J R Coll Physicians Edinb 2005; **35:**286–288

Sir,

Although now not practising, I continue to take an interest in matters medical. I was interested to read the obituary of Dr Clayson, who was President when I became a Fellow. Like him, I spent some time working in a TB hospital, although only as a precursor to taking up Radiology. It was a good introduction to reading a chest X-ray!

One thing I well remember is the large amount of X-radiation received by patients, and maybe some staff. Patients might well have packets containing more than 100 films, maybe taken twice a week or even more, and to this had to be added the additional doses of radiation from screening their artificial pneumothoraces or pneumoperitoneums. Were this radiation to have had a significant adverse affect on health I would have expected a significant epidemic of something nasty, which declined or disappeared when TB was fairly suddenly 'conquered' by chemotherapy. I have yet to discover it. Yet, we have a generation of doctors – as well as the public – scared stiff of X-rays.

As you will know, medicine becomes ever more complex and compartmentalised, and it is difficult to keep abreast with all its developments in a simple sort of way. I suspect the person who devises a way to do this will get a medal. Is the College up for such a medal?

AE Hugh
Retired Radiologist, Cardigan, Wales

Editor: Dr Hugh raises a matter of major importance at a time of increasing medical information and progressive specialisation, namely the problem of easily keeping abreast of general medical knowledge. The New England Journal of Medicine (NEJM) addressed the issue in an editorial last year (Campion EW. Medical research and the news media. *N Engl J Med* 2004; **351:**2436–7.) and we corresponded with the NEJM at that time (Finlayson NDC, Nixon SJ, McAlister GW. Medical research and the news media. *N Engl J Med* 2005; **352:**838–9).

The Fellows and Collegiate Members *Bulletin* on our website (http://www.rcpe.ac.uk/fellows/Bulletin/index.html), our public website (http://www.behindthemedicalheadlines.com) and the Journal aim to fulfil just this function. As it happens, all three of these sites carry an article by PL Allan and JR Williams pointing to the radiation hazards of modern CT scanning where a CT scan of the abdomen and pelvis delivers the equivelent of 500 chest X-rays! Is this worth a medal?

Sir,

In issue 35 of *The Journal*, W Dawson[1] wrote on *Herbal medicines and the EU Directive*; certain fundamental aspects of that legislation give cause for concern. It is on that matter that I now write.

Introduction

The legislation is entitled the EU Directive on Traditional Herbal Medicinal Products (DTHMP).[2] Criteria for registration of a product in its terms include that it should have documentation demonstrating 'long-standing use'; in particular, this is defined in Art. 16c(1)(c) as 'bibliographical or expert evidence to the effect that the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community'.

Concerns fall into two areas: 1) misleading use of the term 'traditional' and 2) questionable adequacy of the qualifying time period.

Basic tenet

Herbalists doubtless regard the materials of their trade as being able to treat illness. Some of them certainly are, otherwise digoxin, quinine, aspirin, vinblastine, and so on would not appear in pharmaceutical pharmacopoeias. It follows that such herbal materials must be pharmacologically active. Anything that is sufficiently pharmacologically active to have a beneficial physiological effect or to treat significant illness must *ipso facto* be sufficiently potent to have an adverse physiological effect or to cause an illness. Hence, the establishment of safety of medicinals is important.

1) Misleading use of the term 'traditional'

According to the *Shorter Oxford English Dictionary*,[3] 'tradition' indicates a '…transmission of statements, beliefs, rules, customs, or the like…from generation to generation' or 'a long-established and generally accepted custom or method or procedure, having almost the force of law; an immemorial usage.' This usage has prevailed since *ca.* 1590. To that extent, the definition is itself traditional.

Case law is often cited in reaching a judgment in new cases. In the case of *Shakoor v Situ*[4] a member of the Register of Chinese Herbal Medicine (RCHM) prescribed a classical formula for a patient. The patient died and the widow sued for negligence. In his judgment, Livesey QC included that 'the decoction [used] had been established over centuries' and also that 'TCHM [Traditional Chinese Herbal Medicine] has … an oral tradition extending back some 4,000 years or more and a written tradition extending back some 2,000 years.' Whether the judge would have ruled similarly

had the prescription contained materials documented for only 15–30 years, is uncertain. However, the judgement coincides more closely with the dictionary definition of 'tradition' than it does with that proposed by the Directive.

