

Table of Contents

1. INTRODUCTION.....	2
2. DATA BY COMPLAINTS RECEIVED	3
2.1 ALL CASES – CONFIRMED, SUSPECTED, PENDING CONFIRMATION.....	3
2.2 CONFIRMED CASES ONLY	3
2.3 INTERPRETATION OF DATA.....	3
3. DATA BY IMPLANT YEAR.....	5
3.1 ALL CASES.....	5
3.2 CONFIRMED CASES ONLY	6

ENCLOSURES

TABLE 1:
All ALCL Cases Tabulated by Complaint Received Year

TABLE 2:
Confirmed ALCL Cases Tabulated by Complaint Received Year

TABLE 3:
All ALCL Cases Tabulated by Implant Year

TABLE 4:
Confirmed ALCL Cases Tabulated by Implant Year

1. INTRODUCTION

Allergan received a letter from Mr. Gaëtan RUDANT of ANSM on 20 May, 2016 requesting the number of Allergan silicone-filled breast implants sold between 2004 and 2015 as well as the number of Anaplastic Large Cell Lymphoma (ALCL) cases reported to the company in the same time period. The letter included a template table to be completed. Data were to be provided for worldwide cases (including France) and French cases separately. The requested data are described below and tables are provided as enclosures.

2. DATA BY COMPLAINTS RECEIVED

In accordance with the request received, in this section and referenced tables, the cases are tabulated based on the year in which the complaint was received.

2.1 ALL CASES – CONFIRMED, SUSPECTED, PENDING CONFIRMATION

Table 1 includes all ALCL cases: those that are closed confirmed (based on pathology reports or complaint from a credible source), those that are closed suspected (no pathology report or complaint not from a credible source), and those that are open and pending confirmation. As noted below the table, cases that were initially reported as ALCL but were investigated and found not to be ALCL have been excluded.

Worldwide, there were 132 confirmed, suspected, and pending confirmation ALCL cases reported to Allergan between 2004 and 2015. Of these, 4 had smooth implants, 104 had textured implants, and 24 had implants with an unknown surface in place at the time of diagnosis. It is important to note that 16 of the 132 worldwide cases had an unknown manufacturer's implants in place at diagnosis. Of the unknown implant cases, 15 had implants with an unknown surface type in place at the time of diagnosis and 1 had textured implants in place at the time of diagnosis.

Of the 132 cases worldwide, in France, there were 17 confirmed, suspected, and pending confirmation ALCL cases reported to Allergan between 2004 and 2015. All of these cases had Allergan textured implants in place at the time of diagnosis.

2.2 CONFIRMED CASES ONLY

Table 2 provides confirmed cases only. Worldwide, there were 85 confirmed ALCL cases reported to Allergan between 2004 and 2015. Of these, 2 had smooth implants, 63 had textured implants, and 20 had implants with an unknown surface in place at the time of diagnosis. Of the 85 worldwide cases, 15 had an unknown manufacturer's implants in place at diagnosis; 1 was textured and 14 had an unknown surface.

Of the 85 ALCL cases worldwide, in France, there were 11 confirmed ALCL cases reported to Allergan between 2004 and 2015; all had Allergan textured implants in place at the time of diagnosis.

2.3 INTERPRETATION OF DATA

Though the ANSM only requested the data based on the year in which the complaints were received, Allergan believes it is important to note that these data (provided in Tables 1 and 2) are not appropriate for annual rate or total rate calculations because the sales volume in the

year the complaint was received has no relation to the actual volume of devices sold/implanted in the year the subject device was implanted. That is, cases received in a given year generally represent devices sold in an entirely different year. A more accurate means for calculating rates is to use the number of cases associated with devices implanted in a given year divided by the sales for that year. Therefore, Allergan has provided two additional tables, described in the section that follows.

3. DATA BY IMPLANT YEAR

In the sections below and referenced tables, all cases reported between 2004 and 2015 were tabulated by implant year. If implant year was unavailable, manufacturing year was used.

3.1 ALL CASES

Table 3 includes all ALCL cases: those that are closed confirmed, those that are closed suspected, and those that are open and pending confirmation. Cases that were initially reported as ALCL but were investigated and found not to be ALCL have been excluded.

Worldwide,

- 80 confirmed, suspected, and pending confirmation ALCL cases had devices in place at the time of diagnosis that were implanted between 2004 and 2015.
- 39 cases reported between 2004 and 2015 had devices in place at the time of diagnosis that were implanted or manufactured prior to 2004 (and are not included in the table).
- 13 cases reported between 2004 and 2015 had implants in place at the time of diagnosis that have an unknown implant year and manufacturing year.

