

## France advises 30,000 to have breast implants removed

December 23 2011, by Veronique Martinache

France's health ministry Friday advised 30,000 women with breast implants made by French firm PIP to have them removed, saying that while there is no proven cancer risk the prostheses could rupture.

The government stressed there was no urgency but the advice will add to the concern of tens of thousands of other women around the world who have the same implants made from industrial rather than medical quality silicone.

Global police agency Interpol, meanwhile, issued a "red notice" seeking the arrest of Frenchman Jean-Claude Mas, the founder of PIP (Poly Implant Prosthese).

Women with PIP implants "do not have a higher risk of cancer than women who have implants manufactured by other firms," a health ministry statement said, but there were "well-established risks of ruptures."

French Health Minister Xavier Bertrand called for their removal as a "precautionary measure".

State-supported medical insurance will pay for the implants' removal, but only women who received the implants as part of reconstructive surgery, rather than for aesthetic reasons, will have new implants paid for.



The total cost for social security is estimated at around 60 million euros (\$78 million).

The French government advised women with PIP implants to contact their doctor and "a precautionary removal will be offered, even without clinical signs of deterioration of the implant."

Any woman who declines the removal must have a breast scan every six months, the ministry added.

The now-bankrupt PIP was shut down and its products banned in April last year after it was revealed to have been using non-authorised silicone gel that caused abnormally high implant rupture rates.

Facing financial difficulties, the company, once the world's third-largest producer of silicone implants, had replaced the medical-grade silicone in its implants with industrial-strength material.

Documents obtained by AFP showed that tens of thousands of women in more than 65 countries, mainly in South America and western Europe, received implants produced by PIP.

In Britain, where 42,000 women have PIP implants, authorities said the prostheses posed no notable risk, while elsewhere in Europe authorities called for the implants to be dealt with on a case-by-case basis.

"While we respect the French government's decision, no other country is taking similar steps because we currently have no evidence to support it," said Britain's Chief Medical Officer Sally Davies.

Germany's BFARM health agency recommended women be evaluated by doctors, while only Belgium echoed the call for preventive removals.



"We've discussed the possibility of a cancer risk a lot recently and there's no proof," BFARM agency spokesman Maik Pommer said, with 19 cases of ruptured implants in Germany since 2004.

Switzerland's health agency said it did not recommend removal of the implants for some 280 Swiss women concerned.

"Every removal is an operation that involves risks," said Swissmedic spokesman Daniel Luethi. "According to our figures, the risk of a secondary effect from these implants is less than one percent."

Spain and Finland recommended women get checkups, and Austrian Health Minister Alois Stoeger said health agency AGES had "guaranteed that doctors who used these implants have contacted their patients and checked their state of health".

In Brazil, where 25,000 women had PIP implants, the country's National Health Surveillance Agency (ANVISA) "has not yet made a recommendation," a spokesman told AFP.

But Belgium's Drugs and Health Products Agency said women should discuss the preventive removal of their implants with their surgeons, "even without clinical signs of deterioration".

Senior French health ministry official Jean-Yves Grall denied the government was being excessively cautious, insisting the recommendation was justified by a five-percent rupture rate.

Prosecutors in Marseille, near PIP's home base of Seyne-sur-Mer, have received more than 2,000 complaints from Frenchwomen who received the implants, and have opened a criminal investigation into the firm.

Interpol lists Mas on its website as being sought in Costa Rica for



offences concerning "life and health".

Yves Haddad, a lawyer for the 72-year-old, told AFP his client was prepared to face prosecution, adding: "For the moment there is no evidence that the product can cause illness."

According to PIP's 2010 bankruptcy filing in the French city of Toulon, it had exported 84 percent of its annual production of 100,000 implants.

Between 2007 and 2009, 50 to 58 percent of its exports went to South American countries including Venezuela, Brazil, Colombia and Argentina, the filing showed.

In the same period, 27 to 28 percent of exports went to western European nations including Britain, Spain, Italy and Germany.

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