It seems likely that the public will understand the meaning of the word 'traditional' in the sense indicated by the dictionary, and associate 'traditional' herbal medicines with being safe because it understands them to have been in safe use for generations. Public expectation might consider the 15–30 years of the DTHMP as 'modern' or 'recent', rather than 'traditional'. In this respect, the DTHMP may tend to mislead the public as consumers; that is not without implications in consumer law.

Art. 16g(2) of the Directive provides that 'any labelling and user package leaflet shall contain a statement to the effect that: (a) the product is a traditional herbal medicinal product'. Section 3 provides that '…any advertisement for a medicinal product registered under this chapter shall contain the following statement: Traditional herbal medicinal product for use in specified indication(s) exclusively based upon long-standing use.' However, the Trade Descriptions Act 1968, s. 3(1) provides that: 'any person who, in the course of a trade or business: (a) applies a false trade description to any goods; or (b) supplies or offers to supply any goods to which a false trade description is applied, shall be guilty of an offence.' Further, s. 3(3) has it that: 'anything which, though not a trade description, is likely to be taken for an indication of any of those matters and, as such an indication, would be false to material degree is deemed to be a false trade description.' Ervine notes that the Act encompasses 'that which, though not false, is misleading'.[5]

Herbal remedies are also subject to the Medicines Act 1968.[6] Part 5 (ss. 85–91) of that Act states that it is 'an offence to sell or supply, or to have in one's possession for such purpose, a medicinal product in a package or container which is falsely labelled or which misleads as to the nature, quality or uses of the product'. The Sale of Goods Act 1979 (as amended) and Supply of Goods and Services Act 1982 raise similar impediments to the use of false and misleading descriptions.[7,8]

In terms of case law, *Beale v Taylor* demonstrates that almost any words describing the goods will be regarded as part of the description.[9]

2) Questionable adequacy of time period adopted

Even supposing the word 'traditional' were omitted from the name and text of the Directive, leaving it only as the DHMP, the 15–30 rule is of questionable adequacy.

For example, the pharmaceutical product Ibuprofen was discovered in 1961, came into use in the UK in 1969 and in the US in 1974; and it was available 'over-the-counter' in the UK by 1980, yet now it is potentially associated with heart failure. In this case, despite a yellow-card reporting system for adverse events, 44 years (or 36 from point of actual clinical use) was only just enough to determine its potential side-effects. There is no reason to suppose that the period necessary to determine herb safety should be less.

Implications for so-called 'TCM'

In the first half of the twentieth century, in Mainland China, attempts were made by the early Chinese Marxists to ban Chinese medicine (CM) such as then existed. Their motives were political rather than medico-scientific; that is reflected in associated historical statements, such as Chinese herbals are 'the collected garbage of several thousand years', and are 'waste paper'. The mood was to ban things because they were old.[10] Then, in 1958, Mao re-launched CM. The re-launch was not entrusted to the old masters, but mediated under the auspices of Marxist ideologies. It has become known as Traditional Chinese Medicine or TCM. However, many of the practices of TCM (e.g. the injection of drugs into acupuncture points, the co-administration of pharmaceutical products and herbs as compounded tablets) are not at all traditional. As part of this political and economic movement, there was a massive expansion in the number of plant species in the Chinese Herbal: it rose from 246, in the first century BC,[11] to around 800, in 1596[12] – a net recruitment rate of one per three years. In the People's Republic of China, a 1994 text recognises some 8,000 plant species[13] – a net recruitment rate of 18 plants per year, from 1596, but probably representing a growth of around 7,200 plants in the years from 1958 to 1994. This is a recruitment rate of 200 per year, or four per week. Many of these species will have been incorporated in the period 1958–1975, and so have over 30 years of documented use. Some of them may also satisfy the 15 year European documentation requirement, but it is doubtful whether they can be regarded as 'traditional' in any reasonable interpretation of the word.

