Bovine spongiform encephalopathy threatens drugs in European Union

Editor—While the debates about bovine spongiform encephalopathy periodically have a high profile in public health, food safety, and agricultural and political environments, the pharmaceutical environment is now becoming seriously entangled in the web of controversy. On 20 February this year the pharmaceutical council of the European parliament accepted the European Commission’s proposed revisions to directive 75/18/EEC.

If the revisions are accepted by the European Union’s Council of Ministers it will mean that drugs for human consumption that have bovine, ovine, or caprine ingredients, or ingredients derived from such, will (with one exception) not be allowed on any member state’s market after 31 December. Over 200 drugs with gelatin will be affected, as will specific products such as HibTITER (Haemophilus influenzae type b vaccine), Hyalase (hyaluronidase), and Hypurin (insulin).1

The only exception to the ban will be drugs with such ingredients that have or secure a pan-European Union product licence through the European Medicines Evaluation Agency’s centralised route and for which no alternative drug is available. This escape route shows another aspect of the growing importance of the pan-European Union drug licensing system.2

On 10 June this year Emma Bonino, the commissioner for fisheries, consumer policy, and the European humanitarian office, announced the creation of another committee of the European Union, the scientific steering committee. This will act as the supreme source of expertise for the commission and offer excellence, independence, and transparency.

The first task for the scientific steering committee must be to make available the scientific evidence and rationale underpinning the decision to revise directive 75/18/EEC. If there is a scientific basis for the policy the committee should, being excellent and independent, produce it for all to see. The more obvious reason for the commission’s actions is that the European parliament had earlier threatened by 422 votes to 49 to force the commission to resign in a body if it did not act on the crises over bovine spongiform encephalopathy. Whether the emerging responses are justified or prudent remains questionable. Who is going to benefit from this malaise in policy and this lack of evidence based decision making: the millions of consumers of meat, jelly, sweets, and drugs?2,3

Alan Earl-Slater
Senior lecturer in health economics
Keele University, Department of Medicines Management, Keele, Staffordshire ST5 5BG

4 (7 June.)

Figures given for bed complement in Edinburgh were wrong

Editor—In a letter the chief executive and chairman of the Royal Infirmary of Edinburgh object to the figures that Allyson M Owens and Cairns Aitken used when they considered the implications of a private finance initiative in Edinburgh.1 Included in their letter was a table that documented the bed status at 31 March 1997. This table included the bed status of the Eastern (not Edinburgh as printed) General Hospital. Unfortunately, the figures for the Eastern General Hospital that John J Owens and Cairns Aitken used were incorrect; the table shows the correct figures.

The figures that Owens and Aitken used were projected figures that had been calculated on the basis of several assumptions and were not the actual staffed bed complement at 31 March 1997. Contrary to what Owens and Aitken state in their letter, these were not discussed with the clinicians involved.

R J Aitken
Chairman, clinical staff committee
P Gabbitas
Chief executive
East and Midlothian NHS Trust, Edenhall Hospital, Musselburgh EH21 7TZ

1 Owens J, Aitken C. What happens when the private sector plans hospital services for the NHS. BMJ 1997;314:1619-20. (31 May.)

Delays in diagnosing oesophagogastric cancer

Attempts to reduce delays in diagnosis should be done in controlled trial

Editor—The finding that gastric cancer detected early has a long doubling time (several years) whereas that diagnosed in an advanced stage has a short doubling time (several months) is consistent with the well known length bias. A non-aggressive course is associated with a long subclinical period with a high chance of early detection, whereas aggressive growth with a rapid onset of severe clinical symptoms leaves little chance of recognition of disease in an early stage. This confounds the observation that “early” cancer has a better prognosis than “late stage” cancer. The low case fatality from gastric cancer in Japan is a logical consequence of such biases, given that over six million Japanese people (presumably a selection of healthy people) have stomach screening annually. The suggestion that “patients with new onset dyspepsia and with changes in long standing dyspepsia must be referred promptly [for gastroscopy]” is therefore not evidence based.

