Proprietary Medicinal Products (CPMP), will be known as Committee for Human Medicinal Products (CHMP).

Other changes will take effect in November 2005, when all 25 member states have updated their national laws. Part of the shift will occur with the decentralized procedure. At present, this route is infamous for delays and protracted arguments between member states. The new rules order the EMEA to solve disagreements in a new 'Coordination Group', in which all member states are represented. Also, all relevant countries will be kept up to date during evaluation in the first member state, cutting months of delays for secondary registrations.

The rest of the changes focus on the centralized procedure, at present mandated mainly for biotech drugs. As of next year, any drug for cancer, HIV, diabetes or neurodegenerative and rare diseases will have to pass through this procedure.

Like the FDA, EMEA plans to put drugs with a high unmet clinical need on a 'fast track' procedure, bypassing less urgent applications and cutting an average of 60 from the 210 active days decisions can take. (EMEA refers to approvals both in terms of 'total review time' and 'active review time'.) Drugs expected to have great public health implications will be eligible for pre-approval release for 'compassionate use' or can be approved on the condition that more safety data will be collected.

Greater emphasis will also be placed on transparency. Doctors and patients will have seats in the EMEA governing board (at present the FDA has patients only in some advisory committees). Scientific committees at the EMEA will publish all decisions and relevant company data, even when the drug is rejected or the application withdrawn. Information like this can be relevant for patients taking drugs in clinical trials or programmes for compassionate use, says Harvey.

So, will this bigger, modernized EU convince companies to register new drugs in Europe before trying their luck in the United States?

It's unlikely, says Redfern, as better approval procedures, although welcome, are just one part of the struggle to get drugs to patients in Europe. It has been getting harder and harder, he says, to get products accepted for reimbursement by health care systems in various countries. "We have seen cases where getting drugs to patients in one country took five years longer than it took in others, whereas in some countries they never reached them at all," says Redfern. "Sometimes there are scientific reasons. But sometimes it's just to keep health care costs down."

Frits Lekkerkerker, chairman of the Medical Evaluation Board in The Netherlands and alternate member of the new CHMP, agrees. Although differences are subtle, Lekkerkerker says, "the EMEA still is somewhat more conservative with drugs that look promising but lack scientifically convincing proof." But, more importantly, says Lekkerkerker, as long as the US market yields bigger profits, the FDA will continue to be many companies' first choice.

## NEWS IN BRIEF

### Battle for Aventis heats up

On condition of the success of its bid for Aventis, Sanofi has reached a €453 million (US $538 million) deal to divest its antithrombosis drugs fondaparinux sodium (Arixtra) and nadroparin calcium (Fraxiparine) to GlaxoSmithKline, as well as the manufacturing plant for these drugs in northern France. Meanwhile, Aventis received a potential boost to pharmaceutical sales by US FDA approval of two key drugs, the antibiotic telithromycin (Ketek) and the rapid-acting insulin analogue insulin glulisine (Apidra). Aventis has also filed legal action against Sanofi's bid in the US District Court for the District of New Jersey. The action states that Sanofi's public filings and statements made in connection with its proposed tender offer contain significant omissions and misrepresentations. Novartis, which had said it would begin merger talks with Aventis only if the French government takes a neutral stance, has decided to start negotiating conditions after France's new industry minister, Patrick Devedjian, said that the French government should stay neutral in any takeover battle, but acknowledged there were differing views within the government.

### Cholesterol combination treatment approved

Merck and Schering-Plough said that Mexico and Germany had approved their simvastatin/ezetimibe (Zocor/Zetia) combination treatment. The treatment is the first to reduce low-density lipoprotein cholesterol through two mechanisms: simvastatin inhibits cholesterol production in the liver and ezetimibe inhibits cholesterol absorption in the intestine. Approval of the treatment, marketed as Inegy in Europe and Vytorin in North America, is a pivotal moment for both companies. It permits Merck to prolong simvastatin beyond its scheduled patent expirations in Germany and the United Kingdom in 2003, and the United States in 2005. For Schering-Plough, it provides relief from recent setbacks, which have created an urgent need to bring this potential blockbuster treatment to market.

### All change at Human Genome Sciences

Human Genome Sciences (HGS), which epitomized the promise of genomics, revealed that it is halting development of around half the drugs in its pipeline to focus on the five most promising treatments in its immunology/infectious disease and oncology therapeutic portfolios. It is also cutting about 200 jobs (20% of its work force), to contain costs and refocus its drug development efforts. The company is also parting ways with its chairman and chief executive William Haseltine, who founded HGS in 1992. Haseltine says the move was voluntary: as HGS shifts from gene research to drug development, he says HGS now needs an experienced pharmaceutical executive at the helm.

### Blow for biogeneric approvals

The approval procedure for biogenerics seems to have hit a hurdle. Sandoz, the generic drugs arm of Novartis, is suing the European Commission for blocking the European Agency for the Evaluation of Medicinal Products' (EMEA) recommended approval in June 2003 for its generic human growth hormone somatropin (Omnitrop). The Commission has not ratified the decision, saying Sandoz did not follow the guidelines, which the company disputes. The biogenerics and biotechnology industries are holding their breath as this case unfolds; Omnitrop is the first biogeneric to be filed for European approval, and EMEA is perceived to be the most progressive agency for regulatory approval of biogenerics (or bioequivalents, as they are called in Europe), but the decision implies that the Commission is not sure how to deal with these products yet.

### Amgen increases small-molecule product portfolio

In a move more akin to large pharmaceutical companies, Amgen said it would pay US $1.3 billion for the outstanding 80% of shares in the South San Francisco company Tularik, at a 47% premium over the closing price. The acquisition adds five experimental drugs to the 40 Amgen already has in development, with four of Tularik's drugs in Phase II/III trials. The most promising compound is T131, a selective modulator of peroxisome proliferator-activated receptor-γ, in Phase II for type 2 diabetes. It also gives Amgen its first base in the San Francisco biotech hub. However, Tularik said that two purported class-action suits had been filed against it and Amgen for alleged breach of fiduciary duty in connection with the proposed merger, and at the time of press no trial date had been set.

### Divine intervention for ex-Pharmacia lab

The purchase of an oncology laboratory by a nonprofit group with close links to the Vatican has come to the welcome rescue of its 800 employees. The Congregazione dei Figli dell'Immacolata Concezione (CFIC) has bought the lab in Nerviano, Italy, which Pfizer inherited after its purchase of Pharmacia and subsequently decided to shut down. CFIC plans to invest €300 million (US $361 million) to reinforce its network of hospitals and create an independent research centre for oncology studies in Italy and Europe. Pfizer will transfer technologies associated with the lab to CFIC, including access to its kinase platform.