



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Use of EMA communications – Survey

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Use and perception of targeted communications to EMA's eligible Patients' and Consumers' Organisations (PCOs) and Healthcare Professionals' Organisations (HCPOs)

PCWP/HCPWP joint meeting, 2 June 2022

Presented by Elisabeth Fleck  
Public and Stakeholders Engagement Department





## Aim of today's presentation



Present results from the EMA targeted communications  
**Survey 2022**



**Share examples** of how organisations are communicating  
EMA information to their members

# EMA **targeted** communications to PCOs and HCPOs

Type of communication	Targeted stakeholder
Newsletters e.g. Human Medicines Highlights	Interested in Newsletters
CHMP communication Human medicines committee (CHMP)	As per indicated areas of interest
PRAC communication Safety committee (PRAC)	
Safety communication	
Ad-hoc communication	
Public consultation	All targeted stakeholders
Events / Invitation	



## Human Medicines Highlights Newsletter

Areas of interest:  
Newsletters




40



35

# EMA **targeted** communications to PCOs and HCPOs


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PRAC communication Safety committee (PRAC)	
Safety communication	
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Public consultation	All targeted stakeholders
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**CHMP communication**

Areas of interest:

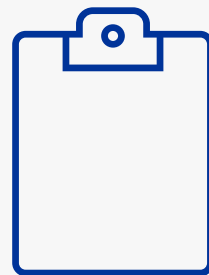
- oncology (blood)
- cell therapy



5



8



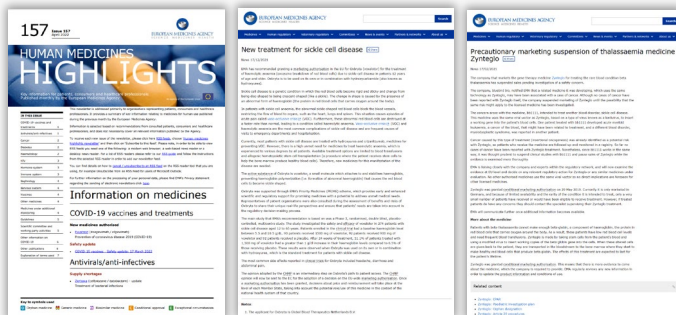
## EMA Targeted Communication Survey



# Objectives of the survey

## Relevance / Satisfaction of three types of EMA targeted communications

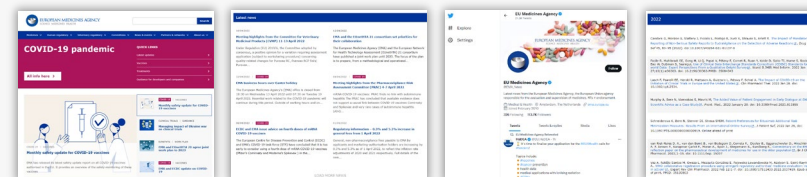
- Human Medicines Highlights Newsletter
- Committee communications (CHMP, PRAC)
- Safety communications



## Sharing practice / Communication channels



## EMA resources / EMA scientific publications



## Methodology

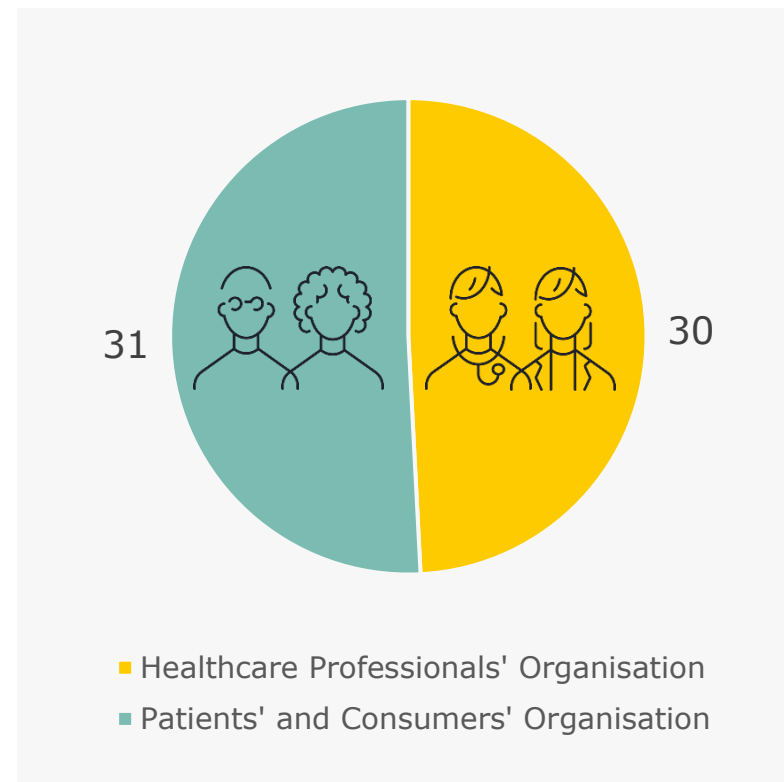
Target group: 78 eligible PCOs and HCPOs

