



Scientific Committee on Health Environmental and Emerging Risks  
SCHEER

**SCIENTIFIC ADVICE ON**  
**Evaluation of the availability of new scientific information**  
**on the safety of PIP breast implants**



The SCHEER adopted this final Scientific Advice  
on 28 September 2017

## ABSTRACT

Following a request from the European Commission, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) hereby provides an inventory of new information available on the safety of Poly Implant Prothèse (PIP) silicone breast implants to evaluate whether an update of the 2014 SCENIHR Opinion on the safety of the PIP breast implants (2014 Opinion) is warranted.

In addition to conducting a literature review, a public call for scientific information was launched. The literature review showed that new information is available regarding the possible health effects of PIP breast implants, but this information is rather limited. Also, the public call for information did not result in the submission of scientific papers regarding health effects specific to PIP implants, but rather on breast implants in general. Therefore, on the basis of the new scientific information gathered, the SCHEER concludes that an update of the 2014 Opinion is not warranted.

New scientific information was found relating to the early and increased PIP implant rupture risk, which suggested that the risk was probably due to the low quality of the implant's shell as already reported in 2014 Opinion. Based on new data, the rupture rate of PIP silicone breast implants was calculated to about 23%, which is similar to the 25% - 30% rupture rate indicated in the 2014 Opinion.

**Keywords:** PIP breast implants, implant failure, safety evaluation, toxicity, silicone, risk assessment

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This Scientific Advice has been subject to a commenting period of ten weeks after its initial publication (from 7 April until 15 June 2017). Comments received during this time were considered by the SCHEER.

The comments received were considered to be outside the scope of this advice as they were providing additional information on possible adverse effects of SBI in general.

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## 1 MANDATE

### 1.1 BACKGROUND

#### A. The safety of the PIP silicone breast implants

Over many years, the PIP manufacturer fraudulently made use of industrial silicone instead of the approved medical grade silicone in many of the breast implants produced. Investigations were triggered by an unusually high short-term breast implant rupture rate. The product was thereafter withdrawn from the EU market.

Following this fraud, SCHENIR was requested to provide two scientific Opinions on the safety of the PIP silicone breast implants. The first one, a rapid scientific Opinion, was adopted by SCENIHR on 1 February 2012<sup>1</sup>. This Opinion was updated by a second one, adopted on 12 May 2014.<sup>2</sup>

Given the importance of the matter, the Commission relevant services, DG GROW and DG SANTE, are committed to monitoring the publication of new and valid scientific information and facilitating possible update of the 2014 Opinion on the PIP silicone breast implants in the light of such new scientific data.

Besides its regular consultation of the National Competent Authorities, DG GROW and DG SANTE recognise the need for a formal scientific evaluation of the current availability of new and relevant information.

This need is also highlighted in the remarks of the European Ombudsman's Decision in case 174/2015/FOR on the Commission's alleged failure to investigate conflicts of interests relating to the adoption of a report on the safety of removing PIP breast implants: "*The Commission should continue to evaluate new scientific data relating to the safety of PIP implants.*"<sup>3</sup>

The investigation into the availability of new scientific data that would warrant an eventual update of the May 2014 Opinion on the safety of the PIP breast implants should take into account all the necessary fields and especially those covered by the previous Opinion, such as the physiochemical properties of PIP implants, their toxicology, the clinical impact and recommendations.

#### B. Possible association between breast implants in general and anaplastic large cell lymphoma

Anaplastic large cell lymphoma (ALCL) is a very rare type of lymphoma. ALCL is not a cancer of the breast tissue and the prognosis of the disease is generally favourable. A possible association between breast implants and ALCL is under scrutiny in the European Union and at international level by regulators and scientists.

According to an estimation<sup>4</sup> of the US-Food Drug Administration, in 2011 there were between 100-250 known cases of ALCL in women with breast implants out of an

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<sup>1</sup> [http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_o\\_034.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_034.pdf)

<sup>2</sup> [http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_o\\_043.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_043.pdf)

<sup>3</sup> <http://www.ombudsman.europa.eu/cases/decision.faces/en/61195/html.bookmark>

<sup>4</sup> <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>

estimated number of 5 to 10 million women who have received breast implants worldwide.

The information to date suggests that women with breast implants may have a very low but increased risk of developing ALCL, while the rarity of the disease makes it difficult to establish a definite causal relationship (Center for Devices and Radiological Health U.S. Food and Drug Administration).<sup>5</sup>

Given that this suspected association between breast implants and ALCL appears to be an emerging risk, the SCHEER should determine whether there is enough scientific information available to allow for a full risk assessment of the matter. The existence of information on a specific association with PIP silicone breast implants should also be investigated.

## **1.2 MEANS OF ACHIEVING THE GOALS**

In order to make a thorough collection of all the data on the two aforementioned issues, two actions were considered:

- 1) Holding a public call for data open to all stakeholders, and holding it open long enough to ensure that any information pertaining to the two topics may be submitted.
- 2) Conducting a review of the published scientific literature and of any other source of relevant data available on the two topics.

The relevant scientific information should be retained and should serve as the basis for the SCHEER to reply to the questions described in the terms of reference. Any rejection of acquired information should be justified. The Committee will decide if both topics may be addressed by one call for data and one scientific literature review at the same time or if separate processes need to be organised.

## **1.3 TERMS OF REFERENCE**

Following the assessment of the availability of the scientific information the SCHEER should:

- 1) Indicate whether there is sufficient new scientific information to warrant an update of the May 2014 Opinion on the safety of the PIP breast implants
- 2) Provide a formal Advice on the state of scientific knowledge regarding a possible connection between breast implants and anaplastic large cell lymphoma

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<sup>5</sup> <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm>

## **2 CONCLUSIONS**

Following the request received from the European Commission, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) performed a literature review and launched a call for information to gather new scientific information related to the safety of the PIP breast implants, which became available after the publication of the Opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants - Update of the Opinion of February 2012<sup>6</sup> (2014 Opinion).

