

# Breast Implant-Associated Anaplastic Large-Cell Lymphoma (BIA-ALCL)

Federal Agency for Medicines and Health Products

BRUSSELS

29th March 2018

Kelly Decaluwe

# Overview

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# National level

## About the FAMHP

**Federal Agency for Medicines and Health Products, famhp** (former Directorate-General for Medicines and Health Products of the FPS Public Health)

**Created:** 01.01.2007

**Minister responsible:** Maggie De Block, Minister of Social Affairs and Public Health

**Chief Executive Officer:** Xavier De Cuyper **Public service institution with a legal personality classified under category A** Competent authority for the quality, safety and efficacy of medicines and health products **Fields of competency:** research and development (R&D), registration and marketing authorisation, production and distribution (inspection and control activities), vigilance, proper use of medicines and health products **Personnel:** 390 employees on 01.01.2012 most with scientific qualifications (doctors, pharmacists, veterinarians) **Slogan:** "Your medicines and health products are our concern."



### Who are we ?

The famhp is the competent authority responsible for the quality, safety and efficacy of medicines and health products. We work together with health professionals and other competent authorities at the national and international level to ensure the population the optimal use of the medicines and health products they need.

### Our fields of competency or activities.

In terms of **research and development (R&D)** the famhp evaluates, approves, follows and controls the requests for clinical trials for medicines and health products. We also give scientific advice.

In terms of **registration or marketing authorisation of medicines**, the famhp is in charge of evaluating new requests for registration or marketing authorisation of a medicine or of requests to change existing registrations or marketing authorisations.

In terms of **vigilance** the famhp supervises the adverse effects due to the use of medicines or health products by collecting information. Information is gathered and evaluated and, if necessary, measures are taken.

In terms of **production and distribution** the famhp grants authorisations and checks that medicines and health products conform current regulations concerning manufacture, distribution, delivery, imports and exports. It also controls pharmacists' activities and combats illegal practices.

In terms of **proper use** the famhp sees to it that patients have relevant information so that medicines and health products are used rationally and safely. It also controls advertising for medicines and health products.



# National level

January 2015: 0 entries in our database



# National level (current projects)

January 20



Als lid van deze werkgroep wenst het fagg zich te verdiepen in de vraag naar de actuele incidentie van ALCL in vrouwen met borstimplantaten alsook de klinische kenmerken van deze aandoening. Daarom startte het fagg een samenwerking met het Belgisch Kankerregister om alle ALCL casussen bij vrouwen met borstimplantaten te kunnen detecteren. Hierdoor hebben we reeds 1 mogelijke casus gedetecteerd die niet rechtstreeks aan de cel materiovigilantie van het fagg werd gemeld. Ik zou daarom graag uw aandacht vestigen op het feit dat het Koninklijk Besluit van 18 maart 1999 betreffende medische hulpmiddelen recent werd gewijzigd (Belgisch Staatsblad 17/02/2015) en nu ook een verplichting inhoudt voor de contactpunten materiovigilantie binnen verzorgingsinstellingen om alle incidenten te rapporteren aan het fagg waar mogelijk een causaal verband bestaat met het medisch hulpmiddel (art. 11 § 1 and 2). Gelieve er rekening mee te houden dat het fagg de diagnose van ALCL in vrouwen met borstimplantaten als een rapporteerbaar incident beschouwt en dus verwacht dat verzorgingsinstellingen dergelijke casussen melden. Vanzelfsprekend worden alle meldingen op een strikt confidentiële manier behandeld.

Ondernemingsnummer: BE 0884 579 424

1 | 2



*(Texte en français ci-dessous)*

Geachte dokter,  
Geachte oncoloog,

Het fagg wenst u te contacteren in uw ho

In bijlage vindt u een communicatie van h  
([meddev@fagg.be](mailto:meddev@fagg.be)) te melden.

Er is heel wat wetenschappelijke literatuur

Anaplastic large cell lymphoma oc  
Mar;135(3):695-705.

SCENIHR rapport: <http://ec.europ>

Indien u nog bijkomende vragen en/of op

Met de meeste hoogachting,

Het aantal meldingen dat wij ontvangen zal vergeleken worden met het totaal aantal ALCL diagnoses geregistreerd bij het Belgisch Kankerregister. Dit zal ons de mogelijkheid bieden om samen met de andere Europese competente autoriteiten dit probleem gedetailleerd in kaart te brengen en na te gaan of het noodzakelijk is om risicobeperkende maatregelen te ondernemen opdat de veiligheid van de patiënten gegarandeerd wordt.

