Regulation of herbal medicinal products

There are many opportunities and challenges for traditional herbal medicines in a changing regulatory environment. Peter Houghton reports.

Christine Gratus, lay member of the Herball Medicines Advisory Committee, said that pharmacists have a vital role to play in advising the public on the safe and appropriate use of herbal medicinal products, but it appears that many lacked the knowledge and training to do so. The discussion was the culmination of the meeting, which had been arranged by Michael Einrich, head of centre for pharmacognosy and phytotherapy, University of London. In his opening remarks, Professor Einrich stated that the high attendance at the meeting of academics, producers and suppliers was an indication of the current interest in herbal medicinal products. The meeting had deliberately been organised just over three years after the introduction of the new European licensing category of products based on traditional use to consider what had happened since. It was also an occasion to highlight to producers the fast approaching deadline of 2011 for the review of existing herbal product licences.

Richard Woodfield, group manager for herbal medicines, Medicines and Healthcare products Regulatory Agency, outlined the reason and methods for the strategy employed by the M H R A for bringing herbal medicines into effective regulation. Until recently, the supply of such products had been largely in an unregulated environment with a limited pool of expertise, which had resulted in products of varying quality and a lack of information available to the public in choosing good quality products.

Mr Woodfield said that the M H R A had introduced the traditional herbal medicines registration scheme (T H R) and had been active in discussions and advice as far as producers of herbal products in the UK were concerned. In addition, it had published 33 public assessment reports on products. He said that the submissions and number of products registered under the T H R was steadily increasing, with 61 applications having been made to date, of which 28 were successful. Most of these were single herb products but some combination products were now registered. Existing herbal product licences were also being reviewed and the number of existing herbal product licences.

Mr Woodfield talked about an Ipsos MORI survey that had been conducted, which showed that one in four people had used a herbal medicine in the past two years, with usage higher among women. A significant finding was that 87 per cent of those using herbal medicines and 71 per cent of those who did not use them thought that such products should be regulated.

Dick M Idleton, technical director, Schwabe Pharma U K, drew on his experience and gave advice to those wishing to achieve success with applications for UK herbal registration. He outlined the need for a wide range of critical competencies, including Good Manufacturing Practice, a quality dossier, artwork and readability testing. He emphasised that time was an important factor for G M P and the quality dossier to be finalised before the deadline of May 2011. He also said that it was unlikely that most producers of herbal products would be able to do everything in-house so service providers had to be sought. Dr M Idleton gave examples of the questions that should be addressed when choosing a service provider.

Quality

Linda Anderson, pharmaceutical assessor at the M H R A, spoke about quality of herbal medicinal products (H M P s) from her perspective as a regulator. She emphasised the challenges of H M P s compared with single chemical entity pharmaceuticals, especially the identification of ingredients, the quantitative composition of the product, the potential contaminants (particularly the toxicological risks involved) and the amplification of these challenges where combination products were concerned. This latter problem was particularly important since many H M P s were of this type rather than consisting of one single herb.

Dr Anderson said that the M H R A had organised various activities to help producers meet these challenges and have had over 150 meetings covering over 800 products, as well as organising a forum where dummy quality dossiers were presented and discussed. She concentrated on some common points that had resulted in the M H R A asking for revisions to the application before it was successful. Details of suppliers, treatments and tests for potential contaminants, aspects of process and controls, and data on stability were often inadequate in the initial submissions. She thinks that the scheme appeared to be working well and it was expected that the number of applications would increase annually in the immediate future.

Rainer Kolkmann, general manager, DCarlpharm, discussed the challenges that producers faced once they had been successful in applying for a licence. These included ensuring compliance with G M P for contracted manufacture and analysis, which posed problems of extra work and costs with increasing regulatory pressure. He suggested that small companies should share best practice and knowledge if they had similar products. Also, auditing of active product ingredients was important as was ongoing stability testing, and the necessity of pharmacovigilance to assure ongoing safety. Dr Kolkmann said that pharmacovigilance included a frequent search of databases for reports of adverse drug reactions and the appointment of a Qualified Person to set up and monitor a system. Proposals were being discussed, which would probably become law by 2012, and these included inspection of each registration holder.