Based on the analysis of the literature review, it is concluded that insufficient new information is available to warrant an update of the 2014 Opinion. New scientific information was found relating to the early and increased PIP implant rupture risk, which suggested that the risk was probably due to the low quality of the implant's shell as already reported in 2014 Opinion. The calculation of the rupture rate based on PIP explants indicates a rupture rate of PIP breast implants of approximately 23%, similar to the 25% - 30% rupture rate presented in the 2014 Opinion.

The call for information did not result in the submission of any scientific data and/or information regarding health effects specific to PIP breast implants. A lot of information was submitted concerning breast implants in general but not focusing specifically on PIP breast implants. This information was considered not relevant for the evaluation of the availability of new scientific data on the safety of PIP breast implants.

In conclusion, the new scientific information gathered, both via the call for information and via the literature review, was considered insufficient and an update of the 2014 Opinion is therefore unwarranted.

## **3 MINORITY OPINION**

None

## **4 DATA AND METHODOLOGY**

### **4.1 Introduction**

This document provides an inventory of the information on the safety of PIP silicone breast implants which became available after the publication of 2014 Opinion, to evaluate whether an update of the 2014 Opinion is warranted.

This Scientific Advice answers question one of the 'Terms of Reference' of the mandate.

The state of scientific knowledge regarding a possible connection between breast implants and anaplastic large cell lymphoma is presented in a separate document.

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<sup>6</sup> [http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_o\\_043.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_043.pdf)



## 4.2 Methodology

New scientific information on the possible adverse effects of PIP breast implants was obtained by two independent methods: a literature search and an open call for information. All submitted information was considered but conclusions were based exclusively on peer-reviewed scientific papers.

The literature search was conducted to retrieve scientific literature available on PIP breast implants. The major search terms, PIP and breast implants were used in combination with additional terms listed below. Papers were selected based on the search terms using PubMed and Find-eR (a tool for searching multiple library resources in one interface which includes the European Commission Library collections, plus millions of online full-text journal articles and eBooks). The publication period of the scientific papers covered was from January 2012 to August 2016.

Literature search using PubMed resulted in 366 entries. Table 1 below shows the key words used and number of papers obtained. Duplicate articles were obtained because the search included more key words.

**Table 1- Results from PubMed**

Key words including MeSH terms (PubMed) <sup>7</sup>	No of hits
("Phys Perspect"[Journal] OR "pip"[All Fields]) AND (("silicones"[MeSH Terms] OR "silicones"[All Fields] OR "silicone"[All Fields]) AND ("breast implants"[MeSH Terms] OR "breast"[All Fields] AND "implants"[All Fields]) OR "breast implants"[All Fields]))	59
(Poly[All Fields] AND Implant[All Fields] AND Prothese[All Fields]) AND implants[All Fields]	51
"PIP" (All Fields) AND ("breast implants"[MeSH Terms] OR ("breast"[All Fields] AND "implants"[All Fields]) OR "breast implants"[All Fields])) AND ("infection"[MeSH Terms] OR "infection"[All Fields])	13
(PIP) breast implant AND cancer	81
(PIP) AND breast implants AND infection	13
(PIP) AND breast implants AND inflammation	12
(PIP) AND breast implants AND rupture	36
(PIP) AND breast implants AND risk assessment	11
(PIP) AND leakage AND breast implants	8
(PIP) AND breast implants AND safety of implants	38
(PIP) AND breast implants AND silicone gel	44

Table 2 below shows the key words used and number of papers obtained using Find-eR, a tool for searching multiple library resources in one interface. It includes the European

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<sup>7</sup> MeSH (Medical Subject Headings) is the NLM controlled vocabulary thesaurus used for indexing articles for PubMed

Commission Library collections, plus online full-text journal articles and eBooks. Duplicate articles were obtained because the search included more key words. Literature search using FIND-eR resulted in 72 entries.

**Table 2- Results from FIND-eR**

<b>Key words</b>	<b>No of hits</b>
PIP AND Silicone Breast Implants	6
PIP AND Breast implants	9
PIP AND silicone implants	7
PIP and implants	13
PIP AND Cancer	5
(PIP) AND Inflammation	0
PIP AND Rupture	3
PIP AND breast implants	5
PIP and Anaplastic Large Cell Lymphoma	2
(PIP) AND breast implants AND risk assessment	3
(PIP) AND safety of implants	5
Breast implants AND safety of implants	12
(PIP) AND silicone gel	2

In addition, a call for information was launched by the European Commission to invite all interested parties to submit scientific information regarding the safety of PIP breast implants. The call for information was published on 14 June 2016 and closed on 4 September 2016. For on-going studies and research that were not completed by the deadline, the call remained open until 20 November 2016.

Among of all information received, the SCHEER considered only peer-reviewed papers focusing specifically on the safety of PIP breast implants.

## **5 ASSESSMENT**

### **5.1 Sources of information**

#### **5.1.1 Results from the literature review**

99 papers were obtained from PubMed and 10 publications from Find-eR. A table was prepared to facilitate the evaluation of the new scientific information collected (both via the literature review and via call for information), containing the following categories:

- Identification number
- Title
- Authors

- Name of the journal
- Year of publication
- Peer review or not
- Concerning PIP: this tag means that the paper contains data and results on clinical studies specifically regarding PIP implants
- Mentioning PIP: this tag means that the paper cites PIP breast implants but not related to the safety assessment of the PIP breast implants
- Type of study design: case report, non-human experimental study, observational study, clinical trial, randomized clinical trial, other=not a clinical study
- Sample size: number of patients included
- Comments made by the evaluators

A compilation of the papers used for the evaluation is presented in Table 3.

Only papers published in peer-reviewed journals describing data and results on clinical studies specifically regarding PIP implants were considered. Commentaries, editorials, and discussions on silicone breast implants (SBI) in general or on the PIP breast implant fraud case were not considered for further evaluation.

The Pubmed search resulted in 99 papers. After the removal of 8 duplicate publications retrieved via Pubmed, a total of 91 papers were included in the compilation of papers to be evaluated.

