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TUAIRISC OIFIGIÚIL—*Neamhcheartaithe*

(OFFICIAL REPORT—*Unrevised*)

Tuesday, 7 *December* 1999.

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[Mr. S. Brennan.]

Oireachtas on 5 November 1999. In his report the inspector noted the continuing decline in the number of patients in psychiatric in-patient facilities from 5,192 at the end of 1997 to 5,101 at the end of 1998. There were almost 26,000 admissions to these facilities in 1998, of which approximately 6,000 were first admissions. The proportion of patients being admitted to general hospital units continued to increase and in 1998 accounted for approximately one third of all admissions. A further 15% were admitted to private hospitals. The number of involuntary admissions at approximately 2,500 remained constant at 10%.

A number of welcome developments were reported in many of the health board regions during 1998. Examples of these developments included the opening of new community residences in a number of the mental health services in the Eastern Health Board area, the purchase of the extensive day facility in Portlaoise town, the acquisition of further residential accommodation in the Clare mental health services and the opening of a refurbished residence in Strokestown, County Roscommon. Although the inspector acknowledged the significant progress that has been made in the provision of community mental health centres, day hospitals and community residential facilities for persons with mental health disorders, he stated that the rate of progress needs to be accelerated.

During 1998 the inspectorate published the document, ''Guidelines on Good Practice and Quality Assurance in Mental Health Services'', which stressed the areas of performance which were felt to be important for patient care and which needed improvement in some cases. The importance of patients' rights across a broad range of issues was stressed and the responsibility of mental health services in such matters was highlighted. The document was distributed to all mental health service providers.

Concern was expressed by the inspector at the lack of multidisciplinary teams in many mental health services, particularly in the area of psychology and social work services. The Department provided additional resources to health boards in 1999 to enable some improvements in paramedical support to be put in place. It was hoped to continue with this initiative as resources permitted. On 1 December 1999 the Minister for Health and Children announced that an additional £1.4 million was being allocated in 2000 to address this issue.

The problem of homeless mentally ill persons, particularly in large urban areas such as Dublin, was highlighted in the inspector's report. The Eastern Health Board had made efforts to address the problem by providing a residential unit for the homeless mentally ill in St. Brendan's Hospital and a new day service at Usher's Island in Dublin. The specialised outreach service for this group of people who work closely with voluntary agencies was in its infancy but was considered an essential service. In response to the inspector's concerns, additional resources have been allocated to the Eastern Health Board for 2000 to provide an additional specialist team for the homeless service.

On its publication, the Minister welcomed the inspector's report and acknowledged the crucial role the inspectorate, as an independent body, played in providing an accurate and detailed account of services in the mental health sector throughout the country. The Minister stressed the importance of publishing the inspector's reports as soon as possible in the year following inspection and said he had asked the inspectorate to finalise the 1999 report at the earliest possible date.

Following the publication of the inspector's report, controversy has arisen about the issue of sudden deaths occurring in the mental health services. In *The Irish Times* on 17 November one of its columnists drew attention to a statement contained in the report which noted the increasing number of sudden deaths in psychiatric hospitals, some of which were attributed to drug-related effects. From this statement the columnist drew some alarming conclusions. In the circumstances and in order to allay any anxiety that public comment on this matter may have caused to psychiatric patients or to their relatives or friends, the Inspector of Mental Hospitals felt it was important that his remarks be clarified.

In his response the inspector states that it has been known for a long time that persons suffering from psychiatric illness had a higher mortality and poorer life expectation than the general population. This raised mortality is due to a variety of causes of death, some the consequence of health damaging lifestyles associated with psychiatric disorder, such as cigarette smoking, alcohol or drug abuse, faulty dietary habits and self-induced or community determined social exclusion. These factors result in greater mortality from cardiovascular diseases, cancers and other less common causes of deaths. To these must be added sudden causes of death, such as suicide and deaths believed to be drug-related, both of which have increased in this country in recent years. These latter two causes of death are by statute reported to the Inspector of Mental Hospitals when they occur in psychiatric hospitals and units in general hospitals.

Since 1983 sudden deaths among patients suffering from psychiatric illness have increased from 23 in 1983 to 36 in 1998. Of those deemed on clinical grounds and by coroners to have been due to suicide, the numbers have gone from 15 in 1983 to 20 in 1998.

Acne Drug Inquiry.

Dr. Upton: Roaccutane, also known as Accu-

tane, isotretintoin or 3-cis retinoic acid, is well recognised as an effective therapy for treatment of severe acne. The precise mechanism of action of Roaccutane, however, is unknown. The licence for Roaccutane states that the drug is indicated for severe acne that is non-responsive to conventional therapy and is available as a hospital-only prescription. Therapeutic response to Roaccutane is usually excellent but, unfortunately, it is not free of side effects. It is, for example, a well known and potent teratogen. It also causes an increase in serum lipids. A Medline search of the scientific literature of Roaccutane therapy and its effects reveals a number of cases of psychological distress associated with the drug. Suicide and suicide attempts in association with Roaccutane therapy have also been reported.

Concerns about the safety of Roaccutane have been raised in the past and in May 1998, data provided by the manufacturers, Roche, revealed that a total of 170 cases of suicide, suicide attempt or suicide ideation were reported as associated with the drug. It also reported at the same time that, overall, 40,000 adverse drug reactions were known to it but the nature of these adverse drug reactions was not made available.

9 o'clock

In February 1998, the FDA issued a talk paper declaring new safety information regarding Roaccutane as a result of adverse event reports which the agency had received. Almost one year prior to the US revision, the French product label was altered in March 1997 to include suicide attempt as a side effect of Roaccutane. It reads, ''In rare cases neuropsychological problems have been recorded — behavioural difficulties, depression, convulsions and suicide attempts''. Revised warnings have been introduced in Ireland and Britain since 1998.

