

MEDICINES CONTROL AGENCY**Mr. Roy K Alder
Head of Executive Support****Introduction**

I am most honoured to be asked to address this important conference alongside your impressive panel of distinguished speakers. I aim to give a UK regulatory perspective on the issue of phytomedicine and consumer protection. Whether by good planning or fortunate coincidence, this event is particularly timely. As the AEGSP study on behalf of the European Commission reaches its conclusion, we are entering a period when there is likely to be wide - ranging and intensive debate across Europe on the best ways of regulating herbal medicines. I have no doubt that some of the insights gained at this ESCOP symposium will help to inform that debate.

As regulators, we in the Medicines Control Agency need frequently to ask ourselves the question: what is the correct and proportionate response when it comes to enhancing and protecting the public in relation to medicines in general and to herbal medicines in particular. It is not easy to find the right answer - and we know that well-informed people can easily come up with different responses. Evidence for this is can be seen readily in the different approaches which have evolved across the member states of the European Union.

As I think may be the case in other countries, we have perhaps now reached the point where the long term health of the herbal medicine sector could - paradoxically - be at some risk from its own success. Such is public's interest in the products and the growth in the market that we are finding - not surprisingly - that at the less regulated end of the market the expanding opportunities have attracted some less responsible operators. These are people whose horizons are short term and who may be unconcerned by the damage they may do to the reputation of responsible operators in the field - and indeed to public health.

It is strongly desirable, therefore, that all those who wish to see a secure long term future for herbal medicine continue to uphold the highest scientific standards, which alone must form the basis of any medicines marketed to

the public. In that context I would like to warmly commend the role of ESCOP and in particular the work of the British Herbal Medicines Association here in the UK. The BHMA has a deserved reputation, developed over many years, for consistently promoting a rigorous approach to standards for herbal medicines. When Keith Jones spoke at the launch of the 1996 Edition of the British Herbal Pharmacopoeia two years ago, he pledged that the MCA would build on the strong links we had established with those in the field of herbal medicine. We have tried genuinely to meet that pledge. I would like to pay particular tribute to Vic Perfitt and to all his colleagues at the BHMA for playing their full part in what has become from our point of view an increasingly valuable dialogue with representatives of herbal practitioners and the trade associations.

Over recent times Vic has of course become a familiar and valued figure in many parts of the industry, the scientific community and in regulatory circles in his role as Chairman of the BHMA. I know that, in many meetings and other gatherings, you will often hear one of the participants saying, with great determination: "You know, and I know that these products are medicines. They should be treated as medicines." The speaker will of course be Vic. The BHMA tirelessly promotes the role and status of herbal medicines and the need for high standards.

I will talk in turn briefly about the current European scene, then about matters relating to the UK's recent experience. I will then conclude with some, necessarily general, remarks about the future.

Current European scene

It has long been known that there are variations between EU member states in the way they handle herbal remedies. The differences seem to emerge right at the outset - in whether borderline products are classified as medicines in the first place. It is clear that there are considerable variations between member states both as

to precisely which herbal medicinal products are regarded as falling within the ambit of EC Directive 65/65, and, beyond that, as to how that Directive is actually applied in practice.

My impression is that some member states may be relatively stringent in determining - at the margins - precisely which herbal products require to be subject to the 65/65 arrangements. But then, in practice, there may be a considerable degree of flexibility in terms of how 65/65 is actually implemented.

Alternatively, the reverse approach may be applied. There may be a degree of flexibility operated in deciding whether 65/65 applies, but once that decision is taken, the requirements of 65/65 are applied more or less rigorously. One way or another - a wide range of products does seem to find its way onto the market place in most member states! And - we must not forget - the public does seem to want access to a wide range of herbal products. The role of the regulator is to protect public health, while enabling the enhancement of public health. This means a balance between the individual's right to choose (an important priority for many politicians in Government) and their personal safety.

Given the current position, we very much welcome the fact-finding study which has been undertaken on behalf of the European Commission. A genuinely authoritative comparison of the varying regimes could serve to increase understanding and inform future debate. We look forward to seeing the outcome of this work and to participating actively in the ensuing debate. In one sense, the fact-finding exercise - although complex - is the easiest part of the work. The much tougher challenge will be to assess the implications of the findings and to assess precisely what action - if any - may be required.