The search using the Find-eR tool resulted in an additional 10 papers which were not duplicates of those retrieved via Pubmed. The papers obtained consisted mainly of book chapters dealing with various aspects of silicone breast implants and one EU report on Notified Bodies. One paper described an assessment of Notified Bodies in the EU. These papers, although included in the list of papers to be evaluated, did not provide information relating to PIP implants specifically but to various aspects of SBI in general. As book chapters and the Notified Body report are usually not peer reviewed, this information was not considered for further evaluation.

**Table 3. Papers evaluated as presented in Annex 1.**

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Papers dealing with rupture evaluation	39
Papers of reviews SBI and/or PIP fraud	14
Papers dealing with comments/news on PIP fraud	20
Papers dealing with other subjects	27

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The evaluation of each paper is presented in Annex 1.

The reviews and studies evaluated did not consistently indicate that PIP implants induced more harm to patients compared to other SBI brands (Moliter *et al.* 2015, Wazir *et al.*, 2015). Therefore, the additional risk of PIP breast implants may be limited to the high rupture rate which is probably due to a low quality of the PIP breast implant shell. Indeed, most studies indicate a higher rupture rate of PIP breast implants when compared to other SBI brands. In one study the prevalence of PIP breast implant

ruptures was comparable to other SBI brands, but with an increase in ruptures over time (Leckenby *et al.*, 2016). Also early adverse events were not different between PIP breast implants and two other SBI brands (Mentor(®) and Allergan(®)) (Fenoll *et al.*, 2015).

In conclusion, the literature review showed that new information is available regarding the possible health effects of PIP breast implants, but this information is rather limited.

### **5.1.2 Results from the call for information**

Five stakeholders submitted information regarding possible health effects of PIP breast implants, accounting for a total of 87 papers. However, only 12 papers are related to PIP breast implants, 6 of which were also included in the literature review mentioned above. The evaluation of the papers provided via the call for information is presented in Annex II. None of these 12 papers contained scientific information related to the health impacts of PIP breast implants on patients. For example, the submitted papers discussed the analytical chemistry of the PIP silicones or shell and some papers discussed the rupture rate of PIP breast implants. Most of the other papers discuss SBI in general or are comments/editorials in journals not containing scientific information on the health aspects of PIP breast implants.

### **5.1.3 Information submitted during commenting period**

A commenting period on the scientific Advices was published on the website of the Scientific Committees from April 7th until June 15th, 2017. Two organisations and one individual (providing in total 10 documents) submitted comments and provided input supposed to be related to the topic of the scientific advice, i.e. the toxicity of PIP silicone breast implants. Each contribution was carefully considered by the SCHEER and submitted papers were evaluated (see Annex III). In general the information did not specifically discuss the toxicity of PIP implants. The SCHEER concluded that the comments were outside the scope of this advice as they were providing additional information on possible adverse effects of SBI in general.

## **5.2 Rupture rate of PIP breast implants**

The probability of rupture for PIP breast implants reported in the 2014 Opinion is around 25-30% at 10 years after implantation. In order to estimate the current PIP breast implant rupture rate, a calculation was made based on the papers obtained in the literature review and also published studies already considered in the 2014 Opinion (Table 4). The rupture rate was determined based on data for 4641 implants and 3461 patients (Table 4). This re-analysis resulted in a rupture rate of about 23% (95% confidence interval 17.5% to 27.9%), which is in the same range as the rupture rate of 25%-30% presented in the 2014 Opinion.

Some studies show that the mean time from PIP implantation to rupture diagnosis and/or explanation was relatively short and generally less than 10 years. This may reflect the consequences of the PIP breast implant fraud case, which prompted regulatory bodies and the plastic surgery society to advise that PIP implants be removed as a preventive

measure rather than only when necessitated by the appearance of clinical symptoms.

Moreover, Swarts *et al.*, 2013 showed a highly variable shell thickness in ruptured PIP implants including shell regions below the minimum thickness specified by the manufacturer.

**Table 4. References on rupture rate**

Author	Number of patients (S)	Rupture rate PIP implants (%) <sup>a</sup>	Implant time at explantation or rupture diagnosis (mean number of years and range)
Billner et al. 2015	64 (115)	23.48	8.4 (n.a.) <sup>c</sup>
Moschetta et al. 2014	21 (40)	50	≥ 7 (n.a.)
Mennie et al. 2015	192 (384)	21	8.7 (6-15)
Schott et al. 2014	72 (108)	23	5.1 (1-11)
Oulharj et al. 2014	455 (828)	7.73	n.a.
Quaba et al. 2013 <sup>b</sup>	338 (676)	21.3	7.8 (1-13)
Berry et al. 2012 <sup>b</sup>	453	24.85 (range 15.9 – 33.8)	n.a. (6-11)
Berry et al. 2013 (update) <sup>b</sup>	460	30.55 (range 22.7 – 38.4)	n.a. (6-11)
Tropet et al. 2013	217 (434)	8.7	4.6 (n.a.)
Aktouf et al. 2012 <sup>b</sup>	99 (192)	11.9	n.a.
Leckenby et al. 2016	455 (905)	14.25	7.8 (0.12-16.8)
De Lorenzi et al. 2015	360 (443)	18.5	4.8 (n.a.)
Scotto di Santolo et al. 2014	64	36	8 (6-14)
Maijers et al. 2014	107 (214)	21	10 (n.a.)
Khan 2013	65	27.7	7.2 (2-12)
Chummun et al. 2013 <sup>b</sup>	39 (78)	21.8	7 (n.a.)
Maijers et al. 2012 <sup>b</sup>	(224)	24	10 (n.a.)

a) Indicated is the rupture rate as determined in explanted PIP breast implants. If the number of explants was not provided in the paper the percentage indicates patients with the diagnosis of implant rupture.

b) Studies on rupture rate of PIP implants included in 2014 Opinion on PIP breast implants.

c) n.a. not available

## 6 REFERENCES

Adams TS, Crook T, Cadier MA. (2007) A late complication following the insertion of hydrogel breast implants. *J Plast Reconstr Aesthet Surg* 60(2):210-2. Epub 2006 Mar 20.

