Language of science

French plans

The French government's campaign to re-establish French as a language of science is under severe stress — as thousands of foreign scientists descend on France for the 1982 conference season, attracted by the climate, the food and wine and, of course, the science. But these scientists mostly wish to speak English, not French, and there are not enough technical translaters to go round (nor money to pay them.)

Breaking point came a couple of weeks ago at the 21st international conference on high energy physics in Paris, where even the French spoke English.

Government determination to push on with the language programme is unbowed. But there has been a shift of emphasis from the tone of the circular sent out to researchers last September, which spoke of the need for French scientists to make presentations "in our language". For at the high energy conference participants were faced with a questionnaire in four languages (French, German, English and Spanish) asking them what they thought of simultaneous translation, multilingual posters and other means of dealing with the language barrier. The point is that the government is now supporting not just French as a language of science, but also Italian, Russian, Japanese, Spanish, Arabic, Chinese and the rest. "We will do all we can to demolish the monopoly of English", said the programme director.

The objection to English is that — outside Anglophone countries — it leads to the creation of an artificial barrier between those scientists who can cope easily with the language and those who cannot, so that English is used as a matter of status and hence of isolation of one group from another. English thus militates against "democracy" in French science. Moreover, in France the government has taken an overriding interest in all means of increasing communication between scientists and industry, and this "snobbish" division is seen as a real barrier to industrial development.

Government determination, however, is not enough. Money is also required. To provide simultaneous translation for a number of languages at a major conference is expensive — about FF350,000 (£30,000) for a conference of 1,500–3,000 participants for three or four days, estimates MIDIST, the Mission Interministerielle de l'Information Scientifique et Technique in which the "French as a language of science" programme is based. Short of the necessary wherewithal, and of technically-trained translators who can deal with immunology on the one hand or high-energy physics on the other, MIDIST this year is resorting to experiments on means cheaper than simultaneous translation.

For a total cost of FF600,000 at 20 conferences over the next couple of months, MIDIST will therefore try out:

- Simultaneous translation at plenary sessions, but not at working groups, which would be divided by subject and language.
- Distribution of a typed resumé of presentations in various languages.
- Bilingual transparencies, to be prepared before each talk.
- Paragraphy-by-paragraph translation of a talk by a bilingual colleague.
- The résumé on request, by a participant, of the essential points of a talk in the language requested.

The results of these experiments will be tested in part by questionnaire, and may result in more positive action during the conference season of 1983. **Robert Walgate**

Astronomer on fast

Patras, Greece

Professor Leonid Ozernoi of the P.N. Lebedev Physical Institute in Moscow began a hunger strike on 17 August in the face of the refusal of the Soviet authorities to grant him and his family visas for emigration to the United States. His case was being widely publicized at the General Assembly of the International Astronomical Union at Patras, Greece which finishes on 26 August.

Professor Ozernoi is well-known for his work in high-energy astrophysics including theoretical studies of processes in quasars and the nuclei of active galaxies. He applied for emigration in June 1979. Following the application, his wife lost her job as a sociologist and has since been unable to obtain another postion; he was barred from attending international conferences, removed from the board of *Letters to the Astronomical Journal of the USSR* and prevented from teaching. A paper of his was omitted from a book for which it was scheduled. Nearly 2½ years after applying to leave the country he was refused, his departure being "considered inexpedient at this time".

The Harvard-Smithsonian Centre for Astrophysics has invited Professor Ozernoi to work there, while the executive committee of the International Astronomical Union (IAU) will be considering whether or not to become involved officially at its next meeting in September.

A petition on behalf of Professor Ozernoi was cirulated at the IAU Assembly. Addressed to E.R. Mustel, Chairman of the Astronomical Council of the USSR Academy of Sciences, it also concerned Dr Alpert of the Institute of Terrestrial Magnetism Radio Research and the Ionosphere of the USSR Academy of Sciences, who has experienced demotion and restrictions on his work since his application for exit in 1975.

Philip Campbell

Drug promotion

FDA steps in

Washington

"A new choice for freedom from arthritis pain . . . Coming soon from Geigy."

This advertisement, accompanied by a colour illustration of a dove flying from a pair of outstretched hands, appeared in medical journals last autumn. At first glance, it seemed much like the many other eye-catching advertising pieces that the drug companies invest in so heavily to promote their wares in their highly competitive business. The strange thing about this advertisement, though, is that nowhere is the name of the drug mentioned. In fact, the drug had not yet received approval from the Food and Drug Administration (FDA).

Over the past year or so, this tactic and others for the pre-approval promotion of drugs have become increasingly common. Recently, FDA has been trying to do something about it.

FDA has broad powers under the federal drug laws to regulate the labelling of prescription drugs it has approved. By extension, this has been applied to advertising and other promotional literature. Any advertisement for a prescription drug must, for instance, include complete information on side effects, precautions and proper dosage. FDA also scrutinizes headlines and claims made in promotional material for accuracy and proper balance. A false or misleading promotion can render a drug "misbranded" and liable for seizure — a remedy FDA has occasionally used.

FDA regulations also prohibit the promotion of a drug's safety or usefulness before approval, since it is the safety and usefulness that FDA is attempting to determine in its review of a new drug application. But what if the drug's name is not mentioned in pre-approval advertising? That was apparently what the drug companies asked themselves; and thus a loophole was opened.

