HealthWatch
for treatment that works

Registered Charity No 1003392

HealthWatch Newsletter no 15: June 1994

The European Medicines Evaluation Agency comes to the UK

The UK has won the battle to house the European Agency for the Evaluation of Medicinal Products (usually abbreviated EMEA). But its name is deceptive because evaluation of medicines is one thing it will not do. UK skills in controlling medicines may not, in fact, be exploited because of the structure of the new system for evaluation of medicines in Europe. And there are fears concerning other weaknesses in the system.

Some say that the UK is an excellent place for the Agency because of the acknowledged success of the UK Medicines Control Agency (MCA) in reaching sound judgements on which medicines should get to the market with little delay. But Health Minister Virginia Bottomley, with the help of the Prime Minister, seems to have secured this agreement within the European Community (EC) not because of the UK's sound virtues but to compensate for the decision that the European Bank would be sited in Germany: in practice, there may not be opportunity to exploit these local skills as much as would be desired.

The new Agency's role will be merely to coordinate the evaluations of drugs that EC member states will make. The task of making EC-wide decisions will fall to a group within the EMEA, the Committee on Proprietary Medicinal Products (CPMP). This is not an expert committee, but one made up of two representatives from each member state who are more likely to be medical generalists than specialists.

There are concerns about the way that the new system will be run:

- will the CPMP have enough experience to judge well?
- will European qualified majority voting on medicines, biased towards countries with smaller populations, produce sound decisions?
- will the experts appointed to the new Agency find the motivation to perform well when their role is restricted to coordinating the decisions of others rather than making the judgements?

To understand these fears, it is necessary to consider how medicines are evaluated now and then look at how they will be evaluated in the future.

Current Methods of Medicines Control

Each country in the EC has developed a system to reflect its own historic attitudes and approach. The UK system is complex and derives from a long tradition based on the idea that voluntary control by gifted amateurs on a voluntary basis provides better decisions. An informal system, set up after the thalidomide disaster, elaborated into the current system. This is not in any way voluntary, which may account for why, unlike voluntary regulation schemes applied to the financial arena, it works very well.

The decision whether to permit a product to be placed on the market is taken by the Ministers of Health on the advice of the MCA. The MCA can only refuse an application on the advice of the Committee on Safety of Medicines (CSM).

The CSM is made up of academics with experience at the cutting edge of science; the MCA has a group of highly professional assessors with wide and relevant experience; Ministers have only once applied their political judgment to the decision-making process and this opinion was reversed on appeal.

Therefore the process allows, as intended, steady or abrupt changes of judgement about new medicines to reflect the latest shifts in knowledge.

This may sometimes be uncomfortable for drug companies, but generally is effective in protecting the public. Another characteristic of the UK system is that it has been very easy for the CSM to reach rapid and informal agreement with a manufacturer for the restriction or withdrawal of a medicine when there are worries about its toxicity.

Other countries have systems that range from an agency in which all decisions are reached internally to others in which advisory committees are as critical as they are in the UK.

In addition to different ways of reaching their decisions there are many basic differences between the medical traditions of the different member states which can make it difficult for them to reach a common position.

Until now, control of medicines has been very much under the traditional control of each EC member state, with cooperation between them increasing.

The key words in Eurospeak are harmonisatlon and approximation. Many matters related to medicines control have been harmonised through guidelines, highly persuasive while not legally binding, and Directives which instruct member states to approximate their laws. There has been a central decision-making body, but its opinions have not been binding upon member states.

This will change with the formation of the EMEA.

The EMEA is to be set up by means of a Regulation, which overrides national law, not by a Directive.

In the EC getting agreement between the opinions of these different medical cultures has been the task of a committee of representatives, the Committee on Proprietary Medicinal Products (CPMP).

Currently there are three ways that a manufacturer can bring a product to the market in the EC:

- it can go through the process of individual negotiation with each member state's regulatory authority;
- it can get approval in an index state and then go through a procedure called the Multi-State to obtain the agreement of the other member states;
- with certain products only, it can go through the Concertation procedure which involves a preapproval alignment (thus concertation) of opinions on the the virtues of the product. This process involves one authority preparing an assessment and all trying to agree it before approaches are made to obtain approval for marketing in any one of the EC states.

With all these systems each member state retains the right to make its own decision. Medical "sovereignty" is maintained. This will change with the new systems.

What will the EMEA do?

The EMEA will have the following structure:

MANAGEMENT BOARD

CPMP

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS (CVMP)

EXECUTIVE DIRECTOR

SECRETARIAT

The EMEA will be sited in the UK. Initial funding has been allocated; its continued funding will be by means of "user fees" paid by the drug companies at the time of application for approval of their medicine by the EMEA. These fees will be large, as needed to pay for a substantial establishment, but the cost will not be significant in relation to the total cost of drug development.

