

An example

Double drug standards

Closing gap in EU pharmaceutical regulation is a moral must

28/9/2008
With its strong history of pharmaceutical innovation and belief in social justice, the European Union should be taking the lead in ensuring that its exported medicines meet the highest international standards. They currently fall short.

The European Medicines Agency and its national counterparts have made great strides in recent years in strengthening the EU's capacity to approve new life-saving drugs swiftly, while ensuring that they are safe and effective to use.

But loopholes exist in the current system which mean that no similarly high standards apply to drugs that are manufactured on European soil exclusively for export beyond the EU. These gaps in regulation should be closed.

A number of EU-based drugs manufacturers trade on Europe's strong reputation for quality by making or exporting via Europe medicines that they then sell into developing countries. Unfortunately, the authorities in many of these importing nations are poorly equipped to ensure that such "European" drugs are safe.

World Health Organisation officials have identified EU-originated drugs in Africa and Asia that are near or past their expiry dates, of poor quality or contain ingredients that would never be approved in the west because of questions over side-effects or lack of adequate clinical trials to prove they are suitable.

Legislators in Belgium should be con-

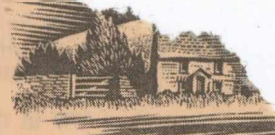
gratulated for taking the lead with a recently drafted decree which is set to be approved in the coming weeks. The aim is to prevent the export of any medicines made by Belgian companies unless they have been approved by a recognised, reputable regulator.

Provisos need to be put in place. A clampdown on EU-produced sub-standard drugs could simply push manufacturers to produce elsewhere. And there is no point in all developing world approvals taking place in the west, where the assessment of relative risks and benefits of a medicine may justifiably be different.

Ultimately, each nation needs to take responsibility to ensure that its own regulatory framework is serving its citizens in authorising only appropriate drugs. Given the lack of resources and experience, however, richer nations need to provide support to help this process directly and via the World Health Organisation.

An important interim step would be for developing countries to swallow their national pride and redouble efforts, with international assistance, to create a network of strong regional regulators - with one, at least, in each of Latin America, Africa and Asia.

Meanwhile, the current system in Europe is unacceptable. For the health of the developing world, not to mention the reputation of Europe, the EU has no justification for allowing the export of drugs that might not be considered safe for its own citizens.



Tories' turn to steal opponents' clothes

Hands up those who remember Labour's "ethical foreign policy" announced by Robin Cook in 1995 before he resorted to old-fashioned gunboat diplomacy in Sierra Leone. The Conservatives do, and as with many other long forgotten policies, they are prepared to whip it from their opponents.

The Tories announced yesterday that they had invited Aung San San Kyi to attend their party conference next week. Since the Burmese democracy leader has been under house arrest for 10 years she is unlikely to appear. Still, William Hague, shadow foreign secretary, I sent her a letter of encouragement how nice. Burmese activist Zoya P. will address the conference instead.

The Conservatives' human rights commission will debate putting rig at the centre of foreign policy. It will feature Craig Murray, the former British ambassador to Uzbekistan, who, ahem, left his job after accusing the British of using intelligence obtained under torture.

Paxman 1 - BBC 0

Forget Guido Fawkes. Long before political bloggers became fashionable aficionados of political comment hav

The same conclusion. National measures are not sufficient to achieve these goals