Of the 80 worldwide cases, 4 had smooth implants, 72 had textured implants, and 4 had implants with an unknown surface in place at the time of diagnosis. Additionally, 1 of the 80 cases had unknown manufacturers' implants in place at the time of diagnosis. Of the 13 cases with an unknown implant year and manufacturing year, 7 had unknown manufacturers' implants in place at the time of diagnosis.

In France,

- 13 confirmed, suspected and pending ALCL cases had devices in place at the time of diagnosis that were implanted between 2004 and 2015.
- 4 cases had devices in place at the time of diagnosis that were implanted or manufactured prior to 2004.

Of the 13 cases, all had Allergan textured implants in place at the time of diagnosis.

3.2 CONFIRMED CASES ONLY

Table 4 provides confirmed cases only.

Worldwide,

- 43 confirmed ALCL cases had devices in place at the time of diagnosis that were implanted between 2004 and 2015.
- 32 cases reported between 2004 and 2015 had devices in place at the time of diagnosis that were implanted or manufactured prior to 2004.
- 10 cases reported between 2004 and 2015 had implants in place at the time of diagnosis that have an unknown implant year and manufacturing year.

Of the 43 worldwide cases, 2 had smooth implants, 39 had textured implants, and 2 had implants with an unknown surface in place at the time of diagnosis. Additionally, 1 of these cases had unknown manufacturers' implants in place at the time of diagnosis. Of the 10 cases that did not have an implant year or manufacturing year, 7 had an unknown manufacturer's implants in place at the time of diagnosis.

In France,

- 8 confirmed ALCL cases had devices in place at the time of diagnosis that were implanted between 2004 and 2015.
- 4 cases had devices in place at the time of diagnosis that were implanted or manufactured prior to 2004.

Of the 8 confirmed cases, all had Allergan textured implants in place at the time of diagnosis.

Table 1: All ALCL Complaints for Silicone-Filled Breast Implants, Manufactured by Allergan and Unknown Manufacturers, Tabulated by Complaint Received Year*

Complaints Received Worldwide Between January 01, 2004 through December 31, 2015

Year	Description	Worldwide by Surface Type				France by Surface Type			
		Smooth	Textured (Biocell, Microcell, Unknown AGN Textured)	Unknown	Total	Smooth	Textured (Biocell, Microcell, Unknown AGN Textured)	Unknown	Total
2004	Count of ALCL Complaints by Received Year	0	0	0	0	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2005	Count of ALCL Complaints by Received Year	0	0	0	0	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2006	Count of ALCL Complaints by Received Year	0	0	0	0	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2007	Count of ALCL Complaints by Received Year	1	2	0	3	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2008	Count of ALCL Complaints by Received Year	0	5	4	9	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2009	Count of ALCL Complaints by Received Year	0	3	3	6	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2010	Count of ALCL Complaints by Received Year	1	0	3	4	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2011	Count of ALCL Complaints by Received Year	0	9	0	9	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2012	Count of ALCL Complaints by Received Year	1	14	2	17	0	2	0	2
	Sales Volume by Distribution Year			NA				NA	
2013	Count of ALCL Complaints by Received Year	1	21	0	22	0	2	0	2
	Sales Volume by Distribution Year			NA				NA	
2014	Count of ALCL Complaints by Received Year	0	18	8	26	0	2	0	2
	Sales Volume by Distribution Year			NA				NA	
2015	Count of ALCL Complaints by Received Year	0	32	4	36	0	11	0	11
	Sales Volume by Distribution Year			NA				NA	
Total (2004-2015)	Count of ALCL Complaints by Received Year	4	104	24	132	0	17	0	17
	Sales Volume by Distribution Year			NA				NA	

*The Above ALCL data are tabulated by the year the complaint was received. It includes confirmed cases, suspected cases, and cases that are pending confirmation.

Out of the 132 complaints received Worldwide, 16 had implants in place at the time of diagnosis where the manufacture was listed as unknown. Of those 16 cases, 15 had implants with an unknown surface type and one had textured implants.

All 17 complaints received in France had Allergan implants in place at the time of diagnosis.

These data do not support calculation of rates since complaints are tabulated by complaint received year and not by implant year.