Survey period: 28 Feb – 14 Mar 2022

Response rate: 14 (18%)

Personal follow-up e-mail on survey

Response rate: **61 (78%)**

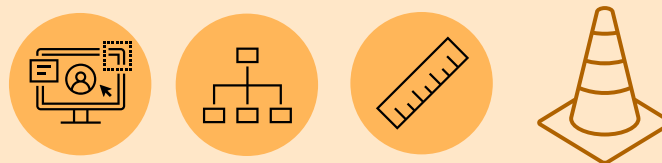


# Satisfaction with different aspects of EMA communications

EMA targeted communication materials are relevant for PCOs / HCPOs.



Overall, satisfaction with **content, language, length and timeliness** of EMA communications is **good** (64% to 75%).



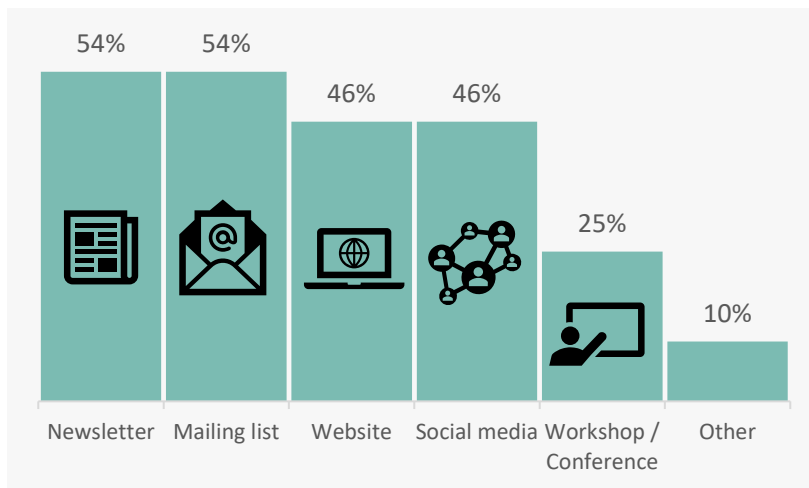
All communications could **improve** from changes to their **layout/visuals, structure, and length**.



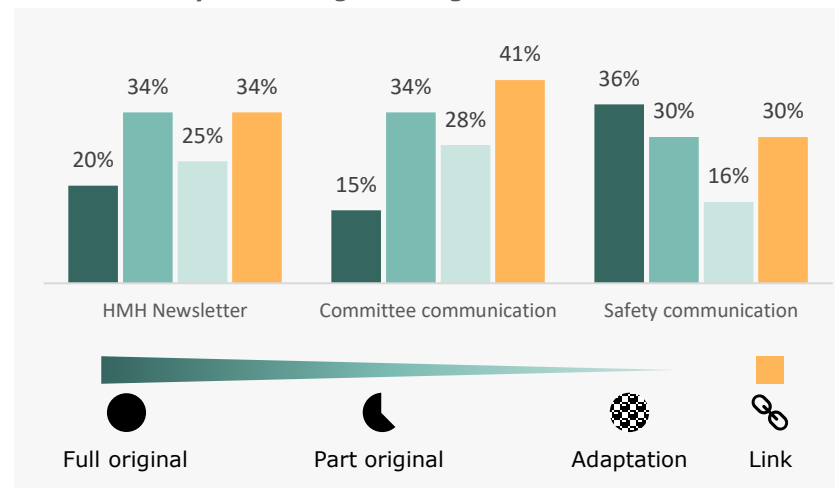
# Dissemination of EMA targeted communications

**More than half** of eligible organisations **regularly read** one or multiple types of EMA targeted communications.  
**About 1/3** of eligible organisations **regularly share** one or multiple types of EMA targeted communications.

