

Slow start for MS risk-sharing scheme

Six months ago, the Department of Health announced that people with multiple sclerosis would be able to take part in an innovative risk-sharing scheme for MS drugs financed jointly by the pharmaceutical industry and Government. Monika Polak investigates what progress has been made since then

ON 4 February, the Department of Health said it would be entering into a revolutionary risk-sharing scheme with the pharmaceutical industry, where the cost of disease-modifying drugs for multiple sclerosis (MS) — beta interferon and glatiramer — would be shared between itself and the manufacturers. If the drugs were found not to be working, the National Health Service would get all of its money back.

At the time, clinicians and patients welcomed the one-off scheme, and hoped the drugs would be quickly supplied to those who needed them most and who had already endured a substantial wait. However, setting up the scheme is proving to be a long, drawn-out process. This slow start follows a protracted appraisal of the drugs by the National Institute for Clinical Excellence, which instead of taking the usual one year to complete, took more than two.

Recruitment to the scheme should have begun in May, but only a minority of patients have so far been assessed and had treatment started. Indeed, the original Department of Health circular that announced the scheme last February recognised it could take up to 18 months to com-

plete the recruitment phase. In an attempt to maintain momentum, the Department reminded all primary care trusts and strategic health authorities of their obligations, including a statutory obligation to provide funding for beta interferon and glatiramer, in a new health service circular last month. SHAs should have already identified local leads for the scheme and notified the Department and PCTs. Similarly, PCTs are expected to forward the name of a local lead to SHAs by 31 August.

David Harrison, spokesman for the Multiple Sclerosis Society, says the slow start was foreseen by many: "Everybody knew that the process of getting people into the system and getting them assessed was going to be a lengthy one."

"The scheme technically started on 6 May and there is obviously an expectation among people who have been waiting a long time that the drugs will be forthcoming quickly. But it is not quite as simple as that — this is part of a structured, national study, so the baselines and the way to collect and analyse data have to be in place first," he added.

Mr Harrison also hopes the appoint-

ment of an overall co-ordinator, announced in last month's circular, will quicken the pace. A consortium led by Professor Jon Nicholl of the School for Health and Related Research (ScHARR) at Sheffield University has been appointed to co-ordinate patient monitoring and oversee the trial at a national level. Although a minimum data set requirement has been issued by the scheme's steering group, allowing established centres to enrol patients as soon as possible, one of the first tasks for Professor Nicholl and his team will be to determine the full data requirements. Initial meetings between specialist centres and co-ordinators are likely to set time scales and identify any difficulties.

According to Mr Harrison, there are a variety of obstacles to be overcome: "There are different reasons for delay in different places — some centres are readier than others. In certain places, there are limited services, for example no MS nurses, or not enough neurologists," he says.

In recognition of this, the MS Society, together with MS drug manufacturers and the NHS are funding 21 specialist MS nursing posts this year. Mr Harrison says recruitment via this fast-track route is going well, and he expects a significant number of posts to be approved imminently. Individual manufacturers are also providing funding for additional consultant sessions and other clinical and administrative posts, as well as for additional MS nurses.

But problems of manpower are not new in the NHS. Perhaps of more concern are reports coming in to the MS Society of neurologists telling patients that these disease-modifying drugs are not available to patients on the NHS, or that funding for treatment is not available.

Mr Harrison says: "There are misunderstandings about what the scheme means, even among health professionals. In one case, the consultant could not work out which PCT the patient fell under and therefore who would fund the treatment — these are the sorts of glitches in the system."

"The Department of Health has asked the MS Society to let it know of any problems that are occurring. We are as keen as anyone to see people on these drugs as soon as possible and with this latest reminder from the Department, we can look to things falling into place," he added.

As well as trying to identify problem spots, the DoH says it will be seeking reassurance from health authorities by mid-September that PCTs have complied with their duties in relation to the scheme. A DoH spokeswoman said details of which specialist centres would be involved in each area were still being finalised, but that the work was likely to be completed "in the next few weeks".

The Association of British Neurologists

The road that led to the risk-sharing agreement

August 1999 NICE is asked to appraise disease-modifying drugs for MS: the beta interferons Avonex (manufactured by Biogen), Rebif (Serono) and Betaferon (Schering HealthCare), and glatiramer acetate (Copaxone, TEVA/Aventis).

July 2000 Appraisal of glatiramer is put on hold, because it does not yet have UK marketing authorisation. However, the final appraisal for beta interferon concludes this drug is not cost-effective and does not recommend it for the NHS. Eight consultees appeal against this draft guidance.

November 2000 The appeal is partially upheld. NICE asks its appraisal committee to reconsider the original evidence and to examine a new economic model submitted by Schering HealthCare. Meanwhile, glatiramer is granted its UK licence and is considered alongside beta interferon.

December 2000 The appraisal committee expresses serious reservations about the economic models submitted. It says flaws in them should be rectified if possible. However the committee maintains that, on the basis of current evidence, neither beta interferon nor glatiramer is cost-effective for the NHS. NICE extends the

appraisal process deadline and commissions new economic modelling, as it is "critically important" to the appraisal.

February 2001 A consortium based at the Sheffield School of Health and Related Research (ScHARR) is appointed to do the new modelling.

July 2001 The appraisal committee considers the new modelling, but again does not recommend beta interferon or glatiramer for the NHS in its provisional appraisal.

November 2001 The final appraisal conclusion mirrors July's provisional decision. Seven consultees appeal.

January 2002 The appeal is not upheld.

