[redacted]

From: [redacted]@health.gov.au>
Sent: Thursday, 24 August 2017 2:23 PM
Subject: RE: Field Safety Notice - 14 to 18 August 2017 [SEC=UNCLASSIFIED]

Yes theres actions I am working on today – basically its being recalled and no longer supplied and I am doing a Hazard Alert with TGA Comms.

[redacted]

From: [redacted] **On Behalf Of** Recalls
Sent: Thursday, 24 August 2017 10:42 AM
To: [redacted]
Cc: [redacted] Recalls
Subject: FW: Field Safety Notice - 14 to 18 August 2017 [SEC=UNCLASSIFIED]

[redacted]

Re: temporary suspension of clinical use for Essure.

We received the attached notification via MHRA, which halts the distribution of CE marked product. Can you please advise if this has any relevance to the Australian market.

The recent Essure recall action is under E17-15547

[redacted]

I am including you in this as [redacted]s away, FYI and input if necessary.

Kind Regards,

Recalls and Case Management Section
Manufacturing Quality Branch

Phone: [redacted]
Fax: [redacted]
Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] **On Behalf Of** Recalls
Sent: Tuesday, 22 August 2017 4:34 PM
To: Recalls
Subject: FW: Field Safety Notice - 14 to 18 August 2017 [SEC=UNCLASSIFIED]

Please liaise with [redacted] if [redacted] is aware of the recent alert.

Bayer: Essure

16 August 2017

Implants, non active, contraceptive implants

Model: ESS305

MHRA reference: 2017/008/017/121/008

Departmental Officer
Recalls
Manufacturing Quality Branch
Departmental Officer
Recalls
Manufacturing Quality Branch

Phone: [redacted] Fax: [redacted]
Email: [redacted]@tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: GOV.UK [mailto:GOVUK@public.govdelivery.com]
Sent: Tuesday, 22 August 2017 12:13 AM
To: Recalls
Subject: Field Safety Notice - 14 to 18 August 2017 [SEC=No Protective Marking]

[redacted]

Alerts and recalls for drugs and medical devices

Field Safety Notice - 14 to 18 August 2017

Summary List of field safety notices (FSNs) from medical device manufacturers from 14 to 18 August 2017

Update: First published.

For further information on this published alert:

https://www.gov.uk/drug-device-alerts/field-safety-notice-14-to-18-august-2017

This is an automatically generated email, enquiries should be sent to: email.support@mhra.gov.uk

Field Corrective Action

Request for voluntary, temporary suspension of clinical use for Essure® product

16 August 2017
Amit Aggarwal
Director Medical Affairs
General Medicine

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United Kingdom

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Dear Healthcare Professional,

Bayer would like to inform you that our relevant certification body, The National Standards Authority of Ireland (NSAI) did not renew the CE Mark certificate to market Essure® in the European Union (EU) because not all queries associated with the recertification review were closed out prior to the expiration date of August 3rd, 2017. The NSAI decided to suspend the CE Mark, for up to 90 days, during which time all outstanding queries could be resolved. Based on this decision, Bayer has halted the distribution of CE marked product that is under Bayer's control. This decision supersedes Bayer UK's previous plan to discontinue sales and distribution as of 1st September 2017, as previously communicated. This suspension of the Essure CE Mark is not related to product safety or quality issues.

A voluntary suspension of further fitting is recommended. If you currently hold stock, Bayer recommends suspending the implantation of all Essure® medical devices until discussions regarding the CE certification are concluded.

Please take the following actions:

- Temporarily suspend any implantation of Essure®;
- Review your current inventory and, if you have unused Essure® units, temporarily quarantine remaining inventory until further notice.

The recommendation to temporarily suspend clinical use does not constitute a recall. Bayer would like to emphasize that recent independent expert reviews of Essure® carried out by medical devices safety authorities and by NICE have concluded that Essure® has a positive benefit / risk profile[1,2,3].

For patients who already have Essure implanted, a Patient Information document is enclosed.

Bayer is fully committed to support you in this matter and remain at your disposal should you have any questions. You may contact Bayer UK Medical Information team on 0118 206 3116 or medical.information@bayer.co.uk.

