UK Pricing Examined

A complete overhaul of the way medicines are reimbursed could be in the cards for UK residents. The Office of Fair Trading is examining the Pharmaceutical Price Regulation Scheme (PPRS), which has been used to determine the prices of medicine since 1957.

The PPRS is renegotiated every five years, most recently at the beginning of this year. The scheme regulates the profits drug companies are allowed to make. Drug companies use it to set prices for their products.

"We want to examine whether the PPRS works well to ensure that pharmaceuticals markets meet the needs of patients by offering adequate rewards to pharmaceutical companies for developing new and useful drugs, while providing the taxpayer with value for money," chairman John Vickers said.

The OFT study is expected to wrap up in the spring, but it may continue until the end of next year. How long the study goes on depends on the results it turns up.

The Association of British Pharmaceutical Industry, which is currently involved in PPRS negotiations, said it intends to cooperate completely with the OFT study.
–SARAH HOULTON

HIV/AIDS

Generic AZT Hits the United States

Impact on profits will be small, but it may provide incentive for research.

The expiration of GlaxoSmithKline's patent on Retrovir, known as AZT, may be a watershed moment in the history of HIV therapy. Although Retrovir (zidovudine) was a comparatively low seller in 2004—thirteenth in the retroviral class, according to IMS Health—its patent expiration could cause ripples in the market.

On September 19, FDA approved four different generic versions of AZT for use in the United States. Peter Young, president of specialized investment-banking firm Young & Partners, said HIV drugs losing patents might drive innovation. It could create financial incentives to develop therapies that dramatically improve treatment in order to get ahead of the generic alternatives.

"There is room for improvement to the extent that if people have patented new drugs that are very effective, they will be able to make money," he said.

The loss of revenues from Retrovir will not hurt GSK much. Its AZT-containing cocktail Combivir was the top selling drug in its market in 2004. It generated $31 billion dollars last year, compared with $36 million from Retrovir, according to IMS Health. GSK also puts AZT in Trizivir, which made $400 million.

The AIDS Healthcare Foundation criticized GSK for extending AZT's patent life through these fixed-dose cocktail drugs.

But even as generic AZT becomes available, state health programs are unlikely to switch away from combination cocktails and distribute drugs individually, predicted Murray Penner, deputy executive director of domestic programs for the National Association of State and Territorial AIDS Directors.

The newly available generics are manufactured by two Indian companies—Ranbaxy Laboratories Limited and Aurobindo Pharma LTD, and by Roxane Laboratories, a subsidiary of Germany's Boehringer Ingelheim. The drugs were already tentatively approved for use in developing countries under the President's Emergency Plan for AIDS Relief (PEPFAR).

FDA says the approvals indicate that drugs purchased under PEPFAR will be available to Americans when patents on the brand versions expire. PEPFAR has tentatively approved eight drugs so far, spokeswoman Karen Mahoney said.–**NATASHA T. METZLER**

TUBERCULOSIS

Halving Treatment Time

Public-private partnership will test the effectiveness of antibiotic for new use.

A collaboration between Bayer HealthCare AG and the Global Alliance for TB Drug Development will attempt to cut the six-month tuberculosis treatment time in half using Avelox (moxifloxacin).

"This would be the most dramatic and important treatment improvement for tuberculosis since the 1960s," said Gwynne Oosterbaan, a spokeswoman for Global Alliance.

As part of the agreement, Bayer committed to ensuring that the drug will be priced affordably for patients in the developing world.

Moxifloxacin is approved to treat varieties of bronchitis, pneumonia, and sinusitis. If the trials organized by Bayer and the Global Alliance are successful, the drug could be approved for this new use within five years, according to Oosterbaan.

"I don't know of any other example where a company has said, 'yeah we trust our drug, and yes we're making a commitment to public health, and yes we're going to make it affordable and yes, OK, well maybe there will be a risk of the drug coming back out [by being copied and shipped elsewhere], but we don't believe so,'" said Maria C. Freire, president and CEO of TB Alliance.–**JOANNA BREITSTEIN AND NTM**