Channels for sharing EMA targeted communications



Ways of sharing EMA targeted communications





# Your feedback: Why don't you share EMA communications?

Relevance

I **only** share information **relevant for our therapeutic area**.

**EMA approval is just one step** in the pathway to patients having access to a new treatment, so it can seem difficult to share info sometimes if **many health systems are not providing access**.

Sources of information

Doctors in the field **receive information otherwise**.

Communication overload

The **level of information** from EMA can feel **overwhelming**.

We always have a lot of **internal news** to share with our members, so we have to **prioritise** the kind of information we disseminate.

Usability

Sometimes the **language is very technical**, and we do **not have time / capacity** in-house to adapt it for a patient audience.

The decisions and content are **technical** and **not visually explanatory**.

## Key Findings

- EMA targeted communication materials are **relevant** for PCOs / HCPOs
- EMA communicates with PCOs / HCPOs in a **timely and clear manner**
- EMA targeted communication materials are **regularly disseminated by one third** of PCOs / HCPOs

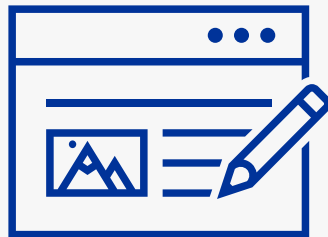
Reasons **not to disseminate** EMA targeted communication materials to members

- Not relevant to all members
- Avoid communication overload
- Ease of usability



Solutions already explored by EMA





- **Simplify the language** used in EMA communications
- Explore new ways of **structuring and visualising** EMA communications (e.g. via sub-headings) to increase usability



Examples of how organisations share EMA information

# Share a **link** of the EMA communication



 Full original
  Part original
  Adaptation
  Link

Where: News

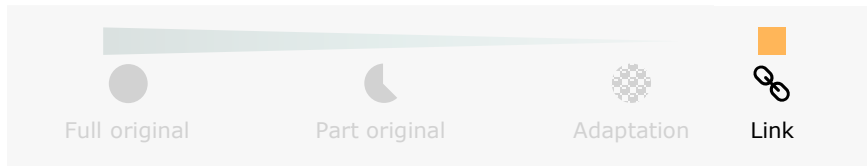
What: Safety communication

How: Link





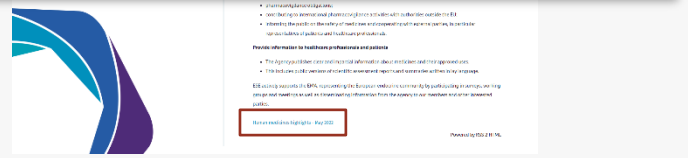
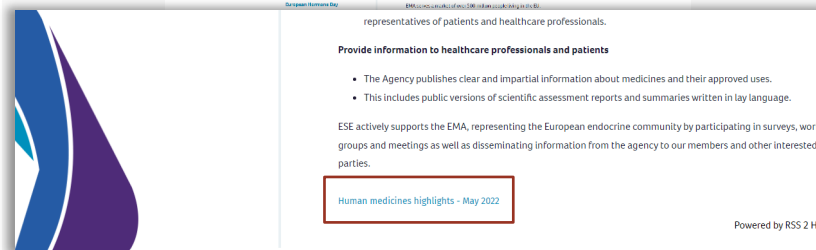
# Share a **link** of the EMA communication