Hierbij wil ik echter nogmaals benadrukken dat ALCL in vrouwen met borstimplantaten een zeer zeldzame aandoening is. Om deze reden adviseert het fagg niet om profylactisch de borstimplantaten te verwijderen bij patiënten die geen symptomen of andere abnormaliteiten vertonen. Als we in de toekomst meer zicht krijgen op de problematiek, kan dit advies nog veranderen.

Dit schrijven is vooral gericht om uw aandacht erop te vestigen dat er een mogelijk causaal verband bestaat tussen borstimplantaten en ALCL en om alle zorgverleners te verzoeken bevestigde ALCL casussen bij vrouwen met borstimplantaten aan de cel materiovigilantie binnen het fagg (e-mailadres: [meddev@fagg.be](mailto:meddev@fagg.be)) te melden.

ilantie binnen het fagg

istr Surg. 2015



# National level (current projects)

January 2015: 0 entries in our database



Retrospective Study in collaboration with the Belgian Cancer Registry



2 BIA-ALCL cases identified



Communication launched to increase awareness amongst clinicians and emphasize reporting obligation

March 2018: 6 entries in our database



# National level (future projects)



## Formulaire de notification d'incident avec un dispositif médical

1. Informations administratives	
<b>Destinataire (autorité compétente)</b> Agence fédérale des médicaments et des produits de santé	<b>Date du rapport</b>
<b>Adresse</b> Place Victor Horta 40/40 1060 Bruxelles meddev@afmps.be	
<b>Numéro de référence de l'incident chez le notificateur</b>	<b>Numéro de référence du fabricant</b>
<b>Numéro de référence de l'afmps</b>	

2. Informations concernant le point de contact matériovigilance des Institutions de soins ou le notificateur	
<b>Nom et fonction</b>	
<b>Adresse e-mail</b>	
<b>Nom de l'Institution de soins</b>	
<b>Rue et numéro</b>	
<b>Code postal</b>	<b>Ville</b>
<b>Numéro de téléphone</b>	<b>Numéro de fax</b>





# National level (future projects)

ALCL melding.xlsx - Excel

Decaluwe Kelly

	A	B	C	D	E	F	G	H	I	J	K	L	M
	Case reference	Date of Birth	Patient Initials	Device at Diagnosis Silicone / Saline, Smooth / Textured, Name MF, References, ...	Implant indication reconstructive / aesthetic	Implantation time	Previous implants yes / no (if known, please provide more info on previous implant)	Symptoms (Description + time indication)	BIA-ALCL Diagnosis (Description + time indication)	BIA-ALCL Stage	BIA-ALCL Treatment	Follow-up	
1	Example	1/jan/80	KD	Silicone, Textured, Reference unknown	Reconstructive	2006	Yes	Seroma (2011)	CD30+ / ALK- (2012)	T1N1M0	Implant removal + total capsulectomy + chemotherapy	Remission	
2													
3													
4													
5													
6													
7													
8													
226													
227													
228													
229													
230													
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232													
233													
234													
235													

Blad1



# National level (future projects)

ALCL melding.xlsx - Excel

BESTAND START INVOEGEN PAGINA-INDELING FORMULES GEGEVENS CONTROLLEREN **BEELD**

Normalaal Pagina-eindevoorbeeld weergeven Pagina-indeling weergeven Aangepaste indeling weergeven

Lijnaan  Formulebalk  Rasterlijnen  Koppen

In-/uitzoomen 100% Inzoomen op selectie

Nieuw venster Alle vensters Blokkeren Verbergen Splitsen Verbergen

Naast elkaar weergeven Synchroon schuiven Vensterpositie herstellen

Ander venster Macro's

A2 Example

Case reference	Date of Birth	Patient Initials	Device at Diagnosis Silicone / Saline, Smooth / Textured, Name MF, References, ...	Implant indication reconstructive / aesthetic	Implantation time	Previous implants yes / no (if known, please provide more info on previous implant)	Symptoms (Description + time indication)	BIA-ALCL Diagnosis (Description + time indication)	BIA-ALCL Stage	BIA-ALCL Treatment	Follow-up
Example				Reconstructive	2006	Yes	Seroma (2011)	CD30+ / ALK- (2012)	T1N1M0	Implant removal + total capsulectomy + chemotherapy	Remission