Review. PMID: 17223521

Aktouf A, Auquit-Auckbur I, Coquerel-Beghin D, Delpierre V, Milliez PY. (2012) Breast augmentation by Poly Implant Prothèses silicone implants: retrospective study about 99 patients. Rupture analysis and management. *Ann Chir Plast Esthet* 57(6):558-66. doi: 10.1016/j.anplas.2012.04.007. Epub 2012 May 29. French. PMID: 22651997

Benkimoun P. (2013) Founder of PIP breast implant company gets four year prison sentence. *BMJ* 16;347:f7528. doi: 10.1136/bmj.f7528. PMID: 24343154

Beretta G, Malacco M. (2013) Chemical and physicochemical properties of the high cohesive silicone gel from Poly Implant Prothèse (PIP) breast prostheses after explantation: a preliminary, comparative analytical investigation. *J Pharm Biomed Anal* 78-79:75-82. doi: 10.1016/j.jpba.2013.01.040. Epub 2013 Feb 10. PMID: 23454600

Beretta G, Richards A, Malacco M. (2013) Chemical and biochemical composition of late periprosthetic fluids from women after explantation of ruptured Poly Implant Prothèse (PIP) breast prostheses. *J Pharm Biomed Anal* 84:159-67. doi: 10.1016/j.jpba.2013.06.003. Epub 2013 Jun 14. PMID: 23835059

Beretta G, Panseri S, Manzo A, Hamid R, Richards A, Malacco M. (2014) Analytical investigations on elastomeric shells of new Poly Implant Prothèse (PIP) breast and from sixteen cases of surgical explantation. *J Pharm Biomed Anal* 98:144-52. doi: 10.1016/j.jpba.2014.05.017. Epub 2014 May 23. PMID: 24915531

Berry M.G. (2015) Commentary to diagnosing PIP breast implant failure: a prospective analysis of clinical and ultrasound accuracy. *J Plast Reconstr Aesthet Surg* 68(4):587-8. doi: 10.1016/j.bjps.2015.02.028. Epub 2015 Feb 27. PMID: 25764968

Berry MG, Stanek JJ. (2013) PIP implant biodurability: a post-publicity update. *J Plast Reconstr Aesthet Surg* 66(9):1174-81. doi: 10.1016/j.bjps.2013.04.050. Epub 2013 May 10. PMID: 23668948

Berry MG, Stanek JJ. (2012) The PIP mammary prosthesis: a product recall study. *J Plast Reconstr Aesthet Surg* 65(6):697-704. doi: 10.1016/j.bjps.2012.02.019. Epub 2012 Mar 9. PMID: 22405818

Berry MG, Stanek JJ. (2013) The poly implant prothèse debacle. *Plast Reconstr Surg* 131(1):110e-2e. doi: 10.1097/PRS.0b013e318272a074. PMID: 23271530

Berry RB. (2007) Rupture of PIP breast implants. *J Plast Reconstr Aesthet Surg* 60(8):967-8. Epub 2007 Apr 20. PMID: 17449340

Berry MG, Stanek JJ. (2014) PIP silicone breast implants. *J Plast Reconstr Aesthet Surg* 67(1): 127-128

Billner M, Wirthmann A, Reif S, Rieger UM. (2016) Poly Implant Prothèse and Rofil Substandard Breast Implant Explantations from a Large German Single Centre from

2011 to 2014: A Comparative Study. *Aesthetic Plast Surg.* 40(4):507-13. doi: 10.1007/s00266-016-0666-1. Epub 2016 Jun 10. PMID: 27286854

Brook MA. (2012) The chemistry and physical properties of biomedical silicones-3, *Biomaterials in plastic surgery.* 3:52-67, Elsevier Ltd, 2012, 978-1-84569-799-0 ; ISBN: 978-0-85709-641-8 ; DOI: 10.1016/B978-1-84569-799-0.50003-7

Cárdenas-Camarena L. (2015) Poly Implant Prothèse: Two Studies of the Same Topic. *Plast Reconstr Surg* 136(3):389e-390e. doi: 10.1097/PRS.0000000000001486. PMID: 25989297

Carillon MA, Giard S, Emmanuelli V, Houpeau JL, Ceugnart L, Chauvet MP. (2012) Breast implants and health alert PIP: experience of the regional cancer center of Lille *Bull Cancer.* 99(2):147-53. doi: 10.1684/bdc.2011.1531. French. PMID: 22265869

Cawrse NH, Pickford MA. (2011) Cutaneous manifestation of silicone dissemination from a PIP implant--a case for prophylactic explantation? *J Plast Reconstr Aesthet Surg* 64(8):e208-9. doi: 10.1016/j.bjps.2011.04.002. Epub 2011 Apr 27. PMID: 21524950

Choi JJ, Lee JH, Kang BJ, Kim SH, Lee JH, Ahn ST, Yoon WJ, Lee HK. (2010) Clinical and imaging characteristics of Polyimplant Prosthesis hydrogel breast implants. *J Comput Assist Tomogr* 34(3):449-55. doi: 10.1097/RCT.0b013e3181d0c751. PMID: 20498553

Chummun S, McLean NR. (2013) Poly implant prothèse (PIP) breast implants: our experience. *Surgeon* 11(5):241-5. doi: 10.1016/j.surge.2013.02.006. Epub 2013 Mar 15. PMID: 23499229

Cooter RD, Barker S, Carroll SM, Evans GR, von Fritschen U, Hoflehner H, Le Louarn C, Lumenta DB, Mathijssen IM, McNeil J, Mulgrew S, Mureau MA, Perks G, Rakhorst H, Randquist C, Topaz M, Verheyden C, de Waal J. (2015) International importance of robust breast device registries. *Plast Reconstr Surg* 135(2):330-6. doi: 10.1097/PRS.0000000000000885. PMID: 25626781

Correia-Sá I, Rodrigues-Pereira P, Marques M. (2013) The "PIP problem": clinical and histologic characteristics. *Aesthetic Plast Surg* 37(5):936-40. doi: 10.1007/s00266-013-0196-z. Epub 2013 Aug 14. PMID: 23943050