Where: Dedicated EMA webpage

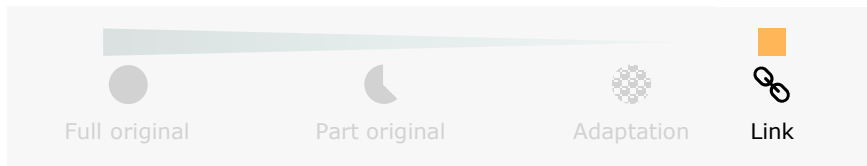
What: HMH Newsletter

How: Link to latest issue





# Share a **link** of the EMA communication



Where:      Newsletter – EU News section

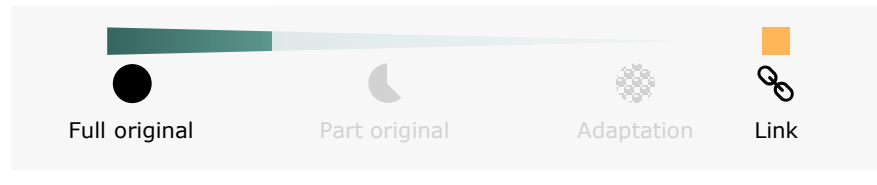
What:      Diverse EMA news

How:      Link



- [Latest on Brexit](#)
- [EMA recommends first COVID-19 vaccine for authorisation in the EU](#)
- [COVID-19 vaccination in the EU](#)
- [#VaccinesWork Toolkit for HCP is out](#)
- [New EC website on safe COVID-19 for Europeans](#)
- [EC presents "Staying safe from COVID-19 during winter" strategy](#)
- [EC launches Re-open EU mobile app for regular updates on coronavirus](#)
- [EC publishes Expert Group report on methods to assess health systems resilience](#)
- [EC welcomes adoption of the EU's long-term budget for 2021-2027](#)
- [OECD and EC launch 'Health at a Glance' report and factsheets](#)
- [Eurostat - Healthcare expenditure across the EU](#)
- [WHO launches global and European actions on NCDs](#)
- [Horizon 2020 awarded €508m to 75 health research projects in 2020](#)
- [EHFG 2020 conference outcomes](#)
- [Portugal takes over the Council of the EU Presidency from Jan-June 2021](#)
- [WHO publishes the Global Strategy to eliminate cervical cancer](#)
- [WHO launches year-long campaign for World No Tobacco Day 2021](#)
- [WHO/Europe's new factsheet on alcohol and cancer](#)
- [EC takes first steps towards building a European Health Union](#)
- [ECL YAs call for a strong EU Health Union](#)
- [EC adopts EU Pharmaceutical Strategy](#)
- [EC welcomes political agreement on EU4Health](#)
- [First BECA newsletter is out](#)
- [BECA held 4 public hearings in 2020](#)
- [MEP Awards 2020 winners](#)
- [Horizon Europe's Cancer Mission improving patient care](#)
- [ECL turned 40 years old](#)
- [EFPN is up and running](#)
- [European Cancer Summit 2020 report and recordings](#)
- [ESMO's position paper on GDPR and research](#)

# Share the full original EMA communication



Where: News  
 What: CHMP communication  
 How: Full original news + link

**The European Medicines Agency (EMA) publishes conclusion of risk of inhibitor development from two classes of VIII medicines**

**Factor VIII medicines: no clear and consistent evidence of difference in risk of inhibitor development between classes**

**EMA concludes review of human factor VIII medicines submitted in EU**

The European Medicines Agency (EMA) has concluded that there is no clear and consistent evidence of a difference in the incidence of inhibitor development between the two classes of Factor VIII medicines. These findings were based on data from 10 clinical studies involving 1,000 patients with haemophilia A, who were treated with either plasma-derived or recombinant Factor VIII medicines.

EMA's review was based on the publication of the SPPEF study (1), which compared the two classes of Factor VIII medicines. The SPPEF study was a randomised, controlled, open-label, parallel-group study that compared the two classes of Factor VIII medicines in terms of their ability to reduce the risk of inhibitor development. The study included 1,000 patients with haemophilia A, who were treated with either plasma-derived or recombinant Factor VIII medicines. The study was designed to evaluate the risk of inhibitor development in patients with haemophilia A who were treated with either plasma-derived or recombinant Factor VIII medicines. The study included 1,000 patients with haemophilia A, who were treated with either plasma-derived or recombinant Factor VIII medicines. The study was designed to evaluate the risk of inhibitor development in patients with haemophilia A who were treated with either plasma-derived or recombinant Factor VIII medicines.

