Event Information Site
for IHR National Focal Points

Potential public health hazard related to sub-standard medical devices (Breast implants).

Breast implants containing non approved silicone and potential higher rates of product rupture.

The purpose of this communication is to share information on a potential public health hazard associated with the implantation of certain silicone-based breast implants, and to suggest appropriate actions.

Concerned medical devices: Poly Implant Prothèse company (PIP) silicone breast implants, M-Implants (Rofil).

Early indications are that these medical devices (breast implants) have been widely distributed internationally and implanted in persons from many countries.

This note relates to the breast implant products that are under investigation. The concerns are related to the use of non-approved silicone material potentially resulting in higher rate of breast implant rupture. The consequences of these two outcomes are under evaluation.

The audience for this communication includes public health authorities, national regulatory authorities, health service providers and affected persons and other stakeholders.

Actions to be considered:

a. To determine whether and how many of these products have been imported and implanted.

b. To determine if breast implants containing substandard silicones are still available in the market, and if so to recall the product from the market and suspend distribution and use.

c. To take into consideration that implantation may have been carried out abroad.

d. To strengthen national regulations, including post market surveillance and adverse event reporting for medical devices.

e. To share surveillance data for analysis in order to better characterize the issue.

f. To develop a system to follow up and to communicate appropriately with affected patients.

g. Persons with PIP or M-Implant prostheses should consult their doctor or surgeon if they suspect rupture, have pain or inflammation or any other concerns.

h. Affected persons and physicians should take note of their national health authority recommendations and act accordingly.

Please find some links below for information provided by national health authorities.

Background:

In March 2010, Poly Implant Prosthèse, (PIP) silicone implants were withdrawn from the EU market following an observed increase in implant ruptures and confirmation of the use of substandard silicone in the manufacture of the implants by French regulator AFSSAPS (Agence Française de Sécurité Sanitaire des Produits de Santé) (http://www.afssaps.fr). Regulatory authorities in other jurisdictions were also notified leading to product withdrawal from a number of non EU countries. PIP implants have also been sold under the trade name of M-Implants and in April 2010 the Dutch Health Care Inspectorate prohibited all trade and usage of both products in The Netherlands.

On 23 December 2011, after a review of data by an expert committee, the French authorities published a recommendation that French residents with PIP breast implants should consider having these removed as a preventive measure. Following this, other national health authorities have issued their own recommendations that have ranged from preventive removal of PIP silicone breast implants, to close monitoring and follow up of persons with these implants.

PIP and M-Implants silicone breast prostheses have been distributed to many countries around

the world. Both standard and substandard silicone has been used to produce PIP implants.

Adverse events of approved breast implants include implant rupture and leakage. While the rupture rate of PIP prostheses was observed to be higher than expected in France, rates reported by other national authorities vary.

Testing of PIP implants carried out by AFSSAPS found that the quality of implants varied, therefore increasing the risk of rupture. AFSSAPS also found that the gel containing non approved silicone was irritant to tissue, and when leaking could give rise to inflammation and pain.

There are unconfirmed media reports about the use of substandard silicone in other PIP prosthetic products.

More information is needed about the risks associated with these implants and how they compare with other implants on the market, and on product distribution, use and surveillance.

Access to safe and effective medical devices is a public health imperative. Perceived risks and benefits associated with medical devices can change over time and it is a WHO priority to monitor and communicate health trends as they develop. Safety from preventable harm by healthcare is a WHO priority. WHO encourages countries to improve patients' safety and the quality of health care.

Specific recommendations by national regulatory authorities, can be found at the following websites:

Argentina
http://www.anmat.gov.ar/principal.asp

Australia
http://www.tga.gov.au/safety/alerts-device-breast-implants-120104.htm

Austria
http://www.basg.gv.at/bundesamt-fuer-sicherheit-im-gesundheitswesen-basg/

Belgium
http://www.fagg-afmps.be/en/news/

Brazil
http://portal.anvisa.gov.br/wps/portal/anvisa/anvisa/home

Chile
http://www.ispch.cl/

China
http://www.sda.gov.cn/WS01/CL0051/68312.html

Colombia
http://www.minproteccionsocial.gov.co/Paginas/default.aspx

Costa Rica
http://portal.ccss.sa.cr/portal/page/portal/Portal

Cuba
http://www.eqmed.sld.cu/Alertas%202010.html

Czech Republic
http://www.mzcr.cz/obsah/2012_2501_1.html

Denmark
http://laegemiddelstyrelsen.dk/en/

Ecuador
http://www.msp.gob.ec/index.php/Boletines-de-Prensa/ministerio-de-salud-publica-frente-a-alerta-de-implantes-mamarios-pip.html

Estonia
http://www.terviseamet.ee/info/uudised.html

France
http://www.afssaps.fr/
http://www.sante.gouv.fr
http://www.afssaps.fr/Dossiers-thematiques/Implants-mammaires-PIP-pre-remplis-de-gel-de-silicone/Actualite-Nouvelles-recommandations-de-suivi-des-femmes-porteuses-d-implants-PIP/(offset)/0

Germany

http://www.bfarm.de/EN/medDev/news/functions/news-node.html

Hungary
http://www.eekh.hu/letoltesek/pip.pdf

Italy
http://www.salute.gov.it/dettaglio/dettaglioNews.jsp?id=1830&tipo=new

Ireland
http://www.imb.ie/

Japan
http://www.mhlw.go.jp/stf/houdou/2r9852000001zco0.html

Malaysia
www.mdb.gov.my

Mexico
http://www.cofepris.gob.mx/Paginas/Inicio.aspx

Netherlands
http://www.igz.nl/

New Zealand
http://www.medsafe.govt.nz/consumers/devices/silicon.asp

Peru
http://www.digemid.minsa.gob.pe/alertas/index.htm

Portugal
http://www.dgs.pt/?f=3&id=21506

Spain
http://www.msps.es/gabinetePrensa/home.jsp

United Kingdom
http://www.mhra.gov.uk/NewsCentre/CON137888