From Europe

EMEA Boast 36 Products in 26 Months

Thirty-six positive opinions for human medicinal products leading to the granting of 27 Community Marketing Authorisations by the European Commission have taken place in the 27 months since The European Agency for the Evaluation of Medicinal Products (EMEA) set up business (Table 1).

Table 1.

Product	Therapeutic area	Active time (days)	Clock-stop time (days)
Follitropin-alpha	For infertility	107	30
Interferon beta-1b	Immunostimulation, multiple sclerosis	138	55
Docetaxel	Cytostatic	100	93
Factor VIIa	Coagulation factor	210	80
Mycophenolate mofetil	Prevention of kidney transplant rejection	243	47
Toremifene	Treatment of certain breast tumours	240	50
Insulin lispro	Diabetes mellitus	245	81
Follitropin-beta	Infertility treatment	203	151
Stavudine	Secondline monotherapy of HIV infection	150	–
Riluzole	Amyo-trophic lateral sclerosis	161	41
Doxorubicin-HCl	AIDS-related Kaposi's sarcoma	222	150
Ibandronic acid	Hypercalcaemia of malignancy	203	52
Combined vaccine	Combination vaccine for hepatitis B, DPT	180	240
Lamivudne	Combination treatment of HIV	150	105
Arcitumomab	Diagnosis of colonic and rectal carcinoma	110	386
Antimelanoma antibody	Visualisation of cutaneous melanoma lesions	187	320
Reteplase	Thrombolytic therapy of acute myocardial infarction	204	83
Combined vaccine	Vaccine for immunisation against hepatitis A and B	197	83
Ritonavir	Combination treatment of HIV	69	–
Igovomab	Diagnosis of ovarian adenocarcinoma	154	363
Saquinavir	Treatment of zidovudine- exp. patients with advanced HIV disease	180	80
Olanzapine	Antipsychotic	198	56
Indinavir	Treatment of patients with AIDS	85	12
Topotecan	Ovary metastatic carcinoma	154	28

The agency also arbitrates where mutual recognition is not possible in the decentralised procedure. There have also been 80 completed mutual recognitions of national authorisations for human medicinal products with only three arbitrations.

A key element of the centralised procedure is the 210-day limit for evaluation of applications. "Despite start-up difficulties, the opinions have been given broadly within this time frame, or even less," said the EMEA status report in November 1996. The times are displayed in Table 1. The "clock-stop time" is the time when evaluation stops because the manufacturers have been asked to provide more information.

Current work load estimates for this year show that over 45 new applications in the centralised procedure are expected for human and veterinary medicines.

EORTC Fellow Profiles: Dr Susan Keating, MD

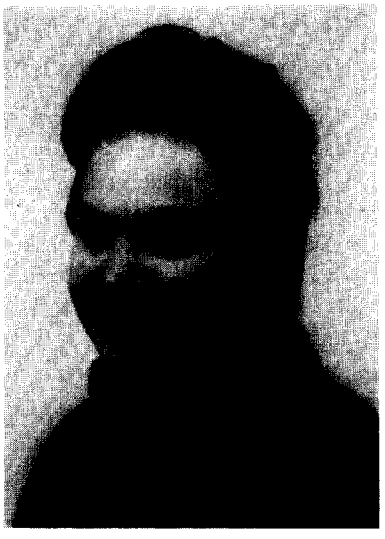
Dr Susan Keating, MD, is the first Medical Research Fellow of the Leukaemia Cooperative Group. She is attached to the EORTC Leukaemia Unit at the Data Centre in Brussels.

"I do various types of analysis in acute myeloid leukaemia trials using the existing data base of the Data Centre. I look at selection procedures for bone marrow transplants. The objective is to write a PhD thesis in Nijmegen University after 4 years of research on that subject," said Dr Keating.

She enjoys being part of the team producing clinical trials. "In the field of haematology, clinical trials are very important because we have not yet established what the best treatment for leukaemia patients is." She is grateful for the opportunities to attend major conferences and meet experts in haematology, the speciality that she intends to make her career in.

The EORTC have helped her formulate a job that gives her a balanced experience. "Unfortunately, I am out of patient contact because I am purely looking at the data that is sent to the centre, although I have a lot of contact with the doctors in charge of the patients. However, for one month every year I do go to a hospital involved in the research to work in the department, so I have full-time patient contact there. The experience I get there helps me to have a clearer picture of what is going on when I am working with the data."

At the beginning of 1999 Dr Keating will finish at the EORTC and will start her speciality training in internal medicine at St Radboud, the University Hospital in Nijmegen. This will consist of 6 years of training, after which she can specialise in haematology and pursue her practice and research in the field of haematological malignancies.



Dr Susan Keating,
First Medical Research Fellow of the Leukaemia Cooperative Group, attached to the EORTC Leukaemia Unit at the Data Centre.

From The Countries

FRANCE

Childhood Leukaemia and Radiation

French researchers have found convincing evidence for environmental radiation exposure, through recreation on beaches, causing childhood leukaemia in an area within 35 km radius of La Hague [1]. La Hague is one of the three nuclear reprocessing plants operating in the world on an industrial scale, the other two being in the U.K.

Dr Dominique Pobel and Dr Jean-Francois Viel of the Faculty of Medicine, Department of Public Health Biostatistics and Epidemiology Unit, Besançon, France, studied 27 cases of leukaemia diagnosed during the period 1978–1993 in under 25 year-olds and compared them with 192 matched controls.

The researchers write: "Increased trends were found for use of local beaches by mothers and children; the relative risk was 2.87 and 4.49 when categories were aggregated in two levels (more or less than once a month). Consumption of local fish and shellfish also showed an increased trend (relative risk 2.66) when categories were grouped at two levels (more or less than once a week). A relative risk of 1.18 a year was observed for length of residence in a granite-built house or in a granite area."

1. Pobel D, Viel J-F. Case–control study of leukaemia among young people near La Hague nuclear reprocessing plant: the environmental hypothesis revisited. *Br Med J* 1997, **314,** 101–106.