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**Factor VIII medicines: no clear and consistent evidence of difference in risk of inhibitor development between classes**

Press release 15092017

**EMA concludes review of human factor VIII medicines submitted in EU**

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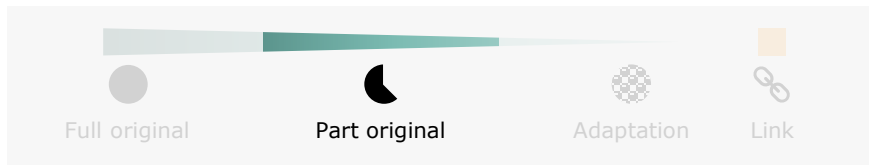
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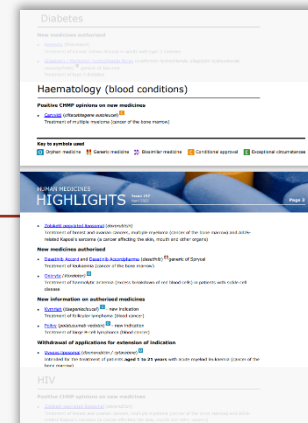
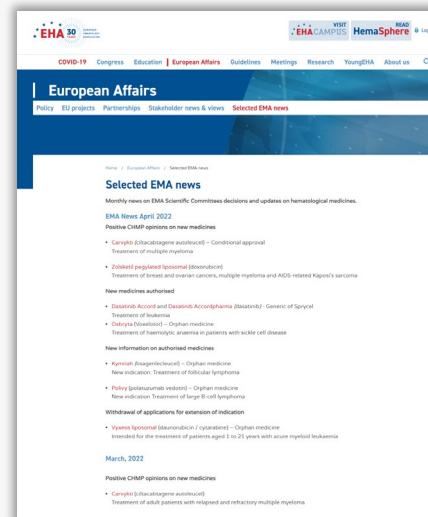
# Share a **part of the original** EMA communication



Where: Selected EMA news page

What: HMH Newsletter

How: Selection relevant to members (haematology)





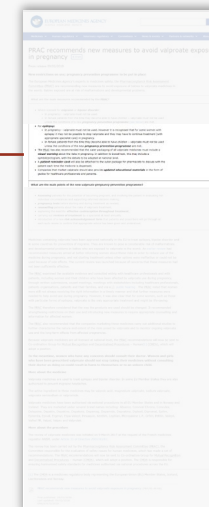
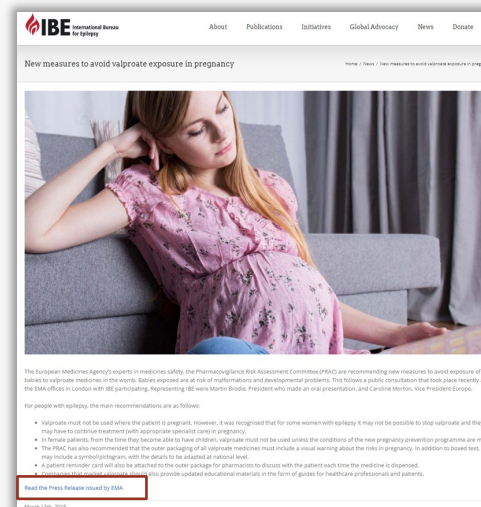
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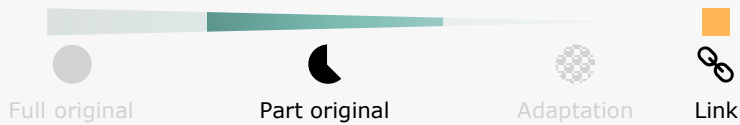
Where: News

What: Safety communication

How: Summary relevant to members (patients with epilepsy) + link



# Share a part of the original EMA communication



Where: Newsletter "EU MONITOR"  
 What: CHMP communication  
 How: Key novel information + link

