PIP Action Campaign's public ID number in the Transparency Register is: 994077824122-21

Mr Salvatore D'Acunto
Head of Unit for health technology and Cosmetics
European Commission
DG Grow

Good Afternoon Mr D'Acunto

Urgent RECALL: Trigger Article 8, safeguarding 93/42/EEC NON-COMPLIANT Breast Implants

Failure of National Competent Authorities & Notified Bodies to comply with Medical Devices Regulations

We are writing to you today to formally request the urgent implementation of Safeguard Article 8 of the MDD 93/42/EE, recalling all textured implants throughout the EU with immediate effect.

1. Evidence ANSM

- In July 2016, the ANSM reported biocompatibility data, part of the technical file for CE licensing, is relying on data supplied by manufacturers based exclusively on smooth implants
- The known carcinogenic effect of textured implants, including PIP implants, is now well documented
- The ANSM has given manufacturers 12 months to supply this data.

http://www.ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Biocompatibilite-des-implants-mammaires-a-surface-texturee-Resultats-des-investigations-Point-d-Information

"Almost all of the arguments put forward by the manufacturers were considered to be unacceptable for justifying the lack of biocompatibility tests."
http://ansm.sante.fr/var/ansm_site/storage/original/application/29c2a7ac5134600ba2724aa07129d559.pdf

The effect of the missing data is NON-COMPLIANCE , since there is no biocompatibility data available on textured implants, patient safety is compromised.

2. Evidence RIVM

In October 2016, the RIVM produced a report based on an unannounced inspection of the 'technical files' of 10 manufacturers of breast implants available in the Netherlands.
The report findings show 10 from 10 manufacturer's technical files were incomplete or inaccurate to a greater or lesser degree.

Technical files must be complete and accurate to ensure compliance with the essential requirements of the MDD 93/42/EEC and to ensure patient safety. The effect of the incomplete and inaccurate technical files is NON-COMPLIANCE, and patient safety is compromised.
http://www.rivm.nl/dsresource?objectid=1fc2c7e5-b393-464e-a60d-af6417e3c204&type=org&disposition=inline

3. Evidence MHRA
In November 2016, the MHRA responded to a Freedom of Information request regarding the number of reported cases of BIA-ALCL in the UK. At the time of the MHRA Medical Devices Alert 10 July 2014, the UK regulator had notified 3 UK cases.

Update: 22 November 2016
"To date MHRA has received 21 reports of BIA-ALCL associated with all makes and models of breast implants in the UK. In 2 of these there was a patient death reported. Of these 21 reports, 1 was reported in a woman implanted with PIP breast implants.

It is important to note that inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the implant. Therefore, reports submitted to MHRA may be adverse reactions to the implant or they may be purely coincidental events that would have occurred anyway in the absence of the device (e.g. events due to underlying medical conditions). The number of reports received, therefore, is not a summary of known or proven adverse reactions to the implant, and must not be interpreted and used as such."

This wording demonstrates regulatory reluctance to be concerned by the 600% increase, in reported cases of IARC recognised BIA-ALCL, in the UK since 2014. As well as the lack of responsible information to clinics, hospitals, drs and patients.

https://www.gov.uk/drug-device-alerts/medical-device-alert-breast-implants-report-cases-of-anaplastic-large-cell-lymphoma-alcl

In January 2012 The Telegraph published an article quoting the editor of the Lancet, Richard Horton:

"The breast implant scandal was "an inevitable result" of "paralysis" at the healthcare regulator, according to the editor of The Lancet, who has accused it of having a "do nothing" attitude.

http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60070-1/fulltext

4. Evidence TGA

Expert advisory panel advice on association with anaplastic large cell lymphoma 20 December 2016

"Since our last safety communication, the TGA has been provided with additional data and is advising that 46 cases of breast implant-associated ALCL have now been confirmed in Australia, including 3 that resulted in death."

https://www.tga.gov.au/alert/breast-implants

5. Concerns are also being raised in the USA & Canada

"Patients with device-related illnesses are trapped in a web of difficult diagnoses, trouble finding care, and roadblocks to paying for treatment. Until knowledge of such problems becomes widespread, many doctors are skeptical that a device has caused harm. Far fewer physicians do procedures to remove and replace defective devices than install them. Health plans may deny coverage for such treatments, or require other treatments first, and force patients to turn to lengthy appeals even as they continue to be harmed by the device. ...All of this is on top of rising copays and deductibles, and lost time from work."

https://www.statnews.com/2016/12/21/medical-devices-safety-congress/

Few if any national registries or adverse event reporting procedures are contributing to our understanding of risk to patients. There is a lack of responsible information on risks or treatment for health professionals or for women who are sick or dying with implant related illness.

We are requesting immediate action by the European Commission, to insist that member states trigger

- Safeguard Article 8, 93/42/EEC on the basis of known non-compliance of class III medical devices. (i)
- Trigger Public Liability Insurance from Notified Bodies for women exposed to non-compliant implants Annex XI 6 93/42/EEC (ii)
- Initiate financial support, information, future, ongoing studies & monitoring of women and children exposed to non-compliant implants
- Moratorium on all textured breast implants subject to compliance
- Collective Redress for all women exposed to, injured and traumatised by fraudulent, non-compliant, toxic and carcinogenic PIP and or other non-compliant implants (iii)

i, ii COUNCIL DIRECTIVE 93/42/EEC and amendments http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG%3A1993L0042%3A20071011%3Aen%3APDF
iii European Parliament resolution of 2 February 2012 on 'Towards a Coherent European Approach to Collective Redress' http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2012-0021&language=EN

We intend to pursue the matter of known regulatory non-compliance of manufacturers by regulatory authorities and refer the matter to the courts seeking protection and compensation from the Civil Law Convention on Corruption Treaty No.174. https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/174

We shall make request for clarity from the European Courts on the interpretation of the regulations for non-compliant Class III surgically implanted medical devices, on the market bearing the CE mark. And to pursue our for urgent claim for redress due to women exposed to criminal, non-compliant PIP implants and to women with other brands of non-compliant implant, suffering harm and injury.

It has become clear to us that the inaction of the Regulatory Authorities, including national competent authorities and notified bodies, is the root cause of regulatory failure in the European Union.

We are aware of the value and economic importance of the breast implant market as well as the consequences for women of NON-COMPLIANT breast implants on the global market bearing a CE mark.

We therefore, urgently request, the European Commission acts immediately to (a) protect the health and safety of women with PIP and issue a recommendation to remove all PIP implants (in member states where removal has still not been recommended) so that public liability insurance can be put in place to help women: and, (b) immediately trigger Safeguarding Article 8 of the MDD 93/42/EEC to recall and place on moratorium all non-compliant breast implants,

pending provision and review of biocompatibility data and full and proper regulatory compliance.

Yours truly

Jan Spivey, Marie Robinson
On Behalf of Members of
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