February 2002 NICE issues formal guidance to the NHS. It says beta interferon and glatiramer are clinically effective in some people with MS, but rules they are not cost-effective and does not recommend them for treatment of MS on the NHS in England and Wales. However, NICE suggests the Government and manufacturers might consider ways to make the drugs available to the NHS in a cost-effective way.

is helping the DoH ensure that sites are suitable as MS centres. Professor of neurology at Liverpool University, Professor David Chadwick, is chair of the ABN advisory group on MS guidelines, currently advising the Government on this issue. He estimates there may be as many as 50 centres in the United Kingdom eventually involved.

Some of these have already been providing a specialist MS service, working to ABN clinical guidelines on beta interferon and glatiramer acetate in multiple sclerosis, published in 2001. These are being used as a basis for prescribing under the risk-sharing scheme and recommend that treatment is initiated by a consultant neurologist with expertise in MS and that patients are followed up monthly or quarterly for the first year by a consultant neurologist. Patients should subsequently be seen at six-month intervals.

Professor Chadwick says: "One or two centres have collected the minimum data set on patients who have already started treatment. There are some centres where patients were getting treatment all the time. In some regions there is a strong hub and spoke pattern of care that can provide the multidisciplinary care needed. Other areas don't have that sort of strength — individual neurologists may take on prescribing for their own patients, rather than handing that over to a central facility."

According to Professor Chadwick, the United Kingdom has one neurologist per 200,000 of the population — many fewer than in other western European countries. And although more MS nurses are now being trained, he believes "a considerable burden" will still fall on ABN members.

"The difficult bit is ensuring that centres have adequate resources to assess and document what may be quite a large number of patients who are deemed eligible for treatment for the first time," Professor Chadwick says. "Data collection forms will be available by September, but I don't think all the centres will start then, because of the resource implications.

"In some parts of the country, patients will get treatment immediately, others will see delay as the resources come in. I would hope that between 10 and 20 centres will be in a position to be working the scheme by

How the risk-sharing scheme works

In February, the Department of Health announced it had made a "payment by results" agreement with the pharmaceutical industry for MS drugs. The deal means that costs to the NHS will be reduced on a sliding scale if patients show no improvement.

All MS sufferers with the relapsing-remitting form of the disease and those with secondary progressive MS, in which relapses are the dominant feature, are eligible, so long as they meet the Association of British Neurologists' clinical guidelines on beta interferon and glatiramer acetate in multiple sclerosis, published in 2001.

Patients should be referred to specialist MS centres by a consultant neurologist — not by their general practitioner. Once referred, patients' eligibility for the scheme is assessed, using the Expanded Disability Status Scale (EDSS). Treatment is initiated by a consultant neurologist with expertise in MS. Specialist MS centres with appropriate infrastructure already in place could have begun prescribing from 6 May this year.

Separate target outcomes have been agreed between the Government and manufacturers for each of the four drugs involved. If these are achieved in full, the drugs will work out to be cost-effective for the NHS. Cohorts of patients will be monitored annually and the amount the NHS has to pay for a particular drug will be adjusted on a sliding scale if patient outcomes differ from the agreed targets for that product.

The DoH estimates that these price adjustments are likely to continue for about 10 years. The scheme co-ordinator, Professor Jon Nicholl from SchARR at Sheffield University, will liaise with each centre and collect and analyse the monitoring data required to assess the success of the scheme in terms of patient outcomes.

Health authorities and PCTs have a statutory responsibility to fund MS drugs prescribed under this scheme. In addition, they should meet the cost of beta interferon and glatiramer purchased privately by patients who could not get the drugs due to local funding or prescribing policies, since the deal was announced in February.

The Department estimates that 7,500–9,000 MS patients in England and Wales (12.5–15 per cent of those with MS) will fall within ABN guidelines and be eligible for the scheme. Costs per patient per year of treatment range from £5,823 for Copaxone to £8,942 for Rebif 44mg, which could mean a bill of £50m per year for the NHS.

September," he added.

Although the Welsh Assembly has ring-fenced £1.8m for the scheme, Ministers in England and Scotland have been less generous, telling SHAs and health boards they must provide funding from their existing budgets. The DoH justifies this position by saying the MS drugs deal had already been taken into account when baseline funding allocation were made the previous year. The risk-sharing scheme could cost the NHS £50m a year and cash-strapped SHAs and PCTs may find it increasingly difficult to prioritise funding.

Professor Chadwick believes the huge organisational changes currently taking place in the NHS have also impacted on implementation of the scheme, and said some neurologists were reporting problems with funding. "How compliant PCTs in

some areas will be with central advice is debatable. There may be costs of around £50m — that's a significant chunk of development money," he said.

However, on a more positive note, Professor Chadwick believes the scheme will help develop neurology services based on multidisciplinary teams, which will improve the management of people with other conditions, such as epilepsy. "That will be an important by-product of this scheme," he concludes.

Clearly all sides are committed to ensuring all eligible patients are treated as quickly as possible. However it seems that variations in the standard of care for MS patients look likely to continue in the short term at least.

Where does the scheme leave NICE?

NICE and the Government are adamant that the institute has not been undermined by the scheme and both say it only happened as a result of the work done by NICE.

When asked if NICE would suggest similar schemes in the future, communications director Anne-Toni Rodgers would not be drawn: "We don't know, as it was all based on the evidence. Every bit of guidance is different — some drugs are recommended for research only, some only as part of a trial — we would have to see the evidence."

NICE recognised that in this particular case, there was a specific group of patients that could benefit, which was why it had made the suggestion, Ms Rodgers said.

At the time, the Department of Health insisted that the scheme would be a one-off, but now it says it would consider doing it again, if NICE suggested it.

A spokeswoman for Schering HealthCare said it was still too early to judge the success of the risk-sharing approach, while medical director for Serono, Dr Mercia Page, said: "This solution has been worked out in this particular area. But we would like to see a shift to a more collaborative approach with NICE."