In a neat example of Orwellian newspeak, evaluation of medicines is something the EMEA will not do. The role of the secretariat is to coordinate evaluations made by the regulatory authorities of the member states; that of the CPMP to reach unified community decisions, by persuasion if possible, by use of a binding arbitration process if not.

Further, there is strong political pressure for appointees to important EC positions to be selected on the basis of their nationality and there are fears this may take priority over ability. However, the appointment of the highly experienced and respected Fernand Sauer as executive director and of a skilled British civil servant Strachan Heppell as chairman of the board suggest these fears may be exaggerated.

Registration procedures for a product will change substantially between the start of the EMEA and the end of this century. In a few years time it will not be possible to register a product in more than one member state of the EC without going through one of two systems, each involving at the end of the process a system of binding arbitration.

The first of these is the Centralised procedure. This will be used for products made by biotechnological methods or other new products of special medical interest. The regulatory authority of one member state will be appointed to perform a single community assessment upon which all other member states must agree, with the EMEA to coordinate and the CPMP to decide.

If agreement cannot be reached without it, binding arbitration will be applied. It follows that the traditional decision-taking modes of the member states will be excluded from this process. In the case of the UK, therefore, the CSM will not have a voice in the approval process.

The second method is the Decentralised procedure. In this, a product will be registered in one member state whose regulatory authority will then send its assessment to the others. The EMEA will coordinate and the CPMP will decide, again with binding arbitration if agreement cannot be obtained without.

The EMEA will also coordinate other established activities of the member states' regulatory authorities, including:

- supervision of Good Manufacturing Practice and inspections to assure the consistent quality of medicines;
- supervision of Good Laboratory Practice and inspections to assure correct performance of animal studies and humane treatment of test animals;
- supervision of Good Clinical Practice to assure the validity of clinical trial results and the protection of the rights of human subjects;
- supervision and decision-making upon the results of postmarketing information on the safety of medicines (pharmacovigilance in Eurospeak).

Implications and Concerns

A number of concerns are raised by these plans:

- Will the CPMP have the expertise to judge well? It is not currently an expert committee like the CSM, but made up of two representatives from each member state who tend to be generalist rather than specialist in medical matters. An immediate initiative of the EMEA will be to increase its expert representation, but it is hard to see how a committee representing 12 states can also provide all shades of expertise;
- Will the process of binding arbitration by qualified majority vote produce sound decisions? The British are not alone in Europe in believing that their approach to medical matters is unusually sound;
- Will pharmacovigilance and the processes set up to restrict or withdraw drugs from the market work well within the complex bureaucratic structure of the EMEA? The present informal and rapid system of the UK will be much missed;
- Will the best member state always be appointed to provide the initial drug evaluation? In the Decentralised procedure there is obviously an element of company choice; in the Centralised, the CPMP has the power to appoint. Will a country's particular expertise be acknowledged or will Buggin's turn be decided on a political basis?
- Will it prove possible to appoint and motivate a first class secretariat? If the project leaders are really expert, will they be content just to coordinate the assessments of the member states? There is the rather depressing example of the European Parliament to suggest that competent people, deprived of power and influence, do not behave too well;
- Could the system just prove too complex to be managed effectively for such a wide variety of people?

The Food and Drug Administration (FDA) in America, which has both evaluation and bureaucratic roles, often seems at risk of total paralysis.

The aim of those who planned the EMEA and its procedures was to avoid the creation of a European FDA. But removing the evaluation role may simply leave us looking right into the face of the beast: an unmanageable bureaucracy, not driven by ideals of medical excellence. This might give Europe the worst of all worlds.

There must be problems whatever system was decided. It will be difficult to make medicines control work within a pan-European frame.

The challenge to be met by those appointed to run the EMEA is to ensure that bureaucracy does not prevent the delivery of safe and effective medicines to the European public.

Easy for us to say - difficult for them to do.

Michael E Allen

See also articles on EMEA by Michael Allen in Newsletter 24 and Newsletter 29

Top of page

Forum - Health of the Nation

Many technologies are over-used in medicine because doctors are ignorant about whether they really benefit the patient, a forum on "The Health of the Nation" has been told other technologies are under-used when they could be saving lives, according to Bryan Jennett, emeritus professor of neurosurgery at Glasgow University.

Hundreds of thousands of patients had received extracranial / intracranial bypass before a trial of 1400 cases showed in that it did not reduce the risk of major stroke in patients with transient ischaemic attacks, Professor Jennett told the forum, held by the Institute of Health Sciences at City University.

Yet thousands of patients have been denied carotid endarterectomy - an alternative operation for the same condition - because it was thought to be much less effective than the bypass operation. Recent trials have shown that it is much more effective than had been thought, he said.

Professor Jennett called for many more trials of medical technologies that have been "established as accepted". There should also be more explicit, widely disseminated guidelines for doctors as a result of the trials, he said.

