EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

List of medicines under additional monitoring

The list of medicines under additional monitoring includes medicines authorised in the European Union (EU) that are being monitored particularly closely by regulatory authorities. Medicines under additional monitoring have a black inverted triangle displayed in their package leaflet and summary of product characteristics, together with a short sentence explaining what the triangle means.

The list includes centrally and nationally authorised medicines in the following categories:

- medicines that contain a new active substance that was not contained in any authorised medicine in the EU on 1 January 2011;
- biological medicines authorised after 1 January 2011 - this applies to all biological medicines including biosimilars;
- medicines for which the marketing-authorisation holder is required to carry out a post-authorisation safety study (PASS);
- medicines given conditional approval or authorised under exceptional circumstances and medicines authorised with specific obligations on the recording or monitoring of suspected adverse drug reactions.

Update - Summary of changes in April 2022

The following CAPs have been added to the list:

- Stimufend – New biological
- Sondelbay - New biological
- KIMMTRAK - New active substance and new biological
- Breyanzi - New biological, new active substance, PASS
- Padcev - New active substance and new biological

The following CAPs have been removed from the list:

- Tagrisso - Five years following its authorisation (February 2016)
- Veltassa - Five years following its authorisation (September 2017)
- Zynteglo - Withdrawal of marketing authorisation
- Oxervate - Five years following its authorisation (July 2017)
- Bosulif - Condition(s) to the marketing authorisation have been fulfilled
- Naglazyme - Condition(s) to the marketing authorisation have been fulfilled

- Kisqali - Five years following its authorisation (September 2017)
- Erelzi - Five years following its authorisation (July 2017)
- Reagila - Five years following its authorisation (July 2017)

The following NAP has been removed from the list:

- ENANPLUS (also known in some EU countries as Skudexa, Skudexum and Lenizak) - Tramadol hydrochloride/ dexketoprofen – PASS - PASS completed

List of medicines under additional monitoring

List of medicinal products under additional monitoring (PDF/667.75 KB) (updated)

First published: 25/04/2013
Last updated: 25/04/2022
EMA/245297/2013 Rev. 99

List of medicinal products under additional monitoring (XLSX/157.65 KB) (updated)

First published: 23/06/2013
Last updated: 25/04/2022
EMA/245297/2013 Rev. 99

Annex I - List of cyproterone-acetate / ethinylestradiol-containing medicinal products in the European Union (PDF/23.75 KB)

First published: 09/08/2013
Last updated: 26/06/2019
EMA/483088/2013 corr. 15*

Annex I - List of cyproterone-acetate / ethinylestradiol-containing medicinal products in the European Union (XLS/160 KB)

First published: 09/08/2013
Last updated: 26/06/2019
EMA/483088/2013 correction 15*

Annex V - List of hydroxyethyl starch (HES)-containing medicinal products in the European Union (PDF/134.99 KB)

First published: 29/01/2014
Last updated: 24/02/2021
EMA/48335/2014 corr. 6

Annex V - List of hydroxyethyl starch (HES)-containing medicinal products in the European Union (XLS/131.5 KB)

First published: 29/01/2014
Last updated: 24/02/2021
EMA/48335/2014 corr. 6

Annex IX - List of combined hormonal contraceptives containing chlormadinone in the European Union (PDF/110.05 KB)

First published: 25/06/2014
Last updated: 27/10/2021
EMA/344487/2014 Corr. 7*

Annex IX - List of combined hormonal contraceptives containing chlormadinone in the European Union (XLS/158.5 KB)

First published: 25/06/2014
Last updated: 27/10/2021
EMA/344487/2014 Corr.7*

Annex XIII - List of Valproate and related substances in the European Union (PDF/253.57 KB)

First published: 28/01/2015
Last updated: 27/10/2021
EMA/11799/2015 Corr. 4

Annex XIII - List of Valproate and related substances in the European Union (XLSX/124.24 KB)

First published: 28/01/2015
Last updated: 24/02/2021
EMA/11799/2015 Corr. 4

Annex XIV - List of Retinoid-containing medicinal products and related substances (acitretin, alitretinoin and isotretinoin) in the European Union (PDF/177.68 KB)

First published: 28/09/2018
Last updated: 24/02/2021
EMA/580272/2018

Annex XIV - List of Retinoid-containing medicinal products and related substances (acitretin, alitretinoin and isotretinoin) in the European Union (XLSX/114.88 KB)

First published: 28/09/2018
Last updated: 24/02/2021
EMA/580272/2018

- European public assessment reports (EPARs) for medicines under additional monitoring (opens in new window)
- Background information: Medicines under additional monitoring
- Product-information templates
- European Commission: The EU pharmacovigilance system

Topics

- Guidance
- Pharmacovigilance

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