### Updates from the EMA

In the second half of March, the European Medicines Agency (EMA) shared several communications. Information relevant to EMA was shared to the latest cancer medicine Tyvetiv, provided an update on the scientific use of combination data in oncology and reported on the benefits of medicines containing combination of methoprednisone and paracetamol when used to manage pain. Concerning COVID-19, EMA warned the public about falsified medicines from unregistered suppliers, shared advice on the use of medicines for hypertension, heart or kidney disease during the pandemic and reported on a workshop with global regulators which discussed the development of COVID-19 vaccines. Also EMA provided [links to the EMA website for further information on COVID-19](#).

**EMA provides information on breast cancer medicine Tyvetiv following re-assessment of data**

The product information for Tyvetiv, a breast cancer medicine, will continue to state that its data are consistent on the effectiveness of Tyvetiv used together with an aromatase inhibitor compared with tamoxifen used with an aromatase inhibitor in patients previously treated with tamoxifen. In July 2019, results of a study involving women with HR-HER2 breast cancer and whose disease had not responded despite previous treatment with tamoxifen were added to Tyvetiv's product information. The results had indicated benefits of Tyvetiv over tamoxifen when such medicine was used with an aromatase inhibitor. However, in April 2020, errors were detected in the data and they were removed from the product information.

During a procedure to re-assess the data, the contract research organisation where the data were analysed had misapplied the inclusion/exclusion criteria in the systems and procedures for managing data and concluded that data handling did not comply fully with good clinical practice (GCP). In addition, the statistical data did not allow a conclusion on whether Tyvetiv is more effective than tamoxifen when either is combined with an aromatase inhibitor. As a result, the study results will not be introduced into the product information for Tyvetiv. These are to be compensated for the current [benefit-risk profile of the medicine as a breast cancer drug](#).

More information is available [here](#).

EMA assesses combination use of medicines for hypertension, heart or kidney disease during COVID-19 pandemic

EMA is aware of recent media reports and publications which question whether some medicines, for instance angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) or cancer medicines, could worsen COVID-19. ACE inhibitors and ARBs are most commonly used for treating patients with high blood pressure, heart failure or kidney disease.

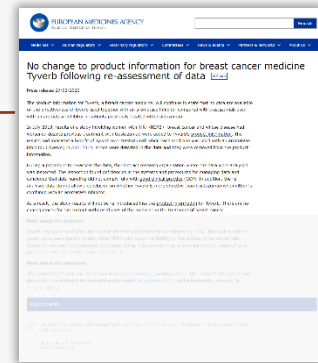
As a medicinal product generally is not intended for treatment with ACE inhibitors or ARBs, there is no need to switch to other medicines. There is currently no evidence from clinical or epidemiological studies that establishes a link between ACE inhibitors or ARBs and the worsening of COVID-19. Experts in the treatment of heart and blood circulation are advising the European Society of Cardiology, through several statements, about this issue. To gather more evidence, EMA is conducting the research, involving a genome-wide study to assess the genetic background of patients with COVID-19. As the public health issue rapidly evolves across the globe, scientific research is ongoing to understand how this can be a more appropriate combination treatment (SARS-CoV-2 inhibitors, if the link, relating with to immune system and cancer disease, and other ongoing treatment with medicines such as ACE inhibitors and ARBs) and impact the prognosis of COVID-19.

The possibility that ACE inhibitors or ARBs treatment can make patients worse in the context of COVID-19 is not supported by clinical evidence. These medicines seem to be affecting the renin-angiotensin-aldosterone system (RAAS). Because the virus uses a large cell-surface receptor (ACE2), which is part of this system, to enter human cells, and the medicines can increase ACE2, the use of the supplements shows there is that they could also increase virus activity, however, the receptors of the virus with the RAAS in the body are complex and the components understood. EMA is monitoring the situation closely and is collaborating with stakeholders to coordinate epidemiological studies on the effects of ACE inhibitors and ARBs in cases with COVID-19.