Crouzet C, Gangloff D, Chaput B, Grolleau JL, Garrido I. (2012) Outcome at 18 months after the recall of Poly Implant Prosthesis, Experience of a cancer center. *Ann Chir Plast Esthet* 57(1):9-15. doi: 10.1016/j.anplas.2012.01.001. Epub 2012 Jan 27. French. PMID: 22285402

Croxatto HB, Díaz S. (1987) The place of progesterone in human contraception. *J Steroid Biochem* 27(4-6):991-4. Review. PMID: 3320572

Daniels AU. (2012) Silicone breast implant materials. *Swiss Med Wkly* 142:w13614. doi: 10.4414/smw.2012.13614. Review. PMID: 22826101

De Lorenzi F, Rietjens M. (2015) Reply: Poly Implant Prothèse: Two Studies of the Same Topic. *Plast Reconstr Surg* 136(3):390e-391e. doi: 10.1097/PRS.0000000000001485. PMID: 26313844

Dieterich M, Stubert J, Stachs A, Radke A, Reimer T, Gerber B. (2013) Ruptured poly-implant protheses breast implant after aesthetic breast augmentation: diagnosis, case management, and histologic evaluation. *Aesthetic Plast Surg* 37(1):91-4. doi: 10.1007/s00266-012-0015-y. Epub 2013 Jan 4. PMID: 23288097

Duchateau J. (2013) Actuality with the breast implants. *Rev Med Brux* 34(4):278-82. French. PMID: 24195240

Duquenne M, Truchan-Graczyk M, Zerhouni A, Fernandez L, Duquenne C, Rousselet MC. (2012) A sus-clavicular adenopathy in patient with PIP breast implants. *Presse Med* 41(11):1153-5. doi: 10.1016/j.lpm.2012.01.012. Epub 2012 Mar 3. French. PMID: 22386482

European Commission. Directorate-General for Health and Food Safety. Food and Veterinary Office. 2015, Luxembourg, Overview report of a series of voluntary joint assessments of notified bodies, Publications Office, ISBN 978-92-79-52054-9

Fenoll C, Leclère FM, Hivelin M, Atlan M, Cothier-Savey I, Lantieri L, Le Masurier P. (2015) Poly Implant Prothèse (PIP®) incidence of complications in breast reconstructive surgery: A retrospective comparative analysis. *Ann Chir Plast Esthet* 60(6):478-83. doi: 10.1016/j.anplas.2015.08.007. Epub 2015 Oct 21. French. PMID: 26472480

Fleming D. (2012) Polyurethane foam covered breast implants-5. *Biomaterials in plastic surgery*, 5:96-120, Elsevier Ltd, 2012, ISBN: 978-1-84569-799-0 ; ISBN: 978-0-85709-641-8 ; DOI: 10.1016/B978-1-84569-799-0.50005-0

Formes A, Diehl B. (2014) Investigation of the silicone structure in breast implants using <sup>1</sup>H NMR. *J Pharm Biomed Anal* 93:95-101. doi: 10.1016/j.jpba.2013.09.005. Epub 2013 Sep 18. PMID: 24342752

Freshwater MF. (2012) The PIP crisis: déjà vu all over again? *J Plast Reconstr Aesthet Surg* 65(6):840-3. doi: 10.1016/j.bjps.2012.03.006. PMID: 22564746

Freshwater MF. (2016) Poly Implant Prothèse™ (PIP) experience in the United Kingdom: A prospective cohort study into the accuracy of diagnostic imaging findings in comparison to operative findings of 1029 implants. *J Plast Reconstr Aesthet Surg* 69(6):878-9. doi: 10.1016/j.bjps.2016.01.025. Epub 2016 Feb 2. PMID: 26876107

Gattiker UE. (2012) Improving the customer experience: how social media can make a difference-10, *Public Interest And Private Rights In Social Media*, 10:153-173, Elsevier Ltd, 2012 ISBN: 978-1-84334-693-7 ; ISBN: 978-1-78063-353-4 ; DOI: 10.1016/B978-1-84334-693-7.50010-6

Gielens M., Koolen PG, Hermens RA. (2013) Imaging in silicone breast implantation. *Ned*



Tijdschr Geneesk 157(47):A6412. Review. Dutch. PMID: 24252405

Godwin Y, Duncan RT, Feig C, Reintals M, Hill S. (2014) Soft, Brown Rupture: Clinical Signs and Symptoms Associated with Ruptured PIP Breast Implants. *Plast Reconstr Surg Glob Open*. 2(11):e249. doi: 10.1097/GOX.0000000000000212. eCollection 2014 Nov. PMID: 25506532

Gopinath PP, Ali A, Van Tornout F, Kamath A, Crawford M, Nicholson AG. (2015) Chronic silicone embolism syndrome due to PIP breast implant leakage – a new entity? *Histopathology* 66(6):904-6. doi: 10.1111/his.12518. Epub 2014 Nov 10. PMID: 25098454

Greco C. (2015) The Poly Implant Prothèse breast prostheses scandal: Embodied risk and social suffering. *Soc Sci Med*. 147:150-7. doi: 10.1016/j.socscimed.2015.10.068. Epub 2015 Nov 2. PMID: 26584233

Gubitosi A., Docimo G., Ruggiero R., Esposito A., Esposito E., Foroni F. (2012) Breast implant (PIP), chronic inflammation and cancer: is there a connection? Case report. *Ann Ital Chir* 83. pii: S2239253X12019883. PMID: 23075481

Hammond DC. (2010) Discussion: Prevalence of rupture in poly implant Prothèse silicone breast implants, recalled from the European market in 2010. *Plast Reconstr Surg* 129(6):1379-80. doi: 10.1097/PRS.0b013e318254ca5b. PMID: 22634655

Hedén P. (2012) Cohesive gel breast implants-4, *Biomaterials in plastic surgery*. 4: 68-95, Elsevier Ltd, ISBN: 978-1-84569-799-0; ISBN: 978-0-85709-641-8 ; DOI: 10.1016/B978-1-84569-799-0.50004-9

