evidence for its place in the control of symptoms and the prolongation of survival. Palliative chemotherapy, carefully supervised by accredited cancer specialists, should no longer be denied to selected patients with inoperable non-small cell lung cancer.

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The European Medicines Evaluation Agency

The new agency can be an important catalyst for drug innovation in Europe

The European Medicines Evaluation Agency (EMA) is to be set up in London—a decision that has been wanted and welcomed by the pharmaceutical industry. Many companies are tired of the long delays and the extra work required in submitting applications to 12 or more different regulatory agencies in the separate states of the European Union. As the life cycle of new drugs becomes steadily shorter, long delays—a year or more has been common in Germany—have become burdensome. A single registration procedure could lead to new products being introduced simultaneously in the 12 different European markets.^{1,2}

The agency will have a twin track procedure: one for centralised community licensing of biotech and innovative drugs and the other for mutual recognition licenses from member states with binding arbitration. The centralised system will have economic as well as health advantages by promoting the free circulation of medicinal products as well as reinforcing the protection of public health.

There could be other gains, too. Patients should benefit from the setting of clearer and higher standards in clinical trials and on the definitions of risk. They should also get quicker access to new and effective drugs. Doctors could benefit in terms of improved ability to deliver patient care and opportunity to take part in the development of new drugs. Above all the agency could give a clear signal that the industry in Europe should be trying to do more in terms of innovation.

The EMA could be a success, but it will need to face some problems. In reviewing some applications itself and also working with regulatory agencies it will have to develop a uniform approach with common standards. Unless it has the staff and the executive drive to make high quality decisions coherently and quickly, much of the initial goodwill might be dissipated. It will have to establish its authority early if the 12 member states are to accept its decisions without questioning them.

One high risk topic will be exclusive to the agency: the approval of biotech drugs. It will need to set procedures not only for their initial approval but also for continuing review and surveillance once the drugs come into general use. Evidence may be needed on precisely how the drugs are actually used—some approved for one indication may come to be used for others, with unexpected side effects. The agency might also work closely with the United States Food and Drug

Administration to agree a common framework for the evaluation of biotech drugs.

Some decisions should be made very soon. For example, there is a strong case for appointing the chief executive and some core staff so that they can have time to develop procedures based on a review of past experience in other agencies. There would then be time for consultation with existing national agencies and the industry in building a new consensus. The likely future economic impact of the agency is also uncertain; it may have a part to play in promoting competition and in reviewing market developments. Possibly the clinical licensing function might be developed across the European Union while economic and reimbursement issues could still be concentrated at the national level. The agency has been given no explicit role in terms of reviewing the costs and effectiveness of drugs but it will need to ensure that reimbursement issues are not used as ways of impeding the introduction of new and innovative drugs.

If, as we hope, the European Medicines Evaluation Agency succeeds it will provide a powerful new stimulus to the location of drug development within Europe. It starts with goodwill and with logic on its side: but success will come only if the agency is seen to be willing to identify the contentious issues and to take effective action to deal with them.

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Some copies of the international edition of the *BMJ* for 8 January were printed with blank pages. Any reader who has one of these journals and would like a replacement should contact the journal sales department, *BMJ*, BMA House, Tavistock Square, London WC1H 9JR (phone: 071 383 6055, fax: 071 383 6402). We apologise for this lapse, caused by a fault on the printing press.