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Captopril marketing decision on hold

The battle between Generics (UK) Ltd and E R Squibb & Sons Ltd for judicial review of the British licensing authority's decision to grant Generics a licence to market captopril for myocardial infarction (but not for diabetic nephropathy) has been adjourned following a reference to the European Court of Justice. A preliminary ruling is not expected until 1998. The regime for granting licences is governed by Directive 65/65 EEC (OJ No 22 Feb 9, 1965) as amended by Directive 87/21/EEC (OJ 1987 L2/15/36).

On Feb 20, 1997, the Court of Appeal refused to grant either Squibb or Generics interim relief based on their conflicting contentions pending the outcome of the European court's decision. Lord Justice Schiemann said that the directive was open to at least three different interpretations.

- Squibb, the initiator of the drug, contended that no licence should be granted to Generics for either indication;
- Generics, a potential competitor, contended that it should have licences for both indications; and
- the licensing authority's interpretation. This favoured the initiator where the new indication was far from existing indications and the competitor when the new indication was close to the existing indication.

The English court had to proceed on the unusual basis that each of the three rival interpretations had an equal chance of success in the European court. A "wrong" decision to refuse an injunction would deprive the other party of a financial asset which, hypothetically, in the public interest, it should have. Since the very issue which had been referred to the European court was which of the two facets of the public interest should prevail, it would be wrong of the court to seek to lay down any rule that in an application for interim relief one of those public interests should prevail over another.

While it was generally useful in cases involving the grant of interim relief to talk of "balance of convenience" and "injustice" those were not apt concepts when considering the exercise of the court's discretion in these unusual circumstances.

Diana Brahams

Jerusalem hospital issues international appeal

The board of directors of the Al-Makased hospital in Jerusalem is increasingly concerned about interference by the Palestinian Authority in the running of the Hospital. This week, the board took the unusual step of issuing an appeal to the international medical community, asking for help in retaining control of the hospital.

Last November, the PA established a committee led by Dr Fathi Arafat, brother of Chairman Yasser Arafat, which proposed changes to the organisation of the hospital. These proposals involved separating the hospital from its charitable trust, and were put forward without consultation with hospital staff or directors. The Board objected to the proposals, and requested further discussions, but on Jan 19 a group of self-appointed directors broke into the administration office and took control of the hospital by force.

This move has been condemned by senior medical staff, who are concerned that decisions will be made which are not well informed and which are not in the best interests of Al-Makased. There is also more widespread concern among the medical community that the PA may look for direct involvement in other medical institutions.

Al-Makased is the largest hospital in the West Bank and played a major part in treating Palestinians injured during the intifada. It houses most of the West Bank's specialist medical services. However, the original board of directors is worried that if the hospital is seen as the direct responsibility of the PA, this could compromise its status and security under the terms of the agreement between Israel and the PA in Jerusalem.

Peter Kandela

Human monkeypox hits beleaguered Zaire

As if the events of recent months had not been enough for this impoverished African country, word has come that the very rare monkeypox virus has shown up in Zaire.

Human monkeypox, which is a DNA virus, has been recorded sporadically in tropical Africa over the past 30 years. The usual presentation is a fever lasting up to 4 days, followed by smallpox-like skin eruptions. There may be marked lymphadenopathy also. Although the mortality rate from the disease is generally low, there have been reported cases of death attributed to monkeypox. There is no known cure.

Health-care organisations around the world have mobilised their resources to assist Zaire. WHO, the US Centers for Disease Control and Prevention, and the Red Cross are dispatching workers to the region of Katakoumbe, where nearly 100 people have been found to be infected. The mode of transmission to human beings is unclear, but infection can be direct—eg, from handling monkey carcasses.

The announcement that monkeypox has re-emerged in Zaire was all the more discouraging to relief agencies who for the past several years have had to devote disproportionately

large amounts of time and resources to Zaire. Just this past month, United Nations spokesmen announced that their humanitarian efforts were being halted because the safety of the workers could no longer be guaranteed. Eastern Zaire has become the site of stepped up fighting by rebel groups opposed to President

Mobutu. Although peace talks have begun in South Africa, there is little hope that a ceasefire will soon be established.

Alongside the humanitarian horrors caused by civil war, the hundreds of thousands of Rwandan refugees passing through Zaire, a monkeypox outbreak may seem just a minor irritation to relief workers. After all, they are still trying to cope with the recently disclosed outbreak of Ebola virus too.

Robert Ivker



Planet Earth Pictures

Posing problems in Zaire