annex III of Regulation 1925/2006 (aka Addition of Nutrients), Part A – prohibited substances, Part B – substances with restricted use and Part C – substances under Community scrutiny. This process was most recently used to prohibit the use of ephedrin and limit the use of yohimbe.

In this latest case, the concern appears to be about a group of polyphenols, mainly EGCG and other cathechins, at levels greatly exceeding those under normal conditions of consumption of a balanced and varied diet, which includes green tea infusions. The application will be passed to EFSA for an opinion, with a timeframe to be agreed in negotiation between the Commission and EFSA. This is thought to be typically nine months. DH is seeking from stakeholders, including HFMA, any initial reactions to this application, and we have alerted those members that might be impacted straight away, and are monitoring this.

All of this is a signal of a shifting landscape and I believe this is our industry's new reality. It is going to be more important than ever for companies in this industry to make sure they are well informed and receiving the best advice possible. That is where the HFMA comes in, and if you are not a member and would like to learn more about us, just get in touch. hfb

To help us in our efforts to protect this industry and benefit from the gold-standard advice we provide, join the HFMA at the earliest opportunity. To learn more about our activities, please contact graham@hfma.co.uk.