Meanwhile, alongside the Commission's study, the work of the EMEA's Ad Hoc Working Group continues. I should like to commend Dr Keller for his skilled chairmanship of this group as it grapples with many complicated and technical issues. I am sure that I am not the first person to say this, but it seems to me that the value of this initiative lies at least as much with the opportunities it has provided for dialogue and increased mutual understanding between member states as for the important detailed work the group is carrying out to facilitate mutual recognition of herbal medicines.

Whilst on the subject of mutual recognition, I note that three herbal medicines have now gone through the mutual recognition procedure. (The UK has had the role of Concerned Member State or Reference Member State with two of these applications.) It is perhaps too early to draw meaningful conclusions from such statistics - but they do provide some indication that there is perhaps greater potential for the mutual recognition procedure to work successfully than some of us had first thought. Certainly I am proud of MCA's track record on mutual recognition procedures as a whole. In 1997/98 the Agency was clearly the leading Reference Member State - handling over 40 per cent of procedures.

I would like at this point also to warmly welcome the increased emphasis which both ESCOP and the European Pharmacopoeia have given over the last few years to herbal monographs. This programme provides growing opportunities for us to work to harmonised standards. I and my colleagues in the MCA will be interested in discussion at this symposium on the best way of making use of these monographs.

I do not make a regular habit of re-reading Keith Jones' speeches, but I did recently take the opportunity to look over the comments he made at the launch of the 1996 British Herbal Pharmacopoeia. On that occasion he paid tribute to those who have expended such an effort in the quest to identify agreed quality standards. It is extremely encouraging to see the increasing momentum during this intervening period.

Recent UK developments

I would like to turn now to recent developments in the UK. I do so in order to illustrate the way the MCA has approached the issue of protecting the public in relation to herbal medicines. Our over-riding aim has been to safeguard the public, but in ways that are proportionate to the perceived risk. We have taken a strongly collaborative approach with professional, commercial and consumer interests. As I will aim to show, we have taken a number of prudent and pragmatic measures. Individually, the measures may be relatively modest in scale, but collectively they represent a clear demonstration of the increasingly active and robust approach we are taking in the face of evidence of some emerging public health problems, particularly in the less regulated sector of the market.

The current UK legal position on herbal medicines can

be summarised as follows. There is a two pronged approach whereby the normal market authorisation procedures are applied rigorously for products falling within 65/65. There is then a further category of products exempt from the requirement for a marketing authorisation for herbal medicines which fall outside the ambit of 65/65. Relatively limited regulatory controls apply to this exempted category of products.

In recent years the UK has experienced continued rapid growth in the market for a range of products in what might be termed the "natural health sector". By and large, herbal medicines have presented us with relatively few concerns as regards safety, and this was borne out by the project carried out recently at the Guy's Medical Toxicology Unit on the safety of traditional remedies. However, it has become clear that in the face of growing demand and a larger market, a number of businesses are pushing away at the boundaries of what is permissible. By no means all are following the high standards espoused by the likes of the BHMA and other responsible trade associations.

There is now a steady trickle of evidence that the quality of some unlicensed herbal products is not all that it might be and that, in a small number of cases, there is a risk to public safety. Some of the resulting problems have achieved considerable publicity, such as a recent survey which showed that a number of herbal skin creams contained liberal quantities of steroids. We, like other EU countries, receive warning reports of herbal remedies contaminated with heavy metals. There are also of course other potential hazards. For example, the increasing use of herbal medicines, used in combination - and sometimes with modern western medicines - gives rise to the possibility of harmful interactions. Let me emphasise that these products, containing as they do non-herbal ingredients, are outside the UK's exemption. They require a marketing authorisation and meantime must not be placed on the market. The MCA has taken enforcement action against products of this type and will continue to do so, as necessary.

What else is the MCA doing to protect the public? There have been a number of measures aimed directly at improving safeguards:

- in 1996 we extended the UK adverse drug reaction reporting system - our Yellow Card Scheme -

to include adverse reaction reports to unlicensed herbal medicines. Since then a small but steady number of reports have been received. This demonstrates the case for such a mechanism for the surveillance of the safety of these medicines - including their potential to interact with licensed preparations. Of course, it is not easy to ensure fully effective pharmacovigilance given that much of the consumption of herbal remedies is unsupervised and the public does not always equate herbal remedies with medicines. We will need therefore to keep the position on this issue under careful review. Certainly, the stance taken by BHMA - that genuine herbal remedies are important products which need to be treated as medicines - is particularly helpful and indirectly serves to increase awareness of the issue of adverse drug reactions

- we are currently reviewing our list of particularly potent herbal substances which are subject to controls on sale and supply. We need, for example, to reflect the recent growth in the market for Traditional Chinese Medicines
- we have targeted the resources of the Agency's Inspection and Enforcement Division more effectively in relation to unlicensed herbal medicines. A special unit has been established for this sector and we are now taking an increasingly robust line where there are breaches of the law which threaten public health - such as the inclusion of undeclared non herbal substances in so-called herbal medicines and the use of unsubstantiated medicinal claims. We have also required a number of companies to withdraw products from the market for non compliance with the law. We are collaborating more effectively with other parties - including the medical profession and Trading Standards departments - to deal with specific problems.

