

New Zealand and to overseas regulatory authorities. Authorities in Holland, Germany and Switzerland have certified that the product complies with environmental regulations and poses no special risks for man and the environment.

### So, what of the future?

The only option for the importer to re-enter the market before the end of the moratorium was to apply to the MoE for an exemption from the moratorium so an application can be made under the HSNO Act. Procedures for applications for exemptions from the moratorium made in accordance with the HSNO Act for field-testing of GMOs have been published. However, there have been no such provisions for exemptions for release of GMOs, as would be necessary in the case of Orochol Berna.

On 9 July 2000, an application was made to the Minister for the Environment

for such an exemption. Not surprisingly, the application was declined on the basis that a GMO release would divert attention from, undermine and pre-empt the Royal Commission. If, however, exemption from the moratorium was granted, an application could be lodged under the HSNO Act, which brings further difficulties. The process for approval of release of GMOs involves public consultation whereby the application is advertised and the public is invited to make written or oral submissions. There is also a special requirement for consultation with the indigenous Maori communities. As New Zealand Government departments operate a user-pays philosophy, the costs of the process are charged to the applicant, including the public consultation. We have received estimates from reliable sources that, for an application such as for Orochol Berna, the charges could be NZ\$50,000–350,000

(US\$22,500–157,500). Clearly, the importer and the manufacturers of Orochol Berna [who have already paid NZ\$15,300 (US\$6,900) in MoH fees] will not be enamoured with paying these sums for a low-sales niche medicine. This begs the question of what is the future for medicines that contain GMOs.

With ongoing advances in scientific research, we are surely going to increasingly see similar situations. In the short term, the moratorium should ensure that there will be no new such medicines introduced in New Zealand. In the longer term, will companies bother to register them in New Zealand when faced with huge compliance costs for a small market financial return? The crunch will come when the medicine is a life-saving vaccine for AIDS or cancer. Perhaps then we will see an effective pro-medicine lobby become active in New Zealand.

### What do you think the impact of the human genome sequence will be on drug discovery?

Have you had any experiences of data-mining the draft sequence, successful or otherwise?

Do you have comparable experiences of data-mining genome sequences from other species?

Please send your comments to Dr Rebecca Lawrence, News & Features Editor, *Drug Discovery Today*,  
e-mail: Rebecca.Lawrence@current-trends.com

Publication of letters is subject to editorial discretion.

### What does the human genome sequence mean to you?

For a thorough and independent analysis of the meaning and importance of the February publications of the draft human genome sequences, visit <http://news.bmn.com/hmsbeagle/96/notes/feature3>.

To mark the importance of the event, we are pre-publishing all the articles for *Drug Discovery Today* and the *Trends* journals on these publications in our free, online magazine, *HMS Beagle*. You cannot afford to miss these up-to-the-minute commentaries, opinions and updates, written by leading players from across the whole of biology. And they're free!