

**Vigilance databases**

Dit overzicht bevat rechtstreekse verwijzingen naar de vigilantie databases van de genoemde bevoegde autoriteiten. Het kan dienen als bron voor post-market surveillance activiteiten.

Het overzicht wordt voortdurend aangevuld en getoetst op juiste werking van de koppelingen. Indien u wijzigingen of aanvullingen heeft, kunt u die aangeven bij Team FSCA via [info@fsca.com](mailto:info@fsca.com). U ontvangt dan van ons de meest recente versie.

Versiebeheer

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| Nr. | Auteur | Datum | Opmerkingen |
| 3 | R. Drost | 25-3-2021 | Verspreid na IGJ webinar d.d. 11 maart 2021 |

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| **Country** | **Database** | **Website** |
| Australia | Database of Adverse Event Notifications - medical devices: TGA DAEN | <https://apps.tga.gov.au/prod/DEVICES/daen-entry.aspx> |
| System for Australian Recall Actions: TGA SARA | <https://apps.tga.gov.au/PROD/SARA/arn-entry.aspx> |
| Belgium | Famhp database | French version:  <https://www.afmps.be/fr/humain/produits_de_sante/dispositifs_medicaux/materiovigilance/fsn>  Dutch version:  <https://www.fagg.be/nl/MENSELIJK_gebruik/gezondheidsproducten/medische_hulpmiddelen_hulpstukken/materiovigilantie/fsn> |
| Brazil | ANVISA (Alertas) | <https://www.gov.br/anvisa/pt-br> |
| Canada | Health Canada | h[ttp://www.healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3](http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3) |
| France | ANSM | <https://ansm.sante.fr/S-informer/Informations-de-securite-Retraits-de-lots-et-de-produits> |
| Germany | BfArM | [https://www.bfarm.de/SiteGlobals/Forms/Suche/EN/kundeninfo\_Filtersuche\_Formu lar\_en.html](https://www.bfarm.de/SiteGlobals/Forms/Suche/EN/kundeninfo_Filtersuche_Formular_en.html) |
| Hong Kong | Hong Kong Department of Health | [https://www.mdd.gov.hk/english/safety/s afety.html](https://www.mdd.gov.hk/english/safety/safety.html) |
| Ireland | HPRA | <http://www.hpra.ie/homepage/medical-devices/safety-information/safety-notices> |
| Italy | Salute | [www.salute.gov.it/portale/news/p3\_2\_1.jsp?lingua=italiano&menu=notizie](http://www.salute.gov.it/portale/news/p3_2_1.jsp?lingua=italiano&menu=notizie) |
| Japan | PMDA | <https://www.pmda.go.jp/english/safety/info-services/devices/0001.html> |
| Netherlands | IGJ | <https://www.igj.nl/onderwerpen/waarschuwingen-medische-hulpmiddelen/documenten> |
| Portugal | SNS-INFARMED | <https://www.infarmed.pt/web/infarmed/alertas/dispositivos-medicos> |
| Saudi Arabia | SFDA | <https://old.sfda.gov.sa/en/medicaldevices/eservices/Pages/default.aspx> |
| Singapore | HSA | <https://www.hsa.gov.sg/announcements> |
| Spain | AEMPS | <https://sinaem4.aemps.es/alertas/alertasPublicadas.do> |
| Sweden | Lakemedelsverket | <https://www.lakemedelsverket.se/sv/nyheter?c=239&c=77&p=2> |
| Switzerland | Swiss Medic | <https://fsca.swissmedic.ch/mep/#/> |
| United Kingdom | MHRA | <https://www.gov.uk/drug-device-alerts> |
| United States | Overview of databases | <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases> |
| MAUDE | <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm> |
| Medical Device Recalls | https://[www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm) |