Calls for inquiry into acne drug

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European medicine watchdogs are reviewing the safety record of the anti-acne drug Roaccutane which has been linked to suicide and depression. The move comes as a consultant, Anthony Chu, of Hammersmith hospital, west London, has called for a commission into the prescribing of Roaccutane.

Campaigners alleging the drug is dangerous say checks, being made to harmonise information to patients and doctors across EU member states, do not go far enough. They want the drug withdrawn until manufacturers agree to help fund independent studies examining the risk of depression.

Families of patients allege dermatologists are persistently prescribing the drug for mild rather than severe acne, contrary to the prescribing rules, and are failing to conduct pregnancy tests, blood tests or psychiatric assessments.

Manufacturer Roche, whose product has been available in Britain for 20 years, insists there is "no causal link between Roaccutane and psychiatric events". The company said the European review had been triggered by the arrival of a potential rival generic drug made possible by the ending of the patent on Roaccutane. It said 13 million people had used the drug worldwide.

The government’s medicines control agency has been under pressure to review reported adverse reactions to the drug, which is known to be dangerous to women of child-bearing age because of the possibility of birth defects. There can be other side-effects, including dryness of skin and eyes, liver disorder and increased cholesterol levels.

British safety information on possible psychiatric reactions was strengthened nearly five years ago. Now the medicines agency is leading the review by the European committee for proprietary medicinal products "to ensure healthcare professionals and patients receive adequate and consistent information to aid the safe use of isotretinoin (Roaccutane)".

The agency said it was impossible to estimate the number of British patients who had received the drug. About 375,000 treatment courses might have been prescribed. There had been 1,259 reports involving 2,134 suspected adverse reactions. Of these, 277 were related to psychiatric disorders, including 33 reports of depression, 13 of suicide, and 10 of suicide attempts. Most patients reported to have committed suicide had a background of depression. In all, 24 deaths had been reported.

"It is important to note that these suspected adverse reactions are not necessarily caused by the drug," it said.

Dr Chu believes there is a causal relationship between the drug and depression, although studies to investigate it might be difficult and costly. "If there was an alternative, Roaccutane would be taken off the market. I think it is grossly overused. I often see patients who have been offered Roaccutane by other consultants. To use a drug which causes major problems when not necessary is not good medicine."

He was surprised by how many patients on Roaccutane said they felt low or depressed. "Acne is one of the most depressing conditions."

People might be depressed before going on Roaccutane but "if Roaccutane is working, why is not the depression lifting?" But many patients were treated successfully with Roaccutane. "I get people who send me Christmas cards saying ‘you have changed my life’."

David Chow, chairman of the Roaccutane Action Group UK, said: "We believe there is sufficient evidence to warrant a public inquiry, similar to the congressional hearing... in the US into the safety of a drug which has been associated with the deaths of many worldwide [240 suicides]."