EU perspective

Werner Knöss, from the German Federal Institute for Drugs and Medical Devices, gave an account of the experience in Germany of fitting the products (used there for a long time) to the new EU regulations. He explained that, in contrast to the UK, there was widespread use and recognition of the value of herbal products by the medical establishment, pharmacists and government. Thirty per cent of the sales in pharmacies were H M P s and 550 products were licensed under the previous scheme, said Dr Knöss. Since the introduction of the EU legislation, there had been six successful applications for registration and about 350 were being considered.

Dr Knöss said that decisions on applications concerning existing products were often reached within 6 weeks because of complete documentation. However, it was expected that over 200 products would cease to be available after the 2011 deadline was reached. He added that scientific advice given to companies had increased annually since 2005 and, in 2008, 77 discussions had taken place, which had been informative for both companies and the regulatory agency. An ongoing discussion was the debate over whether a product’s use should be classified as traditional.
There were arguments for and against abolishing prescription charges in England at the Socialist Health Alliance seminar. Claudia Lyons reports.

Prescription charges are a financial issue and not a medical issue, said Liz Phelps, from the Citizens Advice Bureau. The CAB receives 2,000 enquiries a year about prescription charges and the key issue is difficulty in affording charges, she said. In 2001, the CAB released the report “Unhealthy charges”, which found that 50 per cent of its clients who had paid prescription charges reported difficulties in affording the charge, and 28 per cent had failed to get all or part of a prescription dispensed during the previous year because of the cost.

The CAB commissioned a MORI poll to update these statistics in 2008 and it believes that 800,000 people are going without all or some of their medicines because of cost and the priority must be to tackle affordability, said Ms Phelps.

The CAB believes that there is a case for abolishing prescription charges in England, said Ms Phelps. Although the English prescription charge has increased by 10p to £7.20 this year, Wales progressively decreased its prescription charges until it was abolished in 2007. Scotland is following its lead with a staged reduction; with a view to free prescriptions by 2011. Northern Ireland has also announced that it will abolish prescription charges from 2010. However, if abolition is not acceptable, then the priority must be extending exemptions to the main disability benefits, such as the incapacity benefit, said Ms Phelps.

Eileen Neilson, head of policy development at the Royal Pharmaceutical Society, said that the main impact of prescription charges is to deter the essential use of medicines. Unnecessary prescribing should be tackled through measures to control prescribing, not by trying to deter patients from having unnecessary prescriptions dispensed. She explained that international evidence shows that deterring people from obtaining medicines they need gives rise to costs elsewhere in the healthcare system; these include preventable hospital admissions. Ms Neilson said that, although these costs are hard to estimate, the Wales prescription fee exemption research study into the impact that abolition has had on Wales is due out later this year.

She also expressed concern that the current prescription exemption system was difficult for pharmacists to administer. Any reduction in administrative workload could free pharmacists to spend more time with patients, she said. Ms Phelps.

On the contrary, Barney Gough, research scientist at the independent think tank Social Arktik Foundation, said that now was not a good time to abolish prescription charges. He said that due to the current financial downturn and a lack of good information about the impact of developments in Wales and Scotland, England should wait. Mr Gough thought that, over the next five years, England would be in a better place to implement an evidence-based system.

According to figures from the Department of Health, the prescription charge system generates £450m in revenue but costs £50m a year to administer. Mr Gough said it was clear that public spending would be hit by the financial crisis and that the health budget would be squeezed regardless of whether savings for prescription charges could be found in the budget now. He offered an alternative solution, where the current prepayment certificate was replaced by an annual limit; as soon as patients have paid a certain amount in prescription charges, they receive the rest of their medicines for free that year. This is similar to the system that currently exists in Sweden.

Martin Rathfelder, from the Socialist Health Association, said that prescriptions should be free and, if they are not free for everybody, they should be free for poor people. The association is affiliated to the Labour Party and Mr Rathfelder said that the association was campaigning for free prescriptions for England.

Margaret Naysmith, Labour MP for Bristol North West and a member of the House of Commons Health Select Committee, suggested that Labour may include a statement about prescription charges in its manifesto for the next election, although he said that he did not know the details of current Government plans.

Mr Naysmith’s early day motion in the House on prescription charges urges the Government to commit itself to the abolition of prescription charges as soon as possible and, until that can be achieved, to extend free prescriptions to all people in receipt of incapacity benefit, employment and support allowance and disability living allowance. Meanwhile, the Government has already announced some changes to the prescription charges system in England by creating a new exemption category for cancer patients and appointing Ian Gilmore, president of the Royal College of Physicians, to undertake a review of prescription charges for people with long-term conditions.