- Less administrative burden
- Effective in follow-up of suspected cases
- Additional documentation only requested upon confirmation of diagnosis
- Patients should be identifiable for healthcare professionals via ID references to avoid duplicates

[ALCL@fagg-afmps.be](mailto:ALCL@fagg-afmps.be)




# National level (future projects)



# National level (future projects)



**Scientific Committee on  
Health Environmental and Emerging Risks  
SCHEER**

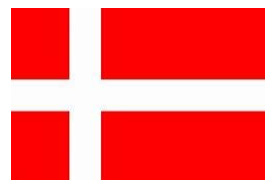
A	B	E	F	G	H	I	J	K	L	M	N	O
Member State	Id Incident	Filler	Surface	Implantation Time	Previous Breast Implants	Implant Indication	Patient Age (year)	Symptoms (Late Seroma, Capsular Contracture, Mass, etc.)	ALCL Diagnosis (CD30+, ALK-, etc.)	ALCL Stage	ALCL Treatment	Follow-up (ALCL remission/Patient death)
BE01	17576	Silicone	Textured	11/04/2012: replacement of the bilaterale protheses (2nd prothesis)	1992: no information available; protheses were performed in another hospital	1992 esthetic surgery; 2012:	age at first prothesis : 49;	Bilaterale capsular rupture	ALCL ALK-	Ann Arbor I E	ALCL diagnosed in right breast. Tumorectomy and 2 cycles ACVBP ( adriamycine-cyclophosphamide-bleomycine-vindesine-dexamethasone); 2 cycles of CHOP (cyclophosphamide-adriamycine-vincristine-prednison); 2 cycles of MXT HD ( methotrexate high dose), Autologous transplant consolidated with BEAM([camustine (BICNU), etoposide, cytosine-arabinoside and melphalan)	Remission
BE02	18482	Silicone	Textured	30/04/2011	un				ALCL CD30+	unknown	total capsulectomy , chemotherapy and bone marrow transplantation	remission
BE03	18862	Silicone	Textured	dec/12	2i				ALCL ALK- CD30+	unknown	implant removal and total capsulectomy	remission
BE04	19343	Silicone	Textured	apr/06	N				ALCL ALK- CD30+	unknown	removal implants and total capsulectomy	remission
BE05	23747	UNKNOWN	UNKNOWN	x/2014	1i	RUCTION		inferomedial redness quadrant left breast and subcutaneous metastatic nodules right arm	ALCL ALK- CD30+	Ann Arbor IV	removal implants and total capsulectomy and protocol Rhomidepsine-CHOP 6 cycles every 21 days	Remission
BE06	24083 and 24330	Silicone	Textured	28/10/2008	unknown	UNKNOWN	unknown	Periprosthetic seroma	ALCL	unknown	removal implants and total capsulectomy	unknown

The SCHEER adopted this final Scientific Advice  
by written procedure on 19 October 2017

# European level



**TASK  
FORCE**



# Worldwide level

U.S. Department of Health and Human Services  
**FDA U.S. FOOD & DRUG ADMINISTRATION**  
 A to Z Index | Follow FDA | En Español  
 Search FDA

Home | Food | Drug  
**Medical Devices**  
 Home > Medical Devices >

Australian Government  
 Department of Health  
 Therapeutic Goods Administration  
 Search TGA

Government of Canada / Gouvernement du Canada  
 Canada.gc.ca | Services | Departments | Français

**Recalls and safety alerts**  
 Canada

Recalls & alerts | Kids | Food | Your Health | Environment | Consumer products  
 Home > Recalls & alerts  
 Share | Contrast | Print

**Breast Implants - Risk of Anaplastic Large Cell Lymphoma (BIA-ALCL)**  
 Report a Concern

**Starting date:** November 24, 2017  
**Posting date:** November 24, 2017  
**Type of communication:** Dear Healthcare Professional Letter  
**Subcategory:** Medical Device  
**Source of recall:** Health Canada  
**Issue:** New safety information  
**Audience:** Healthcare Professionals  
**Identification number:** RA-65188

Issue | Who is affected | Report health or safety concerns

**Audiences**  
 Healthcare professionals including family physicians, obstetricians and gynaecologists, oncologists, general pathologists and hematopathologists, hematologists, radiologists, general and plastic surgeons.

