NICE Alzheimer's veto a "blow for patients"

BRITAIN'S PHARMA industry association has described a UK 'ban' on Alzheimer's medicines as a great blow for "patients and their families, friends and carers".

But Dr Richard Baker, head of the Association for the British Pharmaceutical Industry, said the door was still open for further discussion.

"It is vital that it is not slammed in the faces of people with Alzheimer's and those working with them to alleviate this distressing problem," he added.

His comments follow a request by the UK's National Institute for Clinical Excellence (NICE) for more data on acetylcholinesterase inhibitors, the only treatment currently available for Alzheimer's.

"The decision as it stands would hit hard at those with Alzheimer's as it would effectively ban the only medicines that exist for this distressing condition," said Dr Baker.

According to NICE, additional data was requested in order to identify which subsets of patients could benefit most from the treatment.

But a statement from British-based Shire Pharmaceuticals, which produces acetylcholinesterase inhibitors, says that it and the other firms manufacturing these products have already supplied NICE with a "wealth of evidence" showing efficacy in patients with mild to moderate Alzheimer's disease.

"We are alarmed that NICE is attempting to exclude subsets of patients with Alzheimer's disease from receiving these drugs on the NHS," says John Freeman, Managing Director of Shire Pharmaceuticals in the UK.

Despite the setbacks, Shire says it remains committed to developing Alzheimer's treatments and to its galamantine products Reminyl and Reminyl XL.

EMEA to give industry more say on pharmaceutical guidelines

NEW PROCEDURES INTRODUCED by Europe's medicines agency will give drug firms and the public more say on pharma industry guidelines.

Under the procedure, the public will be allowed to comment on whether they think advice is necessary.

Changes to the existing procedure were prompted by a need for greater openness, while in an attempt to rationalise the terms used to describe its advice, the agency has also proposed the word 'guideline' be used for all pharmaceutical guidance documents. This will replace such phrases as – 'note for guidance' and 'position paper' – and clarify the nature and legal status of the various guidances.

Listed in the procedure are the steps the EMEA will follow when it brings in new guidelines. Some can be omitted under special circumstances – such as minor changes to documents or when a guideline's adoption is urgent.

Selecting a topic and including it in the EMEA work programme. This will be done within the EMEA, with advice from its scientific committees and other groups. There is no one method for proposing new initiatives and suggestions may be made to the EMEA or member state officials on EMEA committees.

Appointing a rapporteur to reflect the views of the relevant committee. Once a topic has been selected, a rapporteur will be appointed to draft the concept paper and guideline. Interested persons may contact guideline rapporteurs directly but this is generally not considered appropriate.

Developing a concept paper. A brief outline of the issues to be covered, plus a few of the options, will be produced to give the public a chance to comment.

Adoption and release of the concept paper. Concept papers will be published on the EMEA's website and made open to comments for two to three months.

Preparing initial draft guideline. The draft should include references to existing EU directives and guidelines, and related guidelines in other regions. It should take into account comments received during consultation on the concept paper.

Release for consultation of draft guideline. Draft guidelines will be published on websites of the EMEA, the European Commission or the European Pharmacopoeia and will normally be open for consultation for three to six months.

Collection and treatment of comments. The rapporteur and drafting group will consider comments received by the rapporteur, member states, other regulatory authorities, European industry associations, scientific societies, patient groups and other interested parties. Comments will be published online unless they are commercially confidential or the author has objected to their publication. The EMEA may also convene meetings in response to "specific justified concerns" or with interested persons on a concept paper.

Preparing the final version. Comments received will be considered.

Adoption of final guideline. Depending on the type of guideline, either the EC or the relevant EMEA committee will adopt the final guideline and publish it online.

Implementation. Guidelines are generally implemented six months after they are adopted. They are rarely applied retrospectively to products already on sale.

Training. The EMEA will train officials in member states to ensure uniform application.

Maintaining and revising guidelines. Guidelines will usually be reviewed after five years and in some cases earlier. The EMEA welcomes suggestions on this issue. ▮

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