EMA is helping to coordinate urgent ongoing research and is fully committed to keep the public up to date with any development on this hot. EMA is also aware of reports questioning whether other medicines such as anticoagulants and non-steroidal anti-inflammatory (NSAID) could worsen COVID-19, and has recently issued a communication on NSAID medicines. It is important that patients who have any questions or are uncertain about their medicines speak to their doctor or pharmacist and do not stop their regular treatment without consulting their healthcare professional. Medicines should be prescribed and used in line with clinical judgement, being far more of any warning and other information provided in the summary of product characteristics (SPC), and the package leaflet, as well as guidance issued by the WHO and relevant national and international bodies. While the EU medicines regulatory authorities, evidence on the safe use of medicines is reviewed and emerges, any area should that arises is disseminated appropriately through EMA and national competent authorities. EMA will provide further information as appropriate.

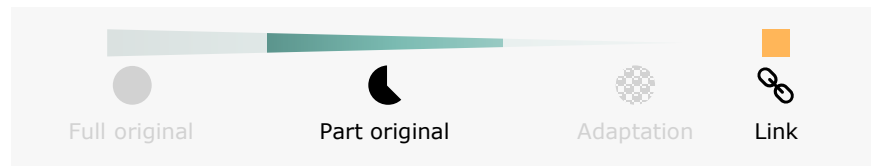
More information is available [here](#).

For the latest updates, access EMA's dedicated webpage on COVID-19.





# Share a part of the original EMA communication



Where:      Newsletter – Medicines Safety / Updates on EMA committees

What:      CHMP highlights, PRAC highlights, HMH Newsletter

How:      Selection key information + visuals + link

**MEDICINES SAFETY**

Pharmacovigilance Risk Assessment Committee (PRAC) Meeting March 2022

**Suspension of hydroxyethylstarch solutions for infusion**

EMA's safety committee (PRAC) has recommended that marketing authorisations for hydroxyethylstarch (HES) solutions for infusion should be suspended across the European Union (EU). These products were authorised as an addition to other treatments for plasma volume replacements following acute (isotonic) blood loss.

As a result of further reviews, the use of HES solutions for infusion was further restricted to accredited hospitals, and healthcare professionals prescribing or administering the medicines had to be trained in their appropriate use. Companies marketing HES solutions for infusion were also required to conduct a drug utilization study to check that the restrictions were adhered to in clinical practice, and to submit the results of this study to EMA.

The PRAC has now received the results from this study, which show that HES solutions for infusion are still being used outside the recommendations included in the product information. In view of the serious risks that certain patient populations are still exposed to, the PRAC has therefore recommended the suspension of the marketing authorisations for HES solutions for infusion in the EU.

For more information, please see EMA website

Medicines safety resources

- List of medicines under additional monitoring
- Essential medicines
- Shortages catalogue
- Recommendations on medication errors
- Good Pharmacovigilance Practices
- Patient engagement
- Rules of procedure on the organisation and conduct of public hearings at the PRAC

What's new in Pharmacovigilance? QPPV UPDATE

Click on the image to get the latest issue of QPPV Update, an EMA newsletter with the latest news on EU Pharmacovigilance

EUROPEAN MEDICINES AGENCY

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 7 - 10 February 2022

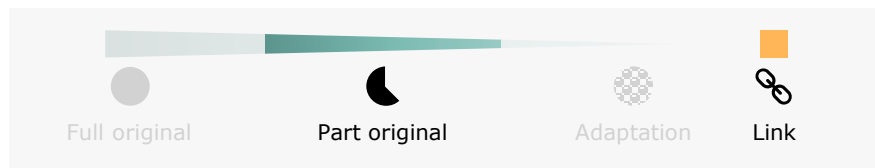
PRAC discussed suspending marketing authorisations for infusion from the market. HES solutions for infusion should be suspended across the European Union (EU). These products were authorised as an addition to other treatments for plasma volume replacements following acute (isotonic) blood loss.