**Key messages**

- Rare cases of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) have been reported in Canada and internationally.
- Available data, from literature and international regulators, suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces compared to those with smooth surfaces.
- Healthcare professionals are encouraged to learn more about the signs, symptoms and testing steps to recognize and diagnose BIA-ALCL.
- Health Canada is working with manufacturers to update this safety information on the product labelling for breast implants.

**Issue**  
 A safety review on the risk of BIA-ALCL was initiated by Health Canada to determine a Canadian-specific rate of BIA-ALCL cases relative to the number of implants sold over the past 10 years. The safety review determined that the rate of BIA-ALCL reported to Health Canada is low and

A- A+ Share

**Related information**

- [Information for women with breast implants](#)
- Information for consumers and patients with breast implants is available from healthdirect Australia
- [Breast implants \(all alerts\)](#)

[ical study](#) of patients in

[issue](#) on 23 March 2017.

alth professionals' contained been updated slightly.

**stic large cell**

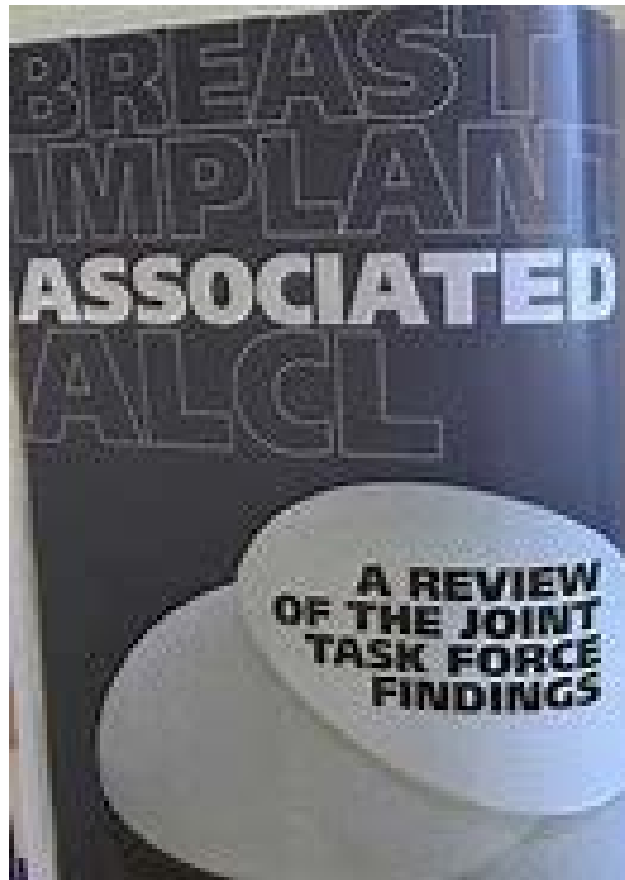


# Worldwide level





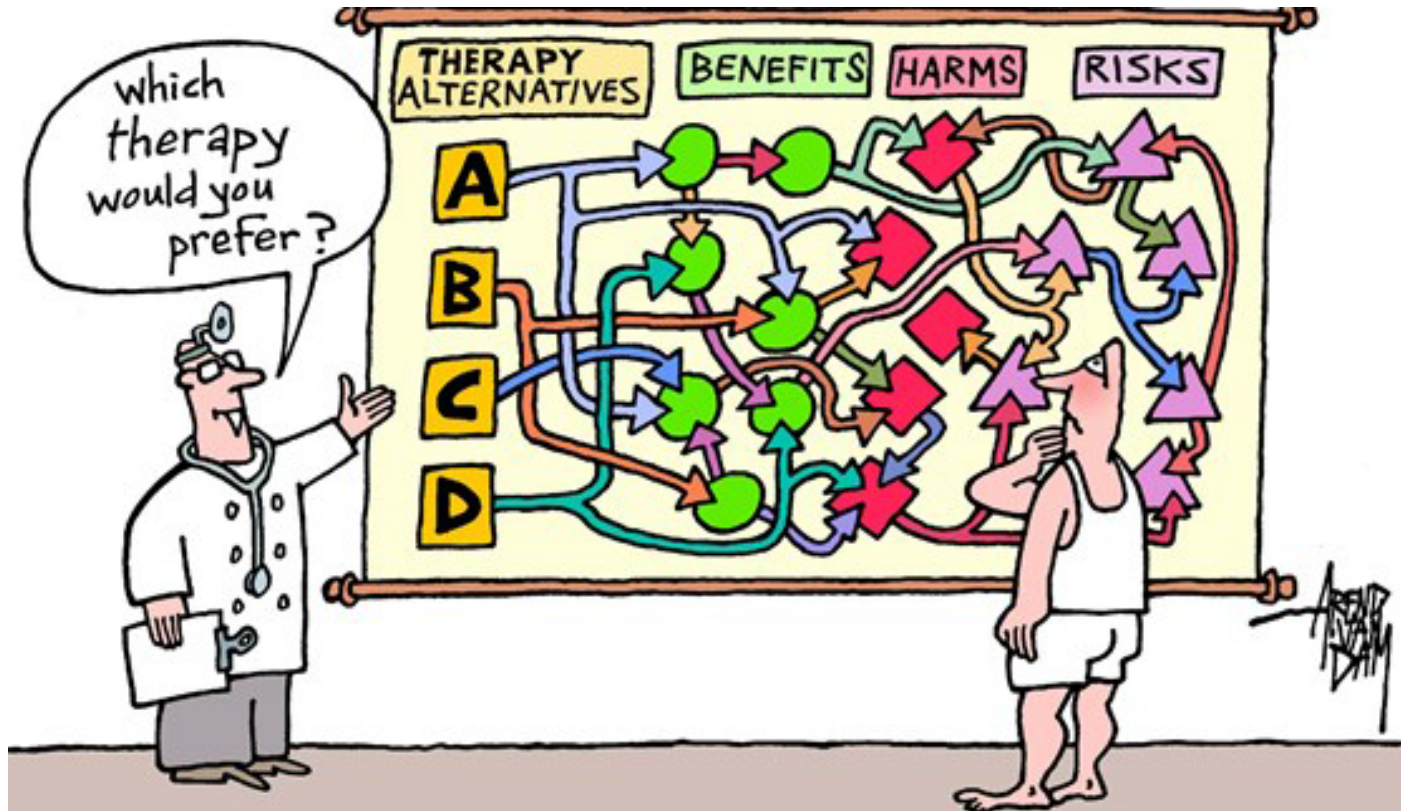
# Task Force findings



# Measures to ensure patient safety



# Measures to ensure patient safety





# Contact

## Federal Agency for Medicines and Health Products – FAMHP

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1060 BRUXELLES

tel. + 32 2 528 40 00

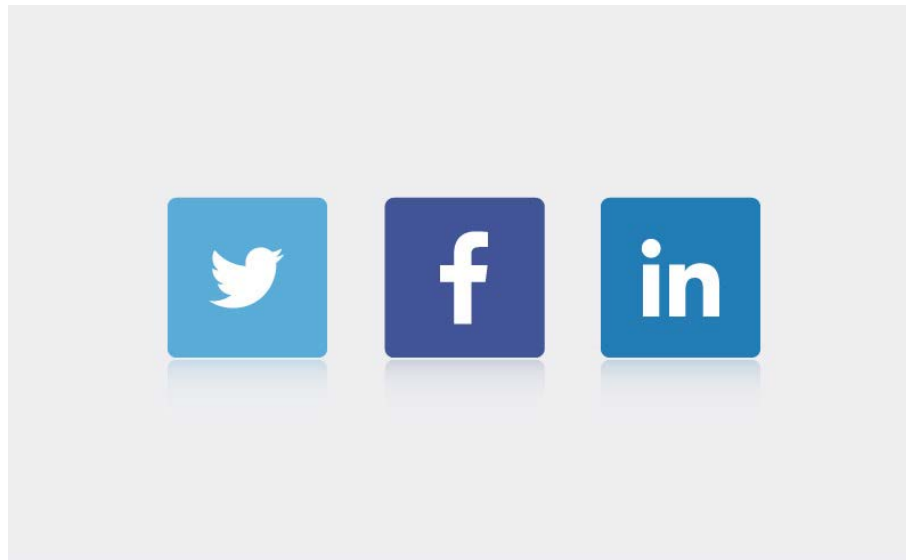
fax + 32 2 528 40 01

e-mail [meddev@fagg-afmps.be](mailto:meddev@fagg-afmps.be)  
[alcl@fagg-afmps.be](mailto:alcl@fagg-afmps.be)

[www.afmps.be](http://www.afmps.be) – [www.fagg.be](http://www.fagg.be)



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A large, stylized graphic of a human eye, rendered in light blue and grey tones, serves as the background for the central text. The eye is composed of a central iris, a pupil, and a surrounding sclera, all depicted with soft, rounded edges.

Your medicines and health products,  
our concern

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