Possibly the most effective of these pre-approval advertisements are of the variety shown opposite. A graphic motif is introduced in the pre-approval advertisement, which is carried over to the post-approval — and, the advertiser hopes, the favourable first impression is carried over as well.

No warnings, precautions or contraindications encumber the pre-approval advertisements. But neither does the drug's name, and that puts FDA in an awkward position. "Without the mention of a drug product, it becomes difficult for us to say that is an advertisement" under FDA regulations, says Kenneth Feather, acting chief of FDA's drug advertising regulation branch.

Now the agency hopes to set limits on pre-approval advertisments. Last month, FDA issued a list of "recommendations" aimed to stop what it sees as infringements of the spirit of the law.

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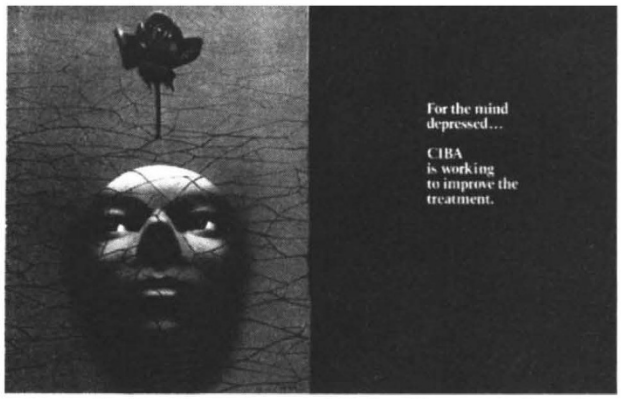

An impressionistic pre-launch . . .

In particular, the agency said, it will object to any advertisements that "make claims of safety and efficacy even if the new drug is not specified". On the other hand, if the name is specified, FDA says, advertising copy may not suggest the drug's indications, uses, safety or effectiveness, nor may any other advertisements or even the graphics that appear. In other words, the advertisement can say only "Fribulate, coming soon from Wonder Drugs, Inc.".

Pre-approval advertisements such as that shown here for Ciba's Ludiomil fall in a middle ground. The FDA says they are in general acceptable, but the dividing line is fine.

A case that came nearer to that line was Marion Laboratories' pre-approval campaign for Carafate, an antiulcer drug. The advertisements proclaimed the new, unnamed drug "a new era in ulcer therapy", a claim that FDA might well take exception to if it appeared in post-approval advertisements naming the drug.

Another loophole that concerns FDA is pre-approval promotion of drugs at scientific meetings. The FDA regulations specifically exempt seminars and scientific publications from its ban on representing a drug as "safe or useful" prior to approval; this is to allow a full exchange of scientific information concerning the drug. But according to Kenneth Feather of FDA, some firms have been stretching their interpretation of this exemption. He says he has seen several "scientific exhibits" at meetings that had all the hallmarks of promotional exhibits of the "flashing lights variety".

At the recent Pan-American Congress of Rheumatology, for example, Lederle Laboratories, had an exhibit which offered to visitors who stopped by free computer photographs along with a flyer with the headline "Fenbufen: a highly effective non-steroidal anti-infammatory drug with an unsually low incidence of serious GI complications". According to a letter that Feather sent Lederle, the exhibit was promoting Fenbufen, which the FDA has not yet approved for sale in the United States, although it is sold elsewhere.

After FDA objected, Lederle issued a statement that it "regarded the congress as an international meeting" and that "since requirements and practices differ from country to country . . . it does not appear equitable to adhere to those of any single country". FDA officials say, however, that it is nothing new for US laws to apply within the United States to US companies.

A similar incident occurred last year at the American Rheumatism Association meeting in Boston, where Pfizer Pharmaceuticals showed a film promoting Piroxicam, an anti-arthritis drug not yet approved. FDA said that the film hardly qualified as a "scientific exchange" since it was shown at a cocktail and buffet reception sponsored by Pfizer and that there was virtually no scientific discussion. According to FDA, the only question from the audience following the screening was, "When will the drug be available?"

FDA's recourse in these cases is unclear. They may order the companies to stop an advertisement or not to show a film again, but this, says Feather, is "shutting the barn door after the horse has bolted", since most of these pre-approval promotions are designed to be one-shot campaigns. And the remedies available after a drug is on the market, such as seizure, do not apply beforehand.

The recent Oraflex case, though, may cast a chill over the industry's own eagerness to pursue aggressive promotional campaigns. In late July, shortly before sales of Oraflex were suspended following reports of 61 deaths among users in Britain, FDA notified Lilly that a press kit prepared for Oraflex contained false or misleading statements. FDA said it seriously understated the drug's side effects and implied that Oraflex had a unique ability to fight the underlying disease in arthritis patients. In fact, FDA says, Oraflex is just another non-steroidal anti-inflammatory agent, and any claims about its disease-fighting ability are based solely on speculative inferences from animal studies.

After such a hard sell, the backlash that came when the reports of adverse effects started accumulating was all the greater. If the drug is ever cleared for sale again, FDA will probably require stiffer labelling designed to counter the false impression that Lilly's press campaign created.

FDA officials have raised the spectre of stiffer labelling requirements to counter pre-approval claims as well, a threat that will probably weigh heavily in the industry's decisions on future promotions.

Stephen Budiansky

. . . . succeeded by the complete story — and a name