Helyar V, Burke C, McWilliams S. (2013) The ruptured PIP breast implant. *Clin Radiol*. 68(8):845-50. doi: 10.1016/j.crad.2013.03.012. Epub 2013 Apr 25. Review. PMID: 23622796

Hoffmann O. (2013) Safety of silicone breast implants, especially of Poly Implant Prothèse (PIP) breast implants. *MMW Fortschr Med*. 155(2):50-2. German. No abstract available, PMID: 23573747

Johnstone B, Read K, Dick W. (2013) Poly Implant Prothèse silicone breast implant rupture, gel bleed and fatigue in a 'blinded' patient. *ANZ J Surg*. 83(3):192-3. doi: 10.1111/ans.12057. PMID: 23465215

Keizers PH, Vredenburg MJ, Bakker F, de Kaste D, Venhuis BJ. (2015) Chemical fingerprinting of silicone-based breast implants. *J Pharm Biomed Anal* 102:340-5. doi: 10.1016/j.jpba.2014.09.008. Epub 2014 Sep 16. PMID: 25459933

Khan UD. (2013) Poly Implant Prothèse (PIP) incidence of device failure and capsular contracture: a retrospective comparative analysis. *Aesthetic Plast Surg* 37(5):906-13. doi: 10.1007/s00266-013-0157-6. Epub 2013 Jul 17., PMID: 23860815

Kmietowicz Z. (2012) PIP implants don't pose risk to health, expert group concludes.

BMJ 344:e4234. doi: 10.1136/bmj.e4234. PMID: 22710012

Kolios L, Hirche C, Spiethoff A, Daigeler A, Lehnhardt M. (2013) Complications of Poly Implant Prothèse breast implants: the current discussion. *Expert Rev Med Devices*. 10(2):167-70. doi: 10.1586/erd.12.87., PMID: 23480085

Koutsomanis A, Bruant-Rodier C, Roedlich MN, Bretz-Grenier MF, Perrot P, Bodin FA. (2015) Radiological trap and oncological precautions in a patient who has undergone a permanent withdrawal of PIP breast implants. *Chir Plast Esthet* 60(6):533-6. doi: 10.1016/j.anplas.2015.06.012. Epub 2015 Jul 29. French. PMID: 26232069

Lampert FM, Schwarz M, Grabin S, Stark GB. (2012) The "PIP scandal" - Complications in Breast Implants of Inferior Quality: State of Knowledge, Official Recommendations and Case Report. *Geburtshilfe Frauenheilkd* 72(3):243-246. PMID: 25308983

Latham M. (2014) 'If it ain't broke, don't fix it?': scandals, 'risk', and cosmetic surgery regulation in the UK and France. *Med Law Rev* 22(3):384-408. doi: 10.1093/medlaw/fwt033. Epub 2014 Jan 9. PMID: 24408910

Leckenby J, Chana J, Harrison D, Grobbelaar A. (2016) Poly Implant Prothèse™ (PIP) experience in the United Kingdom: A prospective cohort study into the accuracy of diagnostic imaging findings in comparison to operative findings of 1029 implants. *J Plast Reconstr Aesthet Surg* 69(4):446-51. doi: 10.1016/j.bjps.2016.01.015. Epub 2016 Feb 3. PMID: 26936318

Leduey A, Mazouni C, Leymarie N, Alkhashnam H, Sarfati B, Garbay JR, Gaudin A, Kolb F, Rimareix F. (2015) Comparison of the Explantation Rate of Poly Implant Prothèse, Allergan, and Pérouse Silicone Breast Implants within the First Four Years after Reconstructive Surgery before the Poly Implant Prothèse Alert by the French Regulatory Authority. *Int J Breast Cancer*. 2015:519497. doi: 10.1155/2015/519497. Epub 2015 Oct 12. PMID: 26543648

Lewis PR. (2012) The failure of synthetic polymeric medical devices-9, Durability and reliability of medical polymers, 9:183-224, Elsevier Ltd, ISBN: 978-1-84569-929-1 ; ISBN: 978-0-85709-651-7 ; DOI: 10.1016/B978-1-84569-929-1.50009-X. Full text available

Lipworth L, Mclaughlin JK. (2012) The safety of breast implants: epidemiologic studies-6, Biomaterials in plastic surgery, 6:121-153, Elsevier Ltd, 2012 ISBN: 978-1-84569-799-0 ; ISBN: 978-0-85709-641-8 ; DOI: 10.1016/B978-1-84569-799-0.50006-2

Maijers MC, Niessen FB, Veldhuizen JF, Ritt MJ, Manoliu RA. (2014) MRI screening for silicone breast implant rupture: accuracy, inter- and intraobserver variability using explantation results as reference standard. *Eur Radiol* 24(6):1167-75. doi: 10.1007/s00330-014-3119-8. Epub 2014 Mar 6. PMID: 24599622

Maijers MC, Niessen FB, Veldhuizen JF, Ritt MJ, Manoliu RA. (2010) Magnetic resonance imaging screening results compared with explantation results in poly implant prothèse

silicone breast implants, recalled from the European market in 2010. *Plast Reconstr Surg* 133(2):114e-20e. doi: 10.1097/01.prs.0000436853.32527.c3. PMID: 24469182

Maijers MC, Niessen FB. (2013) Reply: The poly implant prothèse debacle. *Plast Reconstr Surg* 131(1):112e-4e. doi: 10.1097/PRS.0b013e318272a119. PMID: 23271531

Mallon P, Ganachaud F, Malhaire C, Brunel R, Sigal-Zafrani B, Feron JG, Couturaud B, Fitoussi A, Reyat F. (2013) Bilateral poly implant prothèse implant rupture: an uncommon presentation. *Plast Reconstr Surg Glob Open* 1(4):e29. doi: 10.1097/GOX.0b013e318298e026. eCollection 2013 Jul. PMID: 25289223