In addition to these direct measures we are also taking indirect measures - which in the long term may be equally as important:

- the MCA has over the last year or two greatly increased levels of informal dialogue with representatives of trade associations and the herbal practitioners. These discussions cover a wide

range of regulatory issues of mutual concern and provide both sides an invaluable early warning system about potential problems and issues. Of recent times these discussions have been made more comprehensive by the inclusion of representatives from Ayurvedic and Traditional Chinese Medicine

- this year has in fact seen the development of somewhat of a Traditional Chinese Medicine theme for the MCA work. In September, the MCA sent a delegation to Beijing for a programme of discussions with the Chinese authorities and leading academics and business people. The aim was to explore ways in which the two countries can work together in encouraging TCM in the UK to achieve the highest standards. The visit culminated in a conference as part of the programme of events in "Britain in China" year. The MCA was pleased to be working alongside a number of other UK personnel during the visit, including Christine Leon from the proposed Kew Gardens Chinese plant authentication centre. We were reassured that the Chinese authorities took a similar view to ourselves - that the long term success of TCM in the UK market place will be related closely to the achievement of consistent quality of the product. We have received very positive feedback on the amount of interest the MCA visit has generated in China and we now look forward to a considerable increase in information sharing between the MCA and our opposite numbers in China
- looking specifically at how the current regulatory regime might be improved, the MCA is considering in particular how we can make our decision-making process on the status of products at the borderline more systematic and transparent. The decision to classify a product as medicinal is clearly an important issue for business and we plan to sharpen our procedures in this area.

As I have emphasised, we are taking a strongly collaborative approach. In fact some of the most significant ideas which could ultimately serve to protect the consumer most effectively are coming from other sources. I have time only to touch briefly on a few of these points:

- we warmly welcome the BHMA's initiative in re-

quiring GMP standards as a condition of membership of their organization - even in circumstances where it is not required by law. This is an excellent example of responsible self regulation, and one which has our full support

- in similar vein, we welcome the fact that the Register of Chinese Herbal Medicine has a programme to test samples of herbal medicines and is looking at ways of encouraging its members to use products only from suppliers who meet high standards
- more broadly we are also encouraged by the efforts being made by a number of responsible herbal practitioner groups in the UK to develop a common approach to self regulation, in areas such as training, education, codes of conduct. The MCA's responsibilities of course relate mainly to the herbal medicine itself rather than to the practitioner - but there is a clear connection between the issues. We are aware, for example, that there are some types of herbal remedies which may be beneficial when prescribed by a well trained practitioner - but which can pose a risk in the hands of less well informed practitioners
- another very promising development - to which I have already alluded - is the work to establish the proposed authentication centre for Chinese plants at Kew Gardens. This is the kind of initiative which potentially could serve to strengthen the scientific base of herbal medicine in the UK and far beyond.

The future?

I have surveyed the current scene briefly, first in the European Union and then in the UK. I would like now to say a few words about possible future developments in the regulation of herbal medicines in the European Union. Some of you may be expecting me to say something specific about the UK position on any possible proposals which may emerge from the aftermath of the AESGP study. If so, I am afraid that I am going to have to disappoint you!

Those of you with memories stretching back four or five years may dimly recall that here in the UK we had a little local difficulty on the subject of herbal medicine.

There was, to put it mildly, something of a lively debate about the implications of the new EU marketing authorisation system for herbal medicines in the UK. You will appreciate, therefore, that I would wish to approach this particular issue with a certain degree of caution. As yet, there are of course no EU proposals for change on the table, although we are listening with considerable interest to the speculation emerging from the Commission and other quarters about the various options. The suggestions range from keeping the status quo to some form of fully developed registration scheme, specifically tailored to the requirements of herbal medicine. If and when proposals do come forward, we will need to examine them very carefully and discuss them with our Ministers. But I have no doubt that the UK will be wanting to contribute constructively and positively to such a debate!