> "It has been recognised in the last decade or so that there is a real variation between the rate of performance of present technological diagnostic and therapeutic procedures between one place and another," he told the forum.
>
> 'This reflects professional uncertainty about the indications for those procedures for which wide variations are found. There is a great need for clearer definition of such indications and for these to be translated into guidelines as a basis for management."

He also accused doctors of ignoring the results of trials rather than changing their behaviour to fit the facts:

> "Although the Cochrane Centre in Oxford has made available an inexpensive disc summarising all recent trials in obstetrics, a recent investigation reported in the BMJ showed that many obstetricians had never heard of its existence, whilst less than one in four had a copy," he said.
>
> "Some responding units said they had no need of such data because they were teaching hospitals, others prided themselves on having no protocols, while some had protocols that were directly contrary to published data on appropriate management."

The prospect of a new "tidal wave" of technological innovations makes the need for proper assessment all the more urgent, said Professor Jennett. New techniques, such as minimally invasive surgery, interventional radiology and endoscopic procedures, will probably cut the amount of open surgery required by 70 per cent by the Year 2000.

New techniques may be more hazardous or expensive than open surgery, for example if they require general rather than local anaesthetics or longer time in the operating theatre. Yet patients will perceive that the new technology removes many of the risks of surgery, he said. For example, minimally invasive surgery will reduce the time spent in hospital and cause much less pain after the operation.

> "Technology assessment will be important in order to resist the demand from patients for inappropriate interventions as people become less reluctant to accept surgery," he said. "In fact the increasing demand for technology assessment is likely to come partially from patients anxious to be protected from inappropriate interventions as they more frequently participate in decisions about their care."

He cited other countries where doctors are more strictly controlled over the use of new technologies: "The Netherlands has an act called Article 18 which says that certain technologies are only allowed to be done in certain designated institutions," he said. Studies are done and then "only when it's shown that it is worthwhile is it allowed to go to other institutions."

He admitted that technology assessment "is not cheap" but said that the cost of ignorance could be much greater.

Alan Maynard, Director of the Centre for Health Economics at York University, supported calls for more assessment of the outcomes of treatments in the NHS, particularly using randomised controlled trials. He said that it was one of many aspects of the NHS that needed proper evaluation.

> "There is a great deal of uncertainty facing doctors when they treat patients," he told the forum. "As a consequence there are enormous variations in what doctors do."

Richard Smith, editor of the British Medical Journal, told the forum: "If you look right across the medical literature and apply the strictest standards of scientific accuracy then probably about 5-10 per cent [of the literature] is worthwhile."

Top of page

Miracles at Earls Court

This summer, American TV healer Norris Cerullo returns to London, with his claims of miracles at his meetings. Two years ago, posters showing a broken blind cane, an overturned wheel-chair and a discarded hearing-aid were displayed on bill-boards across the capital, to the anger and dismay of many disabled people.

Challenged in a live television interview to produce his three best cases from the week for public scrutiny, Cerullo found himself under an intense spotlight Joan Bakewell's "Heart of the Matter" team presented the cases in a powerful television documentary, leaving Cerullo protesting that he needed more time. He consequently appealed

to people on his mailing list to come forward with their stories and set up a medical panel to analyse them.

Cerullo's posters claimed they had 2,250 cases from which to choose. A year later, after the medical panel's final meeting, a public statement from one of the doctors said emphatically that "there is no evidence that anything has occurred that is outside the realm of normal clinical experience" (1). A study of his 'best cases' was published recently in the USA (2), allegedly after a vigorous attempt by Cerullo's solicitors to silence the writer.

Cerullo has become a dominant figure in the world of American TV healer-evangelists. His mailing list is his key to success. Fundraising letters are sent out month by month pleading for cash. People in debt are singled out for special treatment, with miracles of 'debt cancellation' offered to those who give thirty pounds or more. Two years ago, his organisation, which operates around the world, was valued at over twenty million pounds.

1. Soole M.J.; Report on the Medical Review Group of MCWE. 30th June 1993
2. Dr Peter May; The Faith Healing Claims of Morris Cerullo. Free Inquiry. Winter 93/94 14:5-11

Top of page

Anti-science and pseudo-science in Russia and Germany

Bernard Dixon, the well known science writer and member of HealthWatch (writing in the journal Biotechnology) draws attention to current signs of an alarming growth in anti-science views and attitudes in both Russia and Germany.

In Russia popular science has almost disappeared from the media since the collapse of the Soviet Union. "Media editors", said a Russian journalist at a recent conference at Geneva, "now refuse to publish articles on scientific achievements. They prefer to fill their readers and viewers with pseudo-erotic writing and the speculations of sorcerers, astrologers and phoney prophets. And the public tends to blame science and scientists for everything that goes wrong".