Manickavasagar T, Morrith AN, Offer GJ. (2013) Bilateral supraclavicular swelling: an unusual presentation of ruptured Poly Implant Prothese (PIP) breast implants. *J Plast Reconstr Aesthet Surg* 66(2):267-9. doi: 10.1016/j.bjps.2012.06.018. Epub 2012 Jul 25. PMID: 22836112

Martindale V, Menache A. The PIP scandal: an analysis of the process of quality control that failed to safeguard women from the health risks. *J R Soc Med* 106(5):173-7. doi: 10.1177/0141076813480994. PMID: 23761525

Maxwell, GP, Gabriel A. (2012) The development of breast implants-2, *Biomaterials in plastic surgery*, 2:40-51, Elsevier Ltd, 2012, ISBN: 978-1-84569-799-0 ; ISBN: 978-0-85709-641-8 ; DOI: 10.1016/B978-1-84569-799-0.50002-5

Mennie JC, Quaba O, Smith M, Quaba A. (2014) Diagnosing PIP breast implant failure: a prospective analysis of clinical and ultrasound accuracy. *J Plast Reconstr Aesthet Surg* 68(4):540-5. doi: 10.1016/j.bjps.2014.11.008. Epub 2014 Nov 20. PMID: 25496719

Mira JA. (2003) Anatomic asymmetric prostheses: shaping the breast. *Aesthetic Plast Surg* 27(2):94-9. PMID: 14629058

Mistry R, Caplash Y, Giri P, Kearney D, Wagstaff M. (2015) Thoracic outlet syndrome following breast implant rupture. *Plast Reconstr Surg Glob Open* 3(3):e331. doi: 10.1097/GOX.000000000000295. eCollection 2015 Mar. PMID: 25878942

Molitor M, Meš'ták O, Popelka P, Vítová L, Matejovská J, Kalinová L, Hromádková V, Meš'ták J. (2015) PIP Implants--current knowledge and literature review. *Acta Chir Plast* 57(1-2):17-23. Review. PMID: 26650109

Moschetta M, Telegrafo M, Cornacchia I, Vincenti L, Ranieri V, Cirili A, Rella L, Stabile Ianora AA, Angelelli GG. (2014) PIP breast implants: rupture rate and correlation with breast cancer. *Chir* 35(11-12):274-8. PMID: 25644728

Mylvaganam S, Taylor R, Thrush S. (2013) Poly implant breast implants (PIP) and the rupture risk in asymptomatic patients: a warning for greater clinician suspicion in assessment and counselling. *J Surg Case Rep* 2013(2). pii: rjs044. doi: 10.1093/jscr/rjs044. PMID: 24964409

O'Dowd A. (2012) Around 1000 women with private sector PIP implants seek NHS help. *BMJ* 344:e972. doi: 10.1136/bmj.e972. PMID: 22315301

O'Dowd A. (2012) UK launches inquiry into safety of PIP breast implants. *BMJ* 344:e11. doi: 10.1136/bmj.e11. PMID: 22214894

O'Dowd A. (2011) UK recommends PIP breast implants should not be removed. *BMJ* 343:d8313. doi: 10.1136/bmj.d8313. PMID: 22194408

O'Dowd A. (2012) Women have had "harrowing" experiences over PIP implants scandal. *BMJ* 345:e4560. doi: 10.1136/bmj.e4560. PMID: 22761250

O'Neill JK, Rigby H, Kenealy JM. (2008) Leakage and osmotic shifts in PIP Hydrogel implants. A case demonstrating increase and decrease of implant volume in the same patient. *J Plast Reconstr Aesthet Surg* 61(9):1122-3. doi: 10.1016/j.bjps.2008.05.008. Epub 2008 Jul 15. PMID: 18632317

Oulharj S, Pauchot J, Tropet YJ. (2014) PIP breast implant removal: a study of 828 cases. *J Plast Reconstr Aesthet Surg* 67(3):302-7. doi: 10.1016/j.bjps.2013.12.016. Epub 2013 Dec 30. PMID: 24522122

Parvizi N, Woods K. (2014) Regulation of medicines and medical devices: contrasts and similarities. *Clin Med (Lond)* 14(1):6-12. doi: 10.7861/clinmedicine.14-1-6. Review. PMID: 24532735

Peters W. (2012) Introduction: Biomaterials in plastic surgery, *Biomaterials in plastic surgery*, pp.xv-xviii, Elsevier Ltd, 2012, ISBN: 978-1-84569-799-0 ; ISBN: 978-0-85709-641-8 ; DOI: 10.1016/B978-1-84569-799-0.50012-8

Petit F. (2013) [PIP-line]. *Ann Chir Plast Esthet* 58(1):2-3. doi: 10.1016/j.anplas.2012.12.002. Epub 2013 Jan 16. French. PMID: 23332583

Quaba O, Quaba A. (2013) PIP silicone breast implants: rupture rates based on the explantation of 676 implants in a single surgeon series. *J Plast Reconstr Aesthet Surg* 66(9):1182-7. doi: 10.1016/j.bjps.2013.05.003. Epub 2013 May 30. PMID: 23725742

Reyal F, Feron JG, Leman Detour S, Pourcelot AG, Valentin M, Phillippe AC, Levy-Zauberman Y, Agman A, Monier S, Blondel A, Cothier-Savey I, Guihard T, Le Masurier P, Fitoussi A, Couturaud B. (2013) The impact of poly implant prothèse fraud on breast cancer patients: a report by the institute curie. *Plast Reconstr Surg* 131(4):690-5. doi: 10.1097/PRS.0b013e3182827605. PMID: 23542243

Rosendahl P, Hippler J, Schmitz OJ, Hoffmann O, Rusch P. (2106) Cyclic volatile methylsiloxanes in human blood as markers for ruptured silicone gel-filled breast implants. *Anal Bioanal Chem* 408(12):3309-17. doi: 10.1007/s00216-016-9401-7. Epub 2016 Mar 11. PMID: 26968566

Salim F, Adlard R, Pickford MA. (2013) The Fleur-de-lis DIEP-Introducing a 5th zone for

