European Commission (EC).

Furthermore, EC officials say that by this summer the European Parliament is expected to approve guidelines similar to the Orphan Drug Acts of the United States and Japan to promote the development of drugs for rare disorders. These Acts provide a period of exclusivity—seven years in the US—for the marketing of orphan drugs, allow tax credits for certain expenses incurred in clinical trials, and authorize a program of research grants. The counterpart legislation within the EU would include ten years of marketing exclusivity, tax incentives for clinical development and the creation of a special central European committee to accelerate drug registration procedures as incentives to develop these small-market drugs.

The Clinical Research Center for Rare Diseases, Italy

But some researchers believe the plans will never come to fruition. Silvio Garattini, director of the Mario Negri Institute for Pharmacological Research, which established a clinical center for rare diseases in 1994, is angry at the fact that under the European Union's Fifth Framework Research Programme, rare diseases have been ranked with chronic and degenerative diseases such as cancer, diabetes and cardiovascular diseases. "This is a sign that Europe will continue to suffer from the lack of a clearly-defined cooperative policy on this issue, thus hampering the cross-boundary research that any serious national project on rare diseases requires," he says.

MARTINA BALLMAIER, MILAN

Mixed success in NHS-research collaboration

British medical schools have been given a mixed report card on their efforts to establish alliances and research networks involving local trusts funded by the National Health Service (NHS)—something they were instructed to do under reforms introduced five years ago.

Annual NHS expenditure on R&D is around £500 million (US$800 million). The reforms, whose primary aim was to raise the quality of research funded through the NHS, partly by making medical researchers more accountable to their funding bodies, were based on the recommendations of a committee headed by Tony Culyer, professor of economics at the University of York.

A report published last month by the Joint Medical Advisory Committee to the four UK higher education funding councils—one of the bodies set up under the reforms to help promote collaborative R&D programs within the NHS—describes successful efforts to achieve this at a number of British medical schools. Those quoted as models of good practice include University College London, where a Clinical Research Network has established an integrated database and website containing profiles of more than 1,000 researchers, a move that, says the report, "is leading to increased collaboration and has reduced the duplication of research effort."

But the report states that responses to the changes have been "patchy" across the country. Without identifying problem locations by name, a survey found that "some universities had established strong alliances and research networks, while others had been slow to develop collaborative approaches."

These conclusions are echoed in a separate survey of university medical schools and NHS trusts on the implementation of the Culyer reforms carried out by Nuffield Trust. One response to the survey by a Scottish group expressed concern that research is "increasingly abrogated from the NHS agenda," whereas an unnamed university was worried that "basic science would suffer under joint arrangements".

Michael Powell, executive secretary of the Council of Heads of Medical Schools, says that despite the success stories, medical schools agree in general that "there is certainly room for improvement." Powell adds that a chief concern reflected in the Nuffield survey is that research assessment processes carried out by the funding councils are different to those executed under the Culyer reforms, "which can result in an institution receiving completely different ratings on the same R&D portfolio."

DAVID DICKSON, LONDON

Japan moves towards experimental tissue regulation

Guidelines for the regulation of cell and tissue banks released by the Japan Tissue Culture Association (JTCA) have been interpreted as a first step towards a legal framework governing the research use of human material in biomedical research. Japan presently lacks such a framework, a fact that is seen as a major constraint on the country's biomedical research work.

Under current legislation, tissue can only be removed from corpses for pathological examination in cases in which cause of death is questionable. And although organ donation from brain-dead individuals has now been permitted in Japan, the law demands that bodies be burned after removal of the organ for transplant. Therefore, research use of tissue remains unregulated, meaning that many scientists avoid using cell and tissue bank facilities because their legal status is not clear.

Setting up new tissue repositories, such as brainbanks that are vital to neuroscience research, is "almost unthinkable at present," according to Nobuyuki Nukina, who heads the molecular neuropathology group at Institute for Physical and Chemical Research (RIKEN). Tissue banks that do exist are small-scale operations run by universities and are accessible only in-house. Most of the human tissue used for research is imported either through commercial suppliers, or through the Human & Animal Bridge Discussion Group, a Japanese organization linked to the US National Disease Research Interchange.

Pharmaceutical companies have found it particularly hard to access sufficient quantities of the variety of tissues that they require, and last year they pressed the health research council of the Ministry of Health and Welfare (MHW) to consider regulating access to excess tissue from surgical interventions. Their lobbying paid off in part with a promise by MHW's council to upgrade an existing cell bank facility at the Osaka research center at a cost of around yen 1.6 billion (US$ 13.3 million).

But so far, MHW has been reluctant to consider the subject of regulating material from corpses. The JTCA's guidelines may force this issue because they call for ethics committees be set-up at all levels of the system—donors, tissues banks and research scientists—and provide general indications for drafting regulation.

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