EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Renewal of the Human Medicines Highlights Newsletter

PCWP/HCPWP joint meeting, 27 February 2024

Presented by Kaisa Immonen
Public and Stakeholders Engagement Department, EMA

Background refresher

- EMA's monthly newsletter intended primarily for patients, consumers and healthcare professionals
- New tool provided by European Commission: Newsroom – used by EC and its Agencies
- Opportunity to improve presentation and content to align with stakeholders' needs
- Survey and interviews with representatives of eligible organisations conducted in 2023: perception, likes and dislikes, areas for improvement


163 Issue 163 November 2022

EUROPEAN MEDICINES AGENCY

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
Published monthly by the European Medicines Agency

IN THIS ISSUE

Antivirals/anti-infectives 1
Cancer 1
Dermatology 2
Diabetes 2
Hepatology 3
Hormone system 3
Immune system 3
Nervous system 3
Ophthalmology 4
Rheumatology 4
Vaccines 4
Medicines under additional monitoring 4
Guidelines 4
Scientific committee and working party activities 5
Other publications on Covid-19 5
Other publications 5
Events 6
Explanation of terms used 8

This newsletter is addressed primarily to organisations representing patients, consumers and healthcare professionals. It provides a summary of key information relating to medicines for human use published during the previous month by the European Medicines Agency.

Information is selected based on recommendations from consulted patients, consumers and healthcare professionals, and does not necessarily cover all relevant information published by the Agency.

To receive each new issue of the newsletter, please click here RSS feeds, choose 'Human medicines highlights newsletter' and then click on 'Subscribe to this feed'. Please note, in order to be able to view RSS feeds you need one of the following: a modern web browser; a web-based news reader or a desktop news reader. For a list of RSS readers please refer to our RSS guide and follow the instructions from the selected RSS reader in order to add our newsletter feed.

You can find details on how to cancel / unsubscribe to an RSS feed on the RSS reader tool that you are using, for example Unsubscribe from an RSS Feed for users of Microsoft Outlook.

For further information on the processing of your personal data, please find EMA's Privacy statement regarding the sending of electronic newsletters click here.

Information on medicines

Antivirals/anti-infectives

New information on authorised medicines

- Xydalba (dalbavancin) - extension of indication
  Treatment of acute bacterial skin and skin structure infections

Cancer

New information on authorised medicines

- Brukinsa (zanubrutinib) - extension of indication
  Treatment of chronic lymphocytic leukaemia (a blood cancer)
- Libtayo (cemiplimab) C - extension of indication
  Treatment of cervical cancer

Key to symbols used

O Orphan medicine | Generic medicine | Biosimilar medicine | C Conditional approval | E Exceptional circumstances

Key improvement areas identified by stakeholders

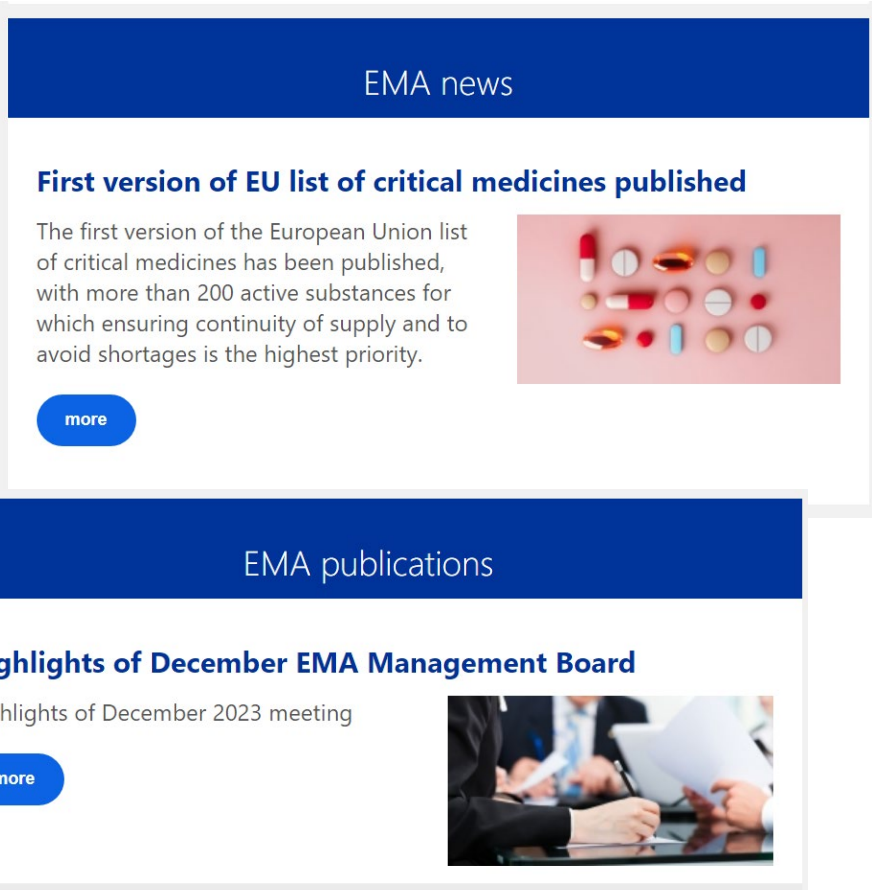
Improvement request	Implementation
Quickly find the information you need	Sections, teaser test explains what the item is about before you click
More information of general interest	Better grouping of information into sections Possibility to develop own content & add sections for recurring topics of interest
More information about how EMA involves patients	Standing item, links to online resources
Better notification of upcoming events and activities	Now a separate section distinct from past events, publications etc.
Multi-language newsletter	Implemented for online version
More attractive look	Improved through the new tool

