AN AUDIENCE WITH…

Sir Michael Rawlins

Sir Michael Rawlins, Professor of Clinical Pharmacology, University of Newcastle-Upon-Tyne and Chairman, National Institute for Health and Clinical Excellence, UK. Sir Michael Rawlins has been Professor of Clinical Pharmacology at the University of Newcastle since 1973. He is also Consultant Physician and Clinical Pharmacologist to the Newcastle Hospitals National Health Service (NHS) Trust. He was Vice-Chairman (1987–1992) and Chairman (1993–1998) of the Committee on Safety of Medicines, and is currently Chairman of the Advisory Council on the Misuse of Drugs. He has been Chairman of the National Institute of Clinical Excellence since its formation in 1999, which in April 2005 absorbed the functions of the Health Development Agency, becoming the National Institute for Health and Clinical Excellence.

Can you clarify the role and function of NICE?
NICE's job is to provide national guidance on the promotion of good health and the prevention and treatment of ill health. Since April 2005 we've had responsibility for developing guidance on public health as well as clinical topics, so our remit is much broader now. Whether we are developing guidance on a single drug, or on the management of a chronic condition, we do this in broadly the same way — we gather the evidence, which is assessed by an independent group of healthcare professionals, academics and patient advocates; we make draft recommendations on the clinical and cost effectiveness of the treatment or intervention; and we consider the comments of stakeholders before publishing final guidance for the NHS.

What is the aim of the recently launched Single Technology Appraisal?
Under this process we would expect a pharmaceutical manufacturer to be able to produce an assessment report for a new drug or device while it is being licensed, so that as soon as we know the licensing indications we can start the appraisal process. We think we can shrink the period of appraisal down to 6 months, so if we started before the drug was licensed then we could produce a conclusion within weeks of it getting market authorization. Industry has, in the past, been opposed to early appraisal because of concerns that there is not enough knowledge about a drug until it's been on the market for a couple of years. To that I asked, what more can we know about a drug after a couple of years? And eventually, some companies did confess that the real problem is that a negative appraisal by NICE could have a global impact on coverage decisions. We know that this is not the viewpoint of many individual companies, but rather the formal position of the Association of the British Pharmaceutical Industry (ABPI). As the ABPI supports the STA process, of which early appraisal is an integral part, I am sure we will now get full cooperation.

How does NICE impact drug innovation?
NICE hasn't turned out to be the rationing body that the industry and patients first thought it would be. We give positive recommendations for many new technologies and medicines; the extent to which they are implemented depends on many factors. I don't think that NICE has had a detrimental effect on drug innovation. Perhaps we have made manufacturers work a bit harder to prove the worth of their product because we ask tough questions, but that can only be a good thing.

Are there aspects of the work NICE does that could be applied in other countries?
Of course, the NICE model can be applied anywhere. Regardless of who is funding healthcare, patients and healthcare providers want to be sure that treatments represent the best quality healthcare and offer the best value for money. We have excellent links with organizations across the world that are interested in how NICE does things and want to share experience and learning with us.

What implications have recent issues with drug safety had on UK healthcare stakeholders?
I think it's made them look hard at how these things can be avoided. The STA and similar processes in Europe should help drug safety efforts by ensuring that when drugs get marketing authorization the competent authority will make a risk assessment of potential problems and look out for special adverse event reports or commission special safety studies. But the industry needs to seriously find out what's wrong and put it right. I think the biggest problem is with not disclosing data. I know that the European Federation of Pharmaceutical Industries and Associations (EFPIA) has come up with a new scheme and it's an improvement, but it still isn't good enough. A more cohesive approach is necessary — a patient looking for clinical trials can't possibly be expected to look at every drug company website in the world.

Does the NHS aid pharmacovigilance efforts?
It does, although the US has databases that have also proved valuable. But we need to harness modern IT to a greater extent than we've done in the past. I've spent a lot of my life promoting the yellow card system for reporting adverse events in the UK, but I think we've got to look beyond that now, towards improving the analytical power of databases so that unexpected associations can be detected. A Europe-wide initiative needs to be taken and the European Commission needs to promote research in this area.

How do you feel about the criticism of NICE surrounding the delay in licensing Herceptin?
We have repeatedly explained that we can't do anything until the regulators have decided that the product is safe and effective for the indications claimed; but some journalists either don't understand this or they don't listen. Journalists could be better educated in these matters! Although some of them understand the process, we still get dozens of enquiries every day from local newspapers blaming NICE for the delays. I think the public are being misled by journalists because it is often through them that they find out about new drugs, and they need balanced information. When Herceptin is appraised, we will consider whether the evidence shows that it is clinically and cost effective, in the same way that we do for all drugs. Taking a consistent approach to decision making is key because we need to ensure that our recommendations stand up to scrutiny.