In practice, early detection of cancer means not only the possible advantage of better curability in some cases but also the possible disadvantage of overdiagnosis and overtreatment in many other cases. Necropsy

Bed complement at Eastern General Hospital, Edinburgh, at 31 March 1997

<table>
<thead>
<tr>
<th>Bed complement at Eastern General Hospital</th>
<th>As stated by Owens and Aitken</th>
<th>Actual</th>
<th>60% of complement at Eastern General Hospitala</th>
</tr>
</thead>
<tbody>
<tr>
<td>General surgery</td>
<td>10</td>
<td>42</td>
<td>25</td>
</tr>
<tr>
<td>General medicine</td>
<td>48</td>
<td>107</td>
<td>64</td>
</tr>
<tr>
<td>Gynaecology</td>
<td>15</td>
<td>13</td>
<td>8</td>
</tr>
<tr>
<td>Obstetrics</td>
<td>15</td>
<td>37</td>
<td>37 (all to RIE)</td>
</tr>
<tr>
<td>Neurology</td>
<td>8</td>
<td>7</td>
<td>7 (all to RIE)</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td><strong>96</strong></td>
<td><strong>206</strong></td>
<td><strong>141</strong></td>
</tr>
</tbody>
</table>

a Calculations assume that 60% of beds at Eastern General Hospital are moved to Royal Infirmary of Edinburgh (RIE) and 40% to Western General Hospital, Edinburgh, except where otherwise stated.
delay in diagnosis influences survival

Errors—Ian G Martin and colleagues report the causes of delays in the diagnosis of oesophageogastric cancer.1 Against a background of a median delay of 17 weeks, the authors argue that long delays matter to outcome. With respect to gastric cancer, this extrapolation should be interpreted with caution.

The basic assumption is that advanced cancers presenting after long delays in diagnosis were potentially earlier stage tumours when their symptoms began; this assumption is questionable. Using a model of tumour doubling time of the oesophagogastroduodenal tumour stage is related more to invasion and spread than simply to tumour size,2 and a tumour may double in size but not be upstaged. Equally, this model assumes that the doubling time occurs within the window of delay, and clearly this is not so for some “early” cancers, where doubling times may be very long (up to 10 years; references 11 and 12 in the paper).

Provision of endoscopy in primary care speeds diagnosis

Errors—Iain G Martin and colleagues highlight the delays in reaching a histological diagnosis of upper gastrointestinal cancer in a specialised hospital with open access gastroscopy. They suggest a one stop service as a remedy. Most hospital units, however, are already struggling to provide an open access service and would be overwhelmed if 1% more of the population were examined annually, as recommended by the British Society of Gastroenterology. Increasing endoscopy services in hospitals also has cost implications.

An alternative is to establish diagnostic endoscopy clinics from within primary care that are run by experienced general practitioner endoscopists in accordance with the guidelines set out by the British Society of Gastroenterologists. Such units would cater for a more local population. During the past two years over 700 patients have had gastroscopy at our two surgeries, with an average waiting time of two weeks from the date of referral. Excellent “turn round” times from our local pathology department add, on average, a further week to obtain a histological diagnosis. Speed of communication between the referring general practitioner and the endoscopist is enhanced by the use of fax to transfer details of referrals and reports. Our cost per case is much less than that charged by our local trust hospitals because of reduced overheads and the omission of sedation.

Faster, cheaper, and easier local access to diagnostic endoscopy is one key element in the earlier diagnosis of upper gastrointestinal malignancy. Although in its infancy, the provision of endoscopy in primary care is highly efficient and looks set to expand, provided support continues from our political masters.

John Galloway
General practitioner
St James Medical Practice, King’s Lynn, Norfolk

Peter Evans
General practitioner
Jubilee Surgery, Titchfield, Hampshire