New HMH newsletter: key features

- Arrives directly in your inbox, clearly visible as a newsletter
- Mobile-friendly interface
- Content divided into more logical sections
  - E.g. Upcoming events, publications, open consultations…
- Possibility to develop editorial content
  - e.g. theme issues, interviews
- Multi-language option available (automatic translation, online version)

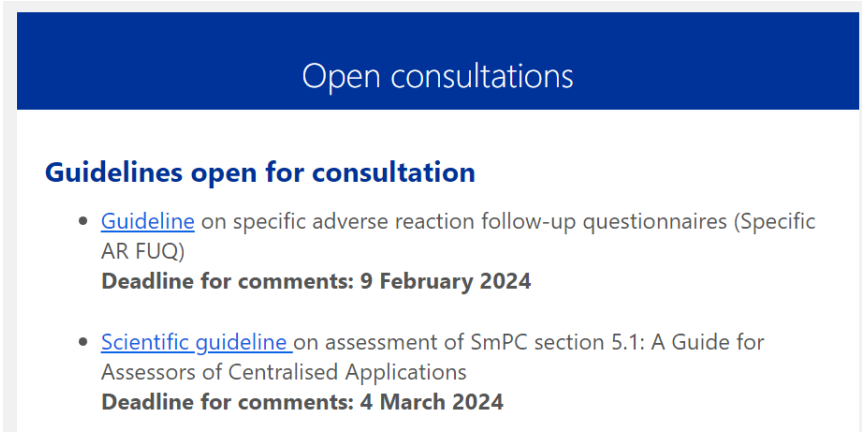
Structure

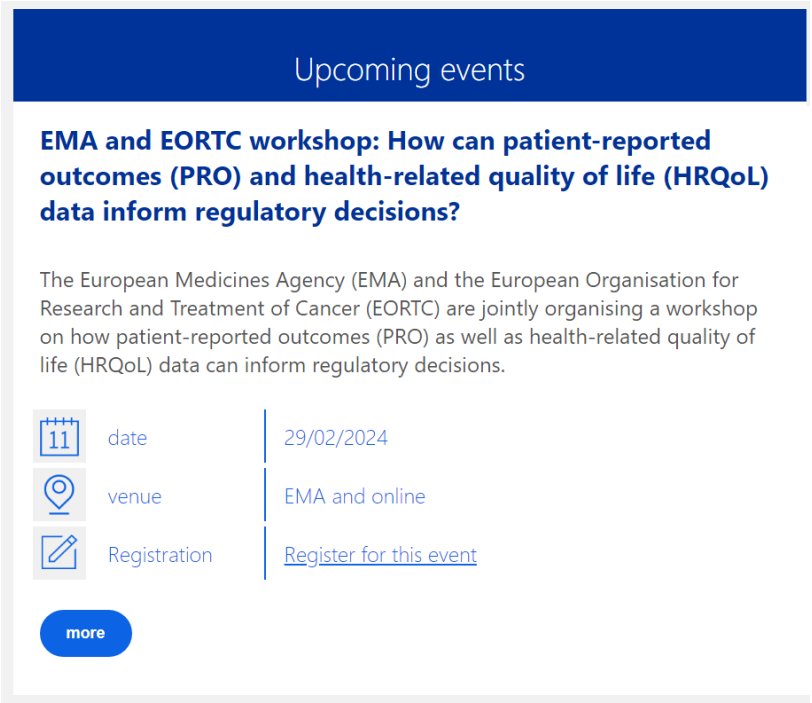
- Table of content: main sections
- Each section has 1+ items
- Most common item layout comprises
  - Title, short teaser text, (image)
- Click "more" to read full article online
- Hyperlinks will also lead to more information on EMA's website
- Each section will have an "up" button → back to top menu