Meanwhile, in Germany, according to one survey, public support for biotechnology is the lowest among the 12 countries of the European Union. Several bioscience companies have located new facilities in other countries rather in their home territory, apparently for this reason. And a speaker from Bonn said that "teachers especially are prone to join specific trends, being AGAINST biotechnology, AGAINST nuclear energy, AGAINST genetic engineering . . while on the other hand overemphasising environmental issues without sufficient reflection or differentiation".

The German situation can perhaps be traced to -

- the historical legacy of Nazi eugenics
- the authoritarian disdain shown by some sections of the scientific establishment towards engagement with journalism and the public
- the rise of the Greens a decade ago

In the former totalitarian countries to the East, on the other hand, the reasons seem to be:

- the replacement of science by pseudoscience
- the scientific community's loss of its privileged position
- the withdrawal of government support for science magazines
- the opening of the floodgates for alternative ideas.

Bernard Dixon fears that (as shown in these reports from Russia and Germany) when given the right ingredients and encouragement, antiscience may thrive in virtually any society.

Top of page

Letter to the Editor

From Brian Wall, Le Chalet, 4 Belvidere Terrace, Inner Rd, St Helier, JERSEY JE2 4NG

Dear HealthWatch,

I have been a member for a couple of years now, and am currently employed on the management side of Occupational Therapy at an elderly day-care hospital. As a relative newcomer to the health scene, I am unsettled by the extent to which many of our occupational therapists subscribe to the many alternative remedies available, such as homeopathy, reflexology and acupuncture, not to mention a serious interest in astrology. Is this usual?

Also our local paper gives alternative practitioners giving each plenty of uncritical publicity.

A typical story is about a colleague who has suffered a chronic eye problem for twelve years. Doctors admitted defeat and prescribed eye drops. So the OT went on a course of Reflexology. On her own admission, this totally

failed. Yet her colleagues seem most anxious to make allowance for this failure whilst simultaneously tut-tutting about how 'useless' the doctors were. And these are well trained, intelligent people. It seems clear that work experience with care for the elderly has created a degree of disillusionment as to the efficacy of conventional medicine, yet at the same time lack of success with alternative medicine is shrugged off or glibly explained.

If even the medical profession can think like this, is it any wonder that the public at large are also confused and disillusioned?

Expectations of medicine have in the past been raised to ludicrous levels by the media, fuelled by appalling public knowledge about even the most basic medical ethos. In particular, I find there is a lack of appreciation of the concepts of evidential proof and clinical trials. Where these are known about, it seems to be in the context a self protection mechanism designed to freeze out the opposition. I appreciate that HealthWatch's goals are precisely addressed to these problems. What I am writing about is to suggest a more aggressive proactive rather than reactive approach. Unfortunately, we are facing a media which finds the barmy more sellable than the truth. If we can't beat them...

In the USA, the Skeptics organisation have been involved in several TV series, one of which, featuring James Randi, was shown in the UK last year. The approach was subtly, but entertainingly, to undermine common misconceptions such as metal bending and telekinesis. Something similar needs to be done in the health field.

Creating a six part TV series is obviously a major undertaking and one that is beyond the scope of HealthWatch itself. However, there may be members with a suitable background, such as myself who spent six years in the TV industry some years ago. Is it beyond the realms of possibility that we could combine our talents and expertise, raise funding and professional services, and go on the attack?

If anyone is interested then, please contact me, Brian Wall at work - William Knott Hospital, OT Admin Services, Westmount, St Helier, Jersey. JE2 3LP (0534) 59000 ext 2052 and at home - (0534)601003

Top of page

Universal Cure in the 18th Century

From Glasgow Past and Present, Vol 2 page 88, quoted in a Glasgow Keek Show by Frank Worsdell, Richard Drew Publishing, Glasgow, 1981:-

'The Doctor (who in his advertisements styled himself Doctor James Graham, President of the Council of Health, sole Proprietor and Principal Director of the Temple of Health in Pall Mall, London) made his appearance in Glasgow in the year 1783.

With reference to the first article of the doctor's grand curative treatment, it consisted of his celebrated earth bath, which, like Morrison's pills, cured all disease.

The patient was first stripped naked and then placed upon a glass stool, where he was electrified by means of an electrifying machine. After being thus electrified, and well rubbed down by silken towels, he was plunged, or rather buried up to the mouth, in an earth pit, the earth having been previously medicated by the doctor.

But however wonderful were the effects of the earth bath, these were thrown quite into the shade by the almost miraculous consequences which followed a sojourn in the Doctor's Temple of Health and Electric Bed. The Temple of Health was fitted up in a most gorgeous style... The celebrated bed itself was adorned with elegant crimson silk damask curtains...

In an adjacent apartment the Doctor had a powerful electrifying machine, from which machine to the bed there was maintained, during the whole course of the night, a constant stream of electricity."

Top of page