Report Date: May 25, 2016

Table 2: Confirmed ALCL Complaints with Silicone-Filled Breast Implants in Place at Diagnosis, Manufactured by Allergan and Unknown Manufacturers, Tabulated by Complaint Received Year*

Complaint Received Worldwide Between January 01, 2004 through December 31, 2015

Year	Description	Worldwide by Surface Type				France by Surface Type			
		Smooth	Textured (Biocell, Microcell, Unknown AGN Textured)	Unknown	Total	Smooth	Textured (Biocell, Microcell, Unknown AGN Textured)	Unknown	Total
2004	Count of ALCL Complaints by Received Year	0	0	0	0	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2005	Count of ALCL Complaints by Received Year	0	0	0	0	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2006	Count of ALCL Complaints by Received Year	0	0	0	0	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2007	Count of ALCL Complaints by Received Year	0	1	0	1	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2008	Count of ALCL Complaints by Received Year	0	3	4	7	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2009	Count of ALCL Complaints by Received Year	0	3	3	6	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2010	Count of ALCL Complaints by Received Year	1	0	3	4	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2011	Count of ALCL Complaints by Received Year	0	7	0	7	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2012	Count of ALCL Complaints by Received Year	1	13	1	15	0	2	0	2
	Sales Volume by Distribution Year			NA				NA	
2013	Count of ALCL Complaints by Received Year	0	13	0	13	0	2	0	2
	Sales Volume by Distribution Year			NA				NA	
2014	Count of ALCL Complaints by Received Year	0	9	8	17	0	2	0	2
	Sales Volume by Distribution Year			NA				NA	
2015	Count of ALCL Complaints by Received Year	0	14	1	15	0	5	0	5
	Sales Volume by Distribution Year			NA				NA	
Total (2004-2015)	Count of ALCL Complaints by Received Year	2	63	20	85	0	11	0	11
	Sales Volume by Distribution Year			NA				NA	

*The Above ALCL data consist of all confirmed complaints and are tabulated by the year the complaint was received.

Out of the 85 confirmed ALCL complaints received Worldwide, 15 had implants in place at the time of diagnosis where the manufacture was listed as unknown.

Out of the 11 confirmed ALCL complaints received in France, all had Allergan implants in place at the time of diagnosis.

These data do not support calculation of rates since complaints are tabulated by complaint received year and not by implant year.

Report Date: May 25, 2016

Table 3: All ALCL Complaints for Silicone-Filled Breast Implants, Manufactured by Allergan and Unknown Manufacturers, Tabulated by Implant Year*

Complaint Received Worldwide Between January 01, 2004 through December 31, 2015 with an Implant/Manufacture Date of January 01, 2004 through December 31, 2015

Year	Description	Worldwide by Surface Type				France by Surface Type			
		Smooth	Textured (Biocell, Microcell, Unknown AGN Textured)	Unknown	Total	Smooth	Textured (Biocell, Microcell, Unknown AGN Textured)	Unknown	Total
2004	Count of ALCL Complaints by Implant/Manufacturing Year	0	5	1	6	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2005	Count of ALCL Complaints by Implant/Manufacturing Year	0	6	1	7	0	2	0	2
	Sales Volume by Distribution Year			NA				NA	
2006	Count of ALCL Complaints by Implant/Manufacturing Year	1	18	0	19	0	4	0	4
	Sales Volume by Distribution Year			NA				NA	
2007	Count of ALCL Complaints by Implant/Manufacturing Year	2	10	0	12	0	4	0	4
	Sales Volume by Distribution Year			NA				NA	
2008	Count of ALCL Complaints by Implant/Manufacturing Year	0	9	0	9	0	2	0	2
	Sales Volume by Distribution Year			NA				NA	
2009	Count of ALCL Complaints by Implant/Manufacturing Year	0	6	0	6	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2010	Count of ALCL Complaints by Implant/Manufacturing Year	0	4	0	4	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2011	Count of ALCL Complaints by Implant/Manufacturing Year	1	7	0	8	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2012	Count of ALCL Complaints by Implant/Manufacturing Year	0	4	2	6	0	1	0	1
	Sales Volume by Distribution Year			NA				NA	
2013	Count of ALCL Complaints by Implant/Manufacturing Year	0	1	0	1	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2014	Count of ALCL Complaints by Implant/Manufacturing Year	0	1	0	1	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2015	Count of ALCL Complaints by Implant/Manufacturing Year	0	1	0	1	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
Total (2004-2015)	Count of ALCL Complaints by Receive Year	4	72	4	80	0	13	0	13
	Sales Volume by Distribution Year			NA				NA	
Unknown	Count of ALCL Complaints Received between January 01, 2004 through December 31, 2015 with an Unknown Implant or Manufacturing Year	0	3	10	13	0	0	0	0

*Complaints are tabulated by implant year. If implant year was unknown, manufacturing year was used. Complaints that did not have either an implant or manufacturing year are provided in a separate row beneath the table. The Above Data Excludes ALCL complaints where the investigation determined it was not ALCL.