Upcoming events and other 'actionable' news

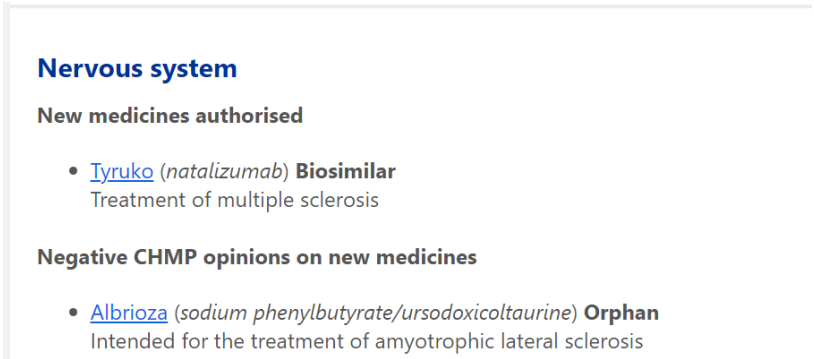
- Sections for upcoming events, open consultations, calls for expression of interest → more visible, action links





Information on medicines

- Newsroom currently does not enable click menu on therapeutic areas
- Hyperlinks point to web information as before
- Biosimilars, generics and orphans marked in bold text



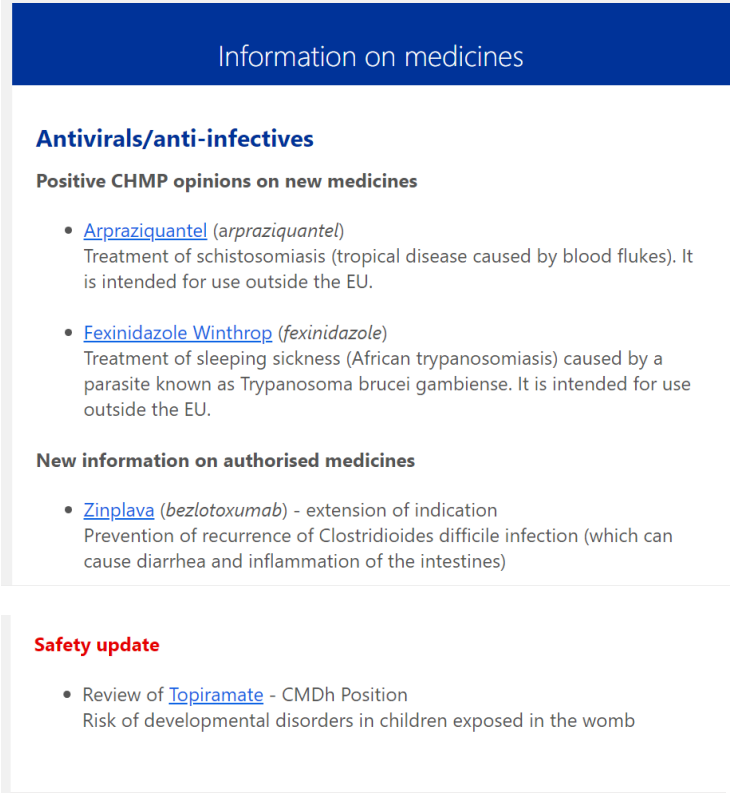
Nervous system

New medicines authorised

- Tyruko (*natalizumab*) **Biosimilar**
  Treatment of multiple sclerosis

Negative CHMP opinions on new medicines

- Albrioza (*sodium phenylbutyrate/ursodoxicoltaurine*) **Orphan**
  Intended for the treatment of amyotrophic lateral sclerosis