Having cautioned that I am not in a position to give a specific UK line on any possible changes I would, however, like to make some general comments about future regulatory arrangements.

First, notwithstanding the potential for controversy, I do believe there would be some value in our having a genuinely well informed debate in the near future on the subject of the future regulatory arrangements for herbal medicines. The size, sophistication and range of the market have all moved on substantially over the last few years. It seems likely that this growth will continue. And it does seem to be the case that a number of countries are not finding it easy to follow through an appropriate regulatory response.

Second, I would stress the need for maturity and sensitivity in any debate. As we all know, the subject of herbal medicines can arouse considerable passion and is sometimes associated with very strongly held beliefs and value systems. The existence of such reactions is not a good reason to avoid applying appropriate scientific standards and systematic regulatory arrangements - but I think we are all under an obligation to approach the subject with due tact and understanding. As we know, very many members of the public take herbal remedies and value them highly. This is an important constituency and individual freedom of choice is a fundamental concept. It would be unfortunate if European debate was dominated by parties with little understanding of, or sympathy with, the ideas behind herbal medicine. There will be a strong

need for all those with regulatory authority to listen as well as to inform and to propose.

In the UK we are seeing a gradual - and welcome - erosion of the one-time sharp distinctions between conventional modern western medicine and alternative and complementary medicines. Developments such as the conference in May on Integrated Healthcare, at which our Secretary of State for Health spoke, are helping to break down old barriers. It would be ideal if any debate about the regulation of herbal medicines could serve to hasten rather than delay this process.

The third point is that the protection of public health, as always, must be at the heart of any future regulatory arrangements. I am sure that we are not alone in finding that there is a continuing misconception in some quarters that "natural" equates to "safe". As I said earlier, there is more work to be done in getting over the message that genuine herbal medicines are serious products which do need to be treated with suitable caution. We must not underestimate the difficulty of striking the right balance. We must bear in mind that herbal remedies cover a very wide spectrum - at one end it is not always easy to distinguish between a food and a medicine; at the other end there are some potentially very toxic plants where there would be general recognition of the needs for tight restrictions on use. Any worthwhile regulatory regime needs to be able to deal effectively with a wide range of products.

At the risk of repetition, I would like to underscore the importance of reaching a clear and defensible position on public health. It would be only too easy over the coming months to get lost in a maze of discussions about the various existing regimes in member states and the various possibilities for new schemes. I have no doubt that in any discussion the UK will be wanting, constantly, to come back to the point: do any proposals constitute a proportionate response to the public health risk.

My fourth point about future regulatory arrangements is that there are also a number of common sense tests which can be used to judge whether any proposals are likely to command general acceptance. Some obvious questions which need to be asked are:

- will the public have continuing freedom of choice from a wide range of products?

- will responsible herbal practitioners retain the freedom to practise? and
- will manufacturers, importers and retailers keep the freedom to pursue trade in a responsible manner?

Fifth, I believe that it will be essential that we keep sufficient flexibility to cope with the different herbal traditions which exist in many member states. We need constantly to bear in mind that the herbals industry is not a homogenous whole. On the one hand we have multi million pound businesses wishing to market highly standardised herbal products across a number of member states; on the other hand we have herbal practitioners who may be making up remedies tailored to the needs of individual patients and using very simple combinations of largely unprocessed herbs. Again, there are herbs in widespread use across most member states. But there will also be others which are only used in certain traditions and therefore rarely seen in some member states.

One final, perhaps rather obvious, point is that I suggest that it is desirable that in any debate a fair range of possible options for the future are considered carefully. Sometimes in any debate there can be a tendency to close down the options too early in order to avoid the discussion getting over-complex. I think we should resist that temptation.

Conclusion

We are clearly reaching a crossroad in the development of herbal medicines. Important decisions will have to be made about regulatory arrangements in the European Union. Should we seek to make the present arrangements work more effectively within the existing legal framework, or is there a need for more fundamental change? We need to protect public health. But we need, too, to safeguard the ability of the market to supply safe, high quality and effective products across the European Union. Too lax a regulatory response and we fail to protect the public and the whole business and profession of herbal medicine may ultimately be brought into disrepute by the excesses of a minority. Too stringent a response, and we could risk strangling the market and alienating the public. That is the challenge - to find a balanced and proportionate regulatory response.

ESCOP will have a pivotal role in helping to shape the coming European debate on herbal medicines. I look forward to the well informed and measured contributions which I know we can expect from this quarter, both during this conference and in subsequent months. I wish your symposium every success. Thank you all for your attention.