HFMA UPDATE

by Graham Keen, Executive Director

The perils of a slow news day

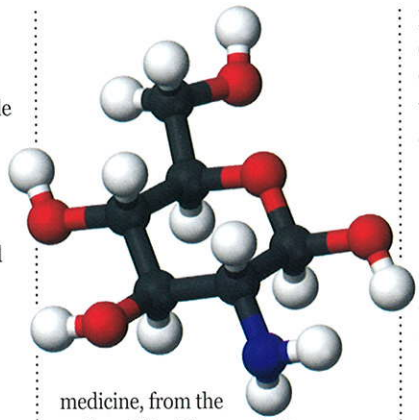
Someone once told me that in this industry the summer months are the 'quiet' time, when it is possible to catch up a little as Brussels and Westminster shuts down for a couple of months. Well, they got the last bit right, but quiet it certainly isn't.

On the contrary, we have needed to address some pretty serious issues for the industry over the last six weeks or so, and this doesn't take into account the fact that we have entered the 'silly-season' in the national consumer media. It seems that a slow news day equals open season on our industry, and we have had to deal with more than our fair share of media issues in recent weeks. But more of that later.

I'd like to start and end this article with some welcome positive news, and deal with some of the challenging stuff in the middle. The good news to report is that the HFMA today welcomed its 16th new member in 2013. It seems that more and more companies are realising that some expert help as you try to navigate the choppy regulatory waters throughout the EU is a much-needed resource, and that the relatively low cost of HFMA membership is a price well worth paying. And increasingly, it is companies from outside the UK that are benefiting from our services – amongst our new member intake for this year are companies from France, Sweden, Hungary and the USA.

That said, there are still a significant number of prominent UK-based companies in our industry that have concluded that supporting their industry association is not a priority, and who steadfastly remain outside membership, leaving it to other companies to support our vital work.

I can think of no better example of the sort of critical issue that emerges with little notice than a current issue the entire industry needs to confront. Over the last few years there have been intermittent threats to challenge the MHRA's position that glucosamine is not a



medicine, from the various EU-wide prescription license holders for glucosamine. A new challenge has been made, by far the most determined yet, seeking a Judicial Review in the High Court. They seek from the Court a declaration that all glucosamine containing products (GCPs) are medicinal, or failing that a declaration that all GCPs marketed with a daily recommended dose of 1500mg are medicinal products.

There are serious and far-reaching implications if this latest challenge were to be successful. Taken in isolation, you don't need me to say how important the glucosamine market is to our industry. However, as I'm sure you will realise, this case is not solely about glucosamine, there are serious implications for the future food supplement status of many substances, in particular those that have licensed equivalents (for example, cod liver oil, folic acid, vitamins D and B12). Also, there is potentially a huge precedent at stake – that being MHRA's ability to continue, based on ECJ case law, to review products on a case-by-case basis, and not substances per se.

The MHRA is robustly defending this case. Judicial Reviews are rare, in fact the last time the MHRA was involved in one was 15 years ago, which further adds to the important significance of this case. As you would expect, the HFMA is on the case and we are very actively supporting the MHRA in its attempts to resist this challenge, and as an Interested Party we have made a comprehensive submission to the Court, via our very professional legal team at Covington & Burling. Once again, the HFMA stands alone in resisting this threat on behalf of its members and the industry in general, and through the generous support of a number of key companies, both in and out of HFMA membership, we have been able to secure funding to support our intervention into the Judicial Review process. It may well now be a few months before we know anything more, but you should watch this space!

In the meantime, the 'silly-season' is upon us, and it seems that not a week goes by without our industry coming under attack in the national media. Fortunately, we are continuing to effectively anticipate these attacks and proactively trying to meet them head-on. Over recent weeks we have engaged with the BBC Radio 4 programme *You & Yours*, which was questioning the value of supplementation for at-risk groups, in particular the elderly, and which we were able to combat very well via the participation on the programme of HFMA Council member, Martin Last. And then we had, based on a study on voles (yes, voles), new research attempting to discredit food supplements, followed by very high profile coverage throughout the mainstream media of research attempting to show a link between omega 3 fish oils and raised incidence of prostate cancer, about which again the HFMA was able to produce a strong statement of rebuttal, which achieved positive national media coverage.

Now we are talking to the BBC about another programme they plan to air, calling into question the need for supplementation, and we know that *Which?* magazine will again shortly be carrying out its ritual annual attack on our industry's products. Someone has to remain vigilant and respond to these attacks, and if the HFMA doesn't do it, who will?

I said that I would end this article on a positive note, and we just received very positive news that the Article 14 Disease Risk Reduction health claim for Folic Acid had received a positive scientific opinion from the European Food Safety Authority (EFSA). As you will know from earlier articles, this project is a collaborative effort of the spina bifida charity Shine, CRN, PAGB and the HFMA. The dossier was written by the HFMA's own Scientific Adviser, Dr Michele Sadler, and the speed with which the dossier was approved is testament to her great work on this project.

For those that don't know, spina bifida (literally 'split spine') is a fault in the development of the spinal cord, leaving a gap or split in the spine of the foetus. This damage occurs during the first 28 days of pregnancy, before many women are aware that they are pregnant. Ninety per cent of those affected will also develop hydrocephalus (fluid on the brain). The amount of disability involved is variable depending on which vertebrae are affected and the amount of nerve tissue involved. This damage also results in bladder and bowel problems. Anencephaly is the most severe Neural Tube Defect and is incompatible with life. The brain either does not develop properly or is absent, and babies are either stillborn or die shortly after birth.

The favourable opinion by EFSA is the first step in a formal process. Before the claim is fully permitted for use in the EU it has to be agreed by the member states of the European Union, which includes the UK, represented by the Department of Health, and put into law by the European Commission. This may take several months, but I'm pleased to say that we are over the most important hurdle.

The valuable work we do at the HFMA is clear for all to see. In most cases, if we don't do it, it just doesn't get done. If you would like to join the HFMA or learn more about our activities, please contact me at graham@hfma.co.uk.