For worldwide between 2004 and 2015 a total of 132 confirmed, suspected, or pending confirmation ALCL complaints were received worldwide. Out of those 132 complaints, 80 were implanted or manufactured between 2004-2015, 13 did not have an associated implant or manufacturing date, and 39 were implanted or manufactured prior to 2004.

Out of the 93 Complaints worldwide, 8 had implants in place at the time of diagnosis where the manufacturer was listed as unknown. Out of the 8 implants in place at the time of diagnosis from unknown manufacturers, all 8 had an unknown surface type.

In France, between 2004 and 2015 a total of 17 ALCL complaints were received. Out of those 17 complaints 13 were implanted or manufactured between 2004 and 2015 and 4 were implanted or manufactured prior to 2004.

For the 13 cases in France that were implanted or manufactured between 2004 and 2015, all had Allergan implants in place at the time of diagnosis.

Table 4: Confirmed ALCL Complaints with Silicone-Filled Breast Implants in Place at Diagnosis, Manufactured by Allergan and Unknown Manufacturers, Tabulated by Implant Year*

Complaint Received Worldwide Between January 01, 2004 through December 31, 2015 with an Implant/Manufacture Date of January 01, 2004 through December 31, 2015

Year	Description	Worldwide by Surface Type				France by Surface Type			
		Smooth	Textured (Biocell, Microcell, Unknown AGN Textured)	Unknown	Total	Smooth	Textured (Biocell, Microcell, Unknown AGN Textured)	Unknown	Total
2004	Count of ALCL Complaints by Implant/Manufacturing Year	0	3	1	4	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2005	Count of ALCL Complaints by Implant/Manufacturing Year	0	2	1	3	0	1	0	1
	Sales Volume by Distribution Year			NA				NA	
2006	Count of ALCL Complaints by Implant/Manufacturing Year	0	12	0	12	0	3	0	3
	Sales Volume by Distribution Year			NA				NA	
2007	Count of ALCL Complaints by Implant/Manufacturing Year	2	7	0	9	0	2	0	2
	Sales Volume by Distribution Year			NA				NA	
2008	Count of ALCL Complaints by Implant/Manufacturing Year	0	6	0	6	0	2	0	2
	Sales Volume by Distribution Year			NA				NA	
2009	Count of ALCL Complaints by Implant/Manufacturing Year	0	2	0	2	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2010	Count of ALCL Complaints by Implant/Manufacturing Year	0	3	0	3	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2011	Count of ALCL Complaints by Implant/Manufacturing Year	0	2	0	2	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2012	Count of ALCL Complaints by Implant/Manufacturing Year	0	1	0	1	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2013	Count of ALCL Complaints by Implant/Manufacturing Year	0	0	0	0	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2014	Count of ALCL Complaints by Implant/Manufacturing Year	0	1	0	1	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
2015	Count of ALCL Complaints by Implant/Manufacturing Year	0	0	0	0	0	0	0	0
	Sales Volume by Distribution Year			NA				NA	
Total (2004-2015)	Count of ALCL Complaints by Implant/Manufacturing Year	2	39	2	43	0	8	0	8
	Sales Volume by Distribution Year			NA				NA	
Unknown	Count of ALCL Complaints Received between January 01, 2004 through December 31, 2015 with an Unknown Implant or Manufacturing Year	0	1	9	10	0	0	0	0

*Complaints are tabulated by implant year. If implant year was unknown, manufacturing year was used. Complaints that did not have either an implant or manufacturing year are provided in a separate row beneath the table.

Worldwide, between 2004 and 2015 a total of 85 confirmed ALCL complaints were received. Out of those 85 complaints, 43 were implanted or manufactured between 2004 and 2015, 10 did not have an associated implant or manufacturing date, and 32 were implanted or manufactured prior to 2004.

Of the 53 Complaints worldwide, 8 had implants in place at the time of diagnosis where the manufacturer was listed as unknown. Out of the 8 cases with implants in place at the time of diagnosis from unknown manufacturers, all 8 had an unknown surface type.

In France, between 2004 and 2015, a total of 11 confirmed ALCL complaints were received. Out of those 11 complaints, 8 were implanted or manufactured between 2004 and 2015 and three were implanted or manufactured prior to 2004.

For the eight Complaints in France that were implanted or manufactured between 2004 and 2015, all had Allergan implants in place at the time of diagnosis.