It can be demonstrated by reference to historical texts that Chinese herbalists were differentiating between plants currently regarded as taxonomically different at the level of sub-species as long ago as times BC, so if certain herb species were not included in the Herbal by 1958, questions have to be asked as to why not. Among modern recruits to the Chinese Herbal are herbs such as *Aristolochia fangchi*, which has been associated with kidney failure; the classical Chinese Herbal included only two out of a total of 39 Chinese *Aristolochia* spp., *A. fangchi* was not one of them. Also among them are herbs which had previously been added to, but subsequently deleted from, the Classical Herbal. Some of them (e.g. stem & leaf of *Cynanchum auriculatum*) are proving to be toxic.[14]

As well as having considerable disregard, in principle, for historical records on which species to use, CHM under Mao also largely disregarded which parts of plants were traditionally used, yet there is no reason to suppose that different parts of a single species have similar effects: apricot flesh is safe, apricot kernels contain cyanogenic glycosides. The classical Chinese Herbal is explicit in that the herb Xi Xin denotes 'root' of *Asarum heterotropoides* var. *mandschuricum*, but the modern TCM herbal gives it as roots & leaves. This modern revision has not stood any significant test of time. In determining the traditionality of a herb, it is not sufficient to say that a given species has been in safe use for a critical number of years, but necessary to specify which part of it has been in use for that period.

Conclusion

If the purpose of the EU DTHMP legislation is to protect and inform the public, there should be a preference for:

a) using the accepted dictionary definition of the term 'tradition', so as to avoid misleading the public;
b) providing an adequate time-frame for determination of the safety of herbal products;
c) providing a time-frame which specifically pre-dates 1958, since from that time an enormous amount of confusion has arisen as to which Chinese herb species are traditional, and which parts of traditional Chinese herb species were used.

Adopting a time-frame of 100 years would a) comply with dictionary definition and public perception, b) provide a more meaningful length of time to claim safety in use, and c) safely exclude the massively disruptive effects on the Chinese Herbal of the political turbulence in China commencing in the 1940s.

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References

1 Dawson W. Herbal medicines and the EU Directive. *J R Coll Physicians Edinb* 2005; **35:**25–7.
2 EU: Directive 2004/24/EC *Directive on Traditional Herbal Medicinal Products*, Official Journal L 136, 30/04/2004 P. 0085 – 0090
3 Onions CT (editor). *Shorter Oxford English Dictionary.* 3rd ed. Oxford: The Clarendon Press; 1959.
4 *Shakoor (Administratrix of the Estate of Shakoor) v Situ (t/a Eternal Health Co)* [2001] 1 WLR 410, [2000] 4 All ER 181, (2001) 57 BMLR 178, Independent, May 25, 2000
5 Ervine WCH. *Consumer Law in Scotland.* 2nd ed. Edinburgh: W Green & Son Ltd.; 2000; p. 245.
6 Stone J, Matthews J. *Complementary Medicine and the Law.* 1st ed. Oxford, New York etc.: OUP; 1996; p. 142.
7 *Sale of Goods Act 1979* (c. 54) (as amended by Sale and Supply of Goods Act 1994, c. 35) s. 13.
8 *Supply of Goods and Services Act* 1982 (c. 29) s. 13.
9 *Beale v Taylor* [1967] 1 WLR 1193; [1967] 3 All ER 253.
10 Wright M. *An Introduction to Chinese Herbal Medicine: with Particular Reference to the Chinese Umbelliferae*. 1st ed. Edinburgh: Greenbank Publications; 2004; p. 16.
11 Anon. *Shen Nong Ben Cao Jing (Shen Nong's Herbal Classic)*. ca. 100 BC.
12 Li Shi-zhen. *Ben Cao Gang Mu (Herbal [Comprising] Main Points and Details)*. 1596.
13 Wu Xiu-ren. *A Concise Edition of Medicinal Plants in China. Zhong Guo Yao Yong Zhi Wu Jian Bian (A Concise Edition of Medicinal Plants in China)*. Guangdong: Guangdong Gaodeng Jiaoyu Chubanshe; 1994.
14 Wright M. *An Introduction to Chinese Herbal Medicine: with Particular Reference to the Chinese Umbelliferae*. 1st ed. Edinburgh: Greenbank Publications; 2004; pp. 19–20.