A number of scientific papers have been published on the association between Roaccutane and depression. Lamberg in 1998 in the *Journal of the American Medical Association* published a paper entitled ''Acne drug depression warnings highlight the need for expert care''; Aubin *et al* in 1995 in *Clinical Experimental Dermatology* wrote an article entitled ''Massive isotretinoin intoxication'' and Scheimal *et al* in 1990, in the *Journal of the American Academy of Dermatology*, wrote an article entitled ''Acute depression from isotretinoin''. These are just some examples of the available scientific publications.

The position of the manufacturer of the drug, as of April 1999, remains that there is no scientific evidence of a link between Roaccutane, depression and suicide. It is worthy of note, however, that the British Government has granted legal aid to finance claims on civil actions against manufacturers in relation to psychiatric side effects of Roaccutane. This is likely to cost the British Government many millions in the financing of free legal fees, scientific studies and the availability of professional witnesses.

Is the Minister aware that Roaccutane may be purchased in Ireland over the Internet? This is the same drug that, according to the manufacturers, should be available on hospital-only prescription and available only for severe acne. It is deeply disturbing that this drug can be ordered in this fashion, effectively without any control. It should be noted, however, that Roaccutane purchased over the Internet did contain a list of side effects and special precautions, including the following: ''Behavioural disorders or seizures have been observed. In the post-marketing period a number of patients have reported depression, psychosis and, rarely, suicide ideation, suicide attempts and suicide. Of the patients reporting depression, some reported that the depression subsided with the discontinuation of the treatment and re-emerged on resumption of treatment''. This information is available with the product on sale in South Africa.

Will the Minister ensure that the Irish Medicines Board will have available from the manufacturers of the drug the full list of adverse drug reactions reports held on the Roche database, to show the number and nature of side effects reported to be caused by this drug? Will the Minister make this information available to me and to other persons with an interest in the side effects of the drug?

Will the Minister agree to set up an independent, scientific inquiry to review the side effects caused by Roaccutane, to interview users and their families who have experienced side effects from the use of the drug, to review the medical data, to report if present warnings should be significantly strengthened and to consider the introduction of some form of psychiatric monitoring of patients throughout treatment on Roaccutane?

Minister of State at the Department of Health and Children (Mr. Fahey): As the Deputy is aware, the Irish Medicines Board is the competent authority for the regulatory control of medicinal products in Ireland. Roaccutane (isotretinoin) is a vitamin A derivative used in the treatment of acne. In Ireland, it is authorised by the Irish Medicines Board for the treatment of severe acne that is unresponsive to other treatments, and its availability is limited in that it must be prescribed and its use monitored by a consultant dermatologist.

The Irish Medicines Board carried out a full review of the safety and efficacy of this product as part of the assessment of the renewal of the product authorisation in 1998 and also as a result of new safety information regarding the development of neuropsychiatric reactions, including depression and suicide.

The Deputy may be assured that the Irish Medicines Board has in the past monitored all

[Mr. Fahey.]
available data on Roaccutane and continues to do so, including reports of adverse reactions, which it reviews both internally with its experts and with the other European regulatory agencies. As a result of this, revised wording for inclusion in the prescribing information of the product outlining the current position regarding its use and warnings relating to the possible development of psychiatric reactions were agreed. The warnings refer to possible side effects, including depression, psychotic symptoms and of rare reports of suicide associated with Roaccutane. The revised warnings have been incorporated into the authorisation documents for the product and the company has circularised all physicians and pharmacists outlining the new warnings regarding the use of Roaccutane.

There is a legal responsibility on the company, as a condition of its product authorisation, that it keep a record of reports of adverse effects associated with the use of the product and that it furnish the Irish Medicines Board with copies of any such reports of which it has a record or of which it is aware. A further condition of the authorisation requires that the company should inform the board of any information received by it which might alter the validity of the data provided in support of the authorisation, or which would further the understanding of the substance or its effects or may alter the directions for the use of the product.

I am advised by the Irish Medicines Board that it currently understands that all information on Roaccutane, required under the conditions applicable to its product authorisation, has been made available to the board by the company. At the same time, the board has held on-going discussions with the company regarding its pharmocovigilance responsibilities — the monitoring and reporting of adverse reactions — and it continues to monitor the functioning of the company's pharmacovigilance unit.

In addition, and at the request of the Irish Medicines Board, the manufacturer has recently initiated a post-marketing surveillance programme to monitor all patient usage of Roaccutane in Ireland. All data collected during this surveillance programme will be reviewed and analysed by the board and further regulatory action will be taken, as required.

While I am aware of recent calls for an independent inquiry into the matter of adverse reactions to Roaccutane, I do not consider it necessary for me to establish or carry out any such inquiry into the matter at this stage, particularly as the Irish Medicines Board, an independent statutory body with a specific remit in this area, is already engaged in monitoring those adverse reactions reported to it.

I am satisfied that the Irish Medicines Board continues to actively monitor the safety profile of the product concerned and I am confident that the board will take any action that may be necessary having regard to the risk/benefit ratio of the product.

Fisheries (Amendment) Bill, 1999: Message from Select Committee.

An Leas-Cheann Comhairle: The Select Committee on Agriculture, Food and the Marine has completed its consideration of the Fisheries (Amendment) Bill, 1999 and has made amendments thereto.

Supplementary Estimates: Message from Select Committee.

An Leas-Cheann Comhairle: The Select Committee on Heritage and the Irish Language has completed its consideration of Votes 42 and 43 of the Supplementary Estimates for the service of the year ending on 31 December 1999.

The Dáil adjourned at 9.10 p.m. until 10.30 a.m. on Wednesday, 8 December 1999.