Information on medicines

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Arpraziquantel (*arpraziquantel*)
  Treatment of schistosomiasis (tropical disease caused by blood flukes). It is intended for use outside the EU.
- Fexinidazole Winthrop (*fexinidazole*)
  Treatment of sleeping sickness (African trypanosomiasis) caused by a parasite known as Trypanosoma brucei gambiense. It is intended for use outside the EU.

New information on authorised medicines

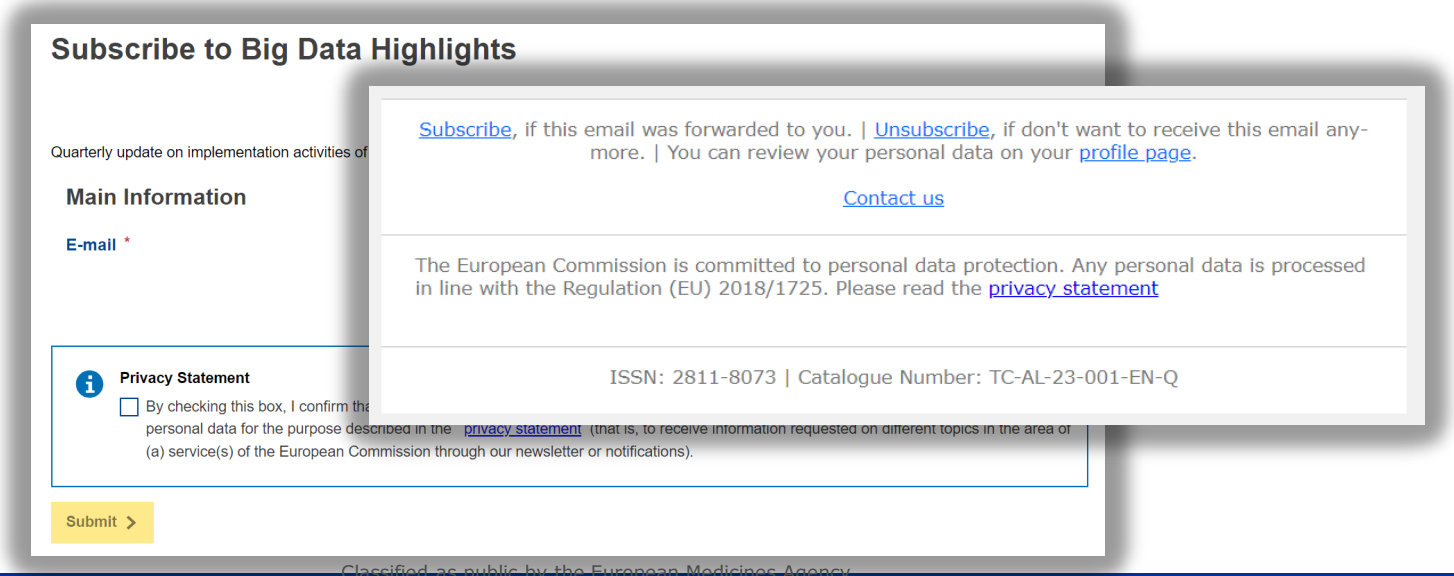
- Zinplava (*bezlotoxumab*) - extension of indication
  Prevention of recurrence of Clostridioides difficile infection (which can cause diarrhea and inflammation of the intestines)

Safety update

- Review of Topiramate - CMDh Position
  Risk of developmental disorders in children exposed in the womb

How to subscribe

- **Existing users will need to re-register**
- Link is included in current HMH Newsletter and will be on EMA's website



Next steps

- New HMH Newsletter implemented from April 2024
- Process of ongoing improvement
  - Exploration of potential improvements in the layout / menu
  - Further work on user-friendly language across platforms
- Development and planning of new content will continue
  - Editorials, themes, interviews…
  - Standing items, e.g. patient involvement
  - Exploration of how to present a section on shortages, signpost more effectively to already existing information (e.g. safety)…

Any questions?

Further information

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**