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PRAC statistics February 2022

# Share a **part of the original** EMA communication



Where:      Newsletter – Medicines Safety / Updates on EMA committees

What:      CHMP highlights, PRAC highlights, HMH Newsletter

How:      Selection key information + visuals + link

**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**

**CHMP Meeting Highlights March 2022** Minutes: January 2022  
Agenda: March 2022  
Meeting Highlights: March 2022

In March, the CHMP recommended **5 medicines for approval**, **1 orphan medicine**:

- **Caspiglit** (lincicabtagene autovec), a new gene therapy that received a positive opinion for a conditional marketing authorisation for the treatment of multiple myeloma.
- **Evushel** (tixagevimab / cilgavimab) received a positive opinion from the CHMP for the prevention of COVID-19.
- **Camvexr**<sup>®</sup> (tildaprostigil) for the treatment of hormone-dependent prostate cancer.
- **Zoledronic acid (zoledronic acid)** (Zoledronic acid) for the treatment of breast cancer, ovarian cancer, progressive multiple myeloma and AIDS-related Kaposi's sarcoma.
- **Amygdaloprin SEB** (amifampridine<sup>1</sup>) received a positive opinion from the Committee for the treatment of Lambert-Eaton myasthenic syndrome.

The CHMP also recommended **6 extensions of therapeutic indication**, and recommended granting marketing authorisations for **1 biosimilars<sup>2</sup>** and **1 generic medicines<sup>3</sup>**.

For further details, read the full **CHMP meeting highlights**.

CHMP statistics - March 2022	
Positive opinions on new medicines	5 <sup>new</sup> / 25 <sup>Total 2022</sup>
New (non-orphan) medicines	1 <sup>new</sup>
Orphan medicines	1 <sup>new</sup>
Biosimilars	0
Generic / hybrids / informed consent	3 <sup>new</sup>

**HUMAN MEDICINES HIGHLIGHTS**

Click on the image to get the latest issue of **Human Medicines Highlights**, a newsletter published by EMA address to organisations representing **patients** and **professionals** providing key information on medicines for human use.

EUROPEAN MEDICINES AGENCY

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 21-24 March 2022





For further details, read the full **CHMP meeting highlights**.

CHMP statistics - March 2022	
Positive opinions on new medicines	5 <sup>new</sup> / 25 <sup>Total 2022</sup>
New (non-orphan) medicines	1 <sup>new</sup>
Orphan medicines	1 <sup>new</sup>
Biosimilars	0
Generic / hybrids / informed consent	3 <sup>new</sup>

# Share a **summary/adaptation** of the EMA communication



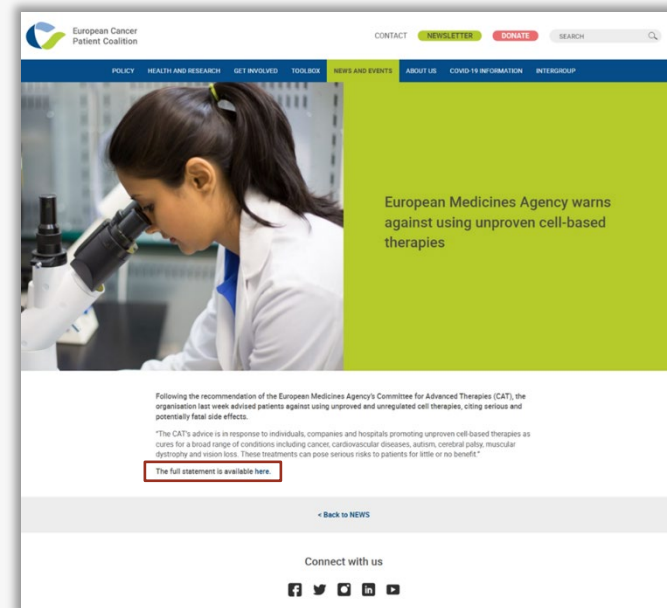
European Cancer Patient Coalition

			
Full original	Part original	Adaptation	Link

Where: News

What: Safety communication

How: Brief summary + link





## Conclusion



Learnings from the survey will be shared with the medical writers, communications team, design team and other colleagues across EMA



Some suggestions can be quickly implemented



Design requests will require further planning and discussion and will be considered as more long term



Follow-up interviews with PCOs / HCPOs are in preparation



# Any questions?

## Further information

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