DIEP reconstruction. *J Plast Reconstr Aesthet Surg* 66(10):1424-7. doi: 10.1016/j.bjps.2013.01.003. Epub 2013 Jan 29. PMID: 23369739

Sanai L. (2012) Coventina's Column. Polyimplant prosthese (PIP) breast implants. *Scott Med J* 57(1):58-9. PMID: 22509535

Schott S, Bruckner T, Golatta M, Wallwiener M, Küffner L, Mayer C, Paringer C, Domschke C, Blumenstein M, Schütz F, Sohn C, Heil J. (2014) Recall management of patients with Rofil Medical breast implants. *J Plast Reconstr Aesthet Surg* 67(7):939-45. doi: 10.1016/j.bjps.2014.03.031. Epub 2014 Apr 8. PMID: 24785684

Schott S, Bruckner T, Schütz F, Wallwiener M, Sohn C, Golatta M, Heil J. (2014) Quality of life and anxiety of patients affected by the PIP/Rofil Medical breast implant recall: results from a prospective monocentre cohort study. *Arch Gynecol Obstet* 290(5):957-62. doi: 10.1007/s00404-014-3326-1. Epub 2014 Jun 26. PMID: 24966121

Scotto di Santolo M, Cusati B, Ragozzino A, Dell'Aprovitola N, Acquaviva A, Altiero M, Accurso A, Riccardi A, Imbriaco M. (2014) Poly Implant Prothèse (PIP) incidence of rupture: a retrospective MR analysis in 64 patients. *Quant Imaging Med Surg* 4(6):462-8. doi: 10.3978/j.issn.2223-4292.2014.08.01. PMID: 25525578

Smith R, Lunt N, Hanefeld J. (2012) The implications of PIP are more than just cosmetic. *Lancet* 379(9822):1180-1. doi: 10.1016/S0140-6736(12)60166-4. Epub 2012 Feb 2. PMID: 22305764

Sukhova I, Müller D, Eisenmann-Klein M, Machens HG, Schantz JT. (2012) Quo vadis? Breast implants--current trends and new concepts. *Handchir Mikrochir Plast Chir* 44(4):240-53. doi: 10.1055/s-0032-1321891. Epub 2012 Aug 29. Review. German. PMID: 22932856

Swarts E, Kop AM, Nilasaroya A, Keogh CV, Cooper T. (2013) Rupture of poly implant prothèse silicone breast implants: an implant retrieval study. *Plast Reconstr Surg* 131(4):480e-9e. doi: 10.1097/PRS.0b013e3182818a00. PMID: 23249979

Tafazal H, Basu NN, Jewkes A. (2014) Sentinel lymph node biopsy in a patient with ruptured poly implant prosthese (PIP) implants: A case report. *A. Int J Surg Case Rep* 5(12):992-4. doi: 10.1016/j.ijscr.2014.09.005. Epub 2014 Oct 5. PMID: 25460455

Takayanagi S. (2012) Augmentation mammoplasty using implants: a review. *Arch Plast Surg* 39(5):448-51. doi: 10.5999/aps.2012.39.5.448. Epub 2012 Sep 12. PMID: 23094237

Tickunas T, Howarth S, Godwin Y. (2013) Inflammatory changes of the nipple areolar complex of a patient with PIP breast implants: a possible immune response to free silicone from gel bleed? *J Plast Reconstr Aesthet Surg* 67(3):423-5. doi: 10.1016/j.bjps.2013.10.028. Epub 2013 Oct 26. PMID: 24280539

Torjesen I. (2012) NHS patients are choosing to have PIP implants removed whether or not they have burst. *BMJ* 344:e1460. doi: 10.1136/bmj.e1460. PMID: 22371866

Torjesen I. (2012) NHS should replace PIP implants even when privately fitted. *BMJ* 344:e2379. doi: 10.1136/bmj.e2379. PMID: 22457448

Tropet Y, Oulharj S, Pauchot J. (2013) PIP breast implants: a series of 217 explants. *Bull Acad Natl Med* 197(1):123-30; discussion 130-1. French. PMID: 24672984

Wazir U, Kasem A, Mokbel KA. (2015) The clinical implications of poly implant prothèse breast implants: an overview. *Plast Surg* 42(1):4-10. doi: 10.5999/aps.2015.42.1.4. Epub 2015 Jan 14. Review. PMID: 25606483 [PubMed]

Wise J. (2013) Review that found PIP implants to be safe was flawed, say campaigners. *BMJ* 201;346:f3034. doi: 10.1136/bmj.f3034., PMID: 23661251

Yildirimer L, Seifalian AM, Butler PE. (2013) Surface and mechanical analysis of explanted Poly Implant Prosthèse silicone breast implants. *Br J Surg* 100(6):761-7. doi: 10.1002/bjs.9094. Epub 2013 Mar 8. PMID: 23475661

Zambacos GJ, Molnar C, Mandrekas AD. (2013) Silicone lymphadenopathy after breast augmentation: case reports, review of the literature, and current thoughts. *Aesthetic Plast Surg* 37(2):278-89. doi: 10.1007/s00266-012-0025-9. Epub 2013 Jan 26. Review. PMID: 23354761

Zuckerman D, Booker N, Nagda S. (2012) Public health implications of differences in U.S. and European Union regulatory policies for breast implants. *Reprod Health Matters* 20(40):102-11. doi: 10.1016/S0968-8080(12)40662-0. PMID: 23245415

## **ANNEX I: Evaluation of papers identified through literature search**

In this Annex are listed the papers identified through literature review, using Pub-Med and Find-eR and the evaluation made by the SCHEER.



**Literature review  
PIP.docx**

## **ANNEX II Evaluation of papers received during the call for information**

In this Annex are listed the papers received via call information which was published on the 14<sup>th</sup> of June 2016 and closed on September 4<sup>th</sup> 2016 and the evaluation made by the SCHEER.



Papers received  
during the call for info



### **ANNEX III Evaluation of papers received during the commenting period**

In this Annex are listed the papers during the commenting period which was opened from April 7th until June 15th, 2017



Evaluation of the  
literature received du