UKESS08170014a
Date of preparation August 2017

Yours sincerely,

[redacted]

[redacted]

References

[1] NICE Interventional Procedures Guidance: Hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implants [IPG587]; July 2017. Available at: https://www.nice.org.uk/guidance/ipg587

[2] FDA Essure Benefits and Risks. November 2016. Available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452250.htm

[3] Bouquet et al. Rapport bénéfice risque du dispositif de stérilisation définitive Essure® 30 May 2017. Available at: www.ansm.sante.fr

Date: 16/08/2017

Information for Essure® Patients

Bayer's certification body for Essure®, The National Standards Authority of Ireland (NSAI), has not been able to renew the CE Mark certificate to market Essure® in the European Union (EU). This is because not all queries associated with the recertification review were closed out prior to the due expiry date of August 3rd, 2017. The NSAI decided to suspend the CE Mark temporarily to allow for outstanding queries to be resolved. Based on this decision, Bayer's sales and distribution of Essure® have been stopped in the UK as of the 4th August 2017. This decision supersedes Bayer UK's previous plan to discontinue sales and distribution from 1st September 2017. This suspension of the Essure CE Mark is not a recall.

Patient safety and appropriate use of Essure are our greatest priorities and Bayer fully stands behind Essure as an appropriate choice for women who desire permanent contraception. In our scientific assessment, the favourable benefit-risk profile[1,2] of Essure, which is based on a comprehensive clinical development programme and more than a decade of post-marketing experience[3,4,5,6,7,8] worldwide, remains unchanged. We would also like to emphasize that recent independent expert reviews of Essure® carried out by medical devices safety authorities and by NICE have concluded that Essure® has a positive benefit / risk profile[1,9,10].

Women who currently have Essure in place can continue to rely on the device and should have no concern based on this decision. Furthermore, Bayer will continue to fully support women with Essure in place and Healthcare Professionals who have questions on the product. Women and Healthcare Professionals can contact Bayer UK Medical Information team on 0118 206 3116 or medical.information@bayer.co.uk in case of questions or a need to report a suspected product related adverse event.

Yours sincerely,

[redacted]

[redacted]

UKESS08170014b
Date of preparation August 2017

References

[1] NICE Interventional Procedures Guidance: Hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implants [IPG587]; July 2017. Available at: https://www.nice.org.uk/guidance/ipg587

[2] FDA Essure Benefits and Risks. November 2016. Available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452250.htm

[3] Cooper J. Microinsert nonincisional hysteroscopic sterilization. Obstetrics & Gynecology. 2003;102(1):59-67. doi:10.1016/s0029-7844(03)00373-9.

[4] Chudnoff S, Nichols J, Levie M. Hysteroscopic Essure Inserts for Permanent Contraception: Extended Follow-Up Results of a Phase III Multicenter International Study. Journal of Minimally Invasive Gynecology. 2015;22(6):951-960. doi:10.1016/j.jmig.2015.04.017.

[5] Kerin J, Carignan C, Cher D. The safety and effectiveness of a new hysteroscopic method for permanent birth control: results of the first Essure TM pbc clinical study. The Australian and New Zealand Journal of Obstetrics and Gynaecology. 2001;41(4):364-370. doi:10.1111/j.1479-828x.2001.tb01311.x

[6] Kerin J. Hysteroscopic sterilization using a micro-insert device: results of a multicentre Phase II study. Human Reproduction. 2003;18(6):1223-1230. doi:10.1093/humrep/deg256 Cooper J. Microinsert nonincisional hysteroscopic sterilization. Obstetrics & Gynecology. 2003;102(1):59-67. doi:10.1016/s0029-7844(03)00373-9.

[7] Levie M, Chudnoff S. A comparison of novice and experienced physicians performing hysteroscopic sterilization: an analysis of an FDA-mandated trial. Fertility and Sterility. 2011;96(3):643-648.e1. doi:10.1016/j.fertnstert.2011.06.047.

[8] Munro M, Nichols J, Levy B, Vleugels M, Veersema S. Hysteroscopic Sterilization: 10-Year Retrospective Analysis of Worldwide Pregnancy Reports. Journal of Minimally Invasive Gynecology. 2014;21(2):245-251. doi:10.1016/j.jmig.2013.09.016.

[9] FDA Essure Benefits and Risks. November 2016. Available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452250.htm

[10] Bouquet et al. Rapport bénéfice risque du dispositif de stérilisation définitive Essure® 30 May 2017. Available at: www.ansm.sante.fr