



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Review and publication of direct healthcare professional communications (DHPCs)

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Joint PCWP/HCPWP meeting

21 September 2021  
Morgane De Verdier

An agency of the European Union





# What are DHPCs?

- A.K.A. 'dear doctor' letters
- Intended for healthcare professionals (doctors, pharmacists, nurses etc.)
- Sent directly to their workplaces (usually by companies)
- Contain important/urgent information about medicines
- Include communication plan with dates and target recipients
- Reference doc: GVP Module XV Rev.1

## COVID-19 mRNA Vaccines Comirnaty and Spikevax: risk of myocarditis and pericarditis

Dear Healthcare professional,

BIONTECH/PFIZER and MODERNA BIOTECH SPAIN, S.L. in agreement with the European Medicines Agency and <National competent authority> would like to inform you of the following:

### Summary

- **Cases of myocarditis and pericarditis have been reported very rarely following vaccination with the COVID-19 mRNA Vaccines Comirnaty and Spikevax.**
- **The cases primarily occurred within 14 days after vaccination, more often after the second dose and in younger men.**
- **Available data suggest that the course of myocarditis and pericarditis following vaccination is similar to the course of myocarditis and pericarditis in general.**
- **Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis.**
- **Healthcare professionals should advise vaccinated individuals to seek immediate medical attention should they experience chest pain, shortness of breath, or palpitations.**

### Background on the safety concern

The COVID-19 mRNA vaccines Comirnaty and Spikevax have been

## When DHPCs are necessary (GVP Module XV Rev.1)



Suspensions, withdrawals of a marketing authorisation for safety reasons

Important restrictions of indication, new contraindications, or changes in the recommended dosing due to safety reasons

Restrictions in the availability with potential detrimental effects on patient care (shortages)

## Other situations where DHPCs may be necessary



New major warnings or precautions

New data identifying previously known risk or change in severity/frequency of known risk

New evidence that medicine is not as effective as previously considered

New recommendations for preventing/treating side effect or avoid misuse or medication errors

Ongoing assessment of an important potential risk for which is too early to take regulatory action

## Deciding on DHPCs at EU level



### Collaborative approach – DHPCs are agreed between MAH and EMA

- Ongoing procedure at EU level affecting more than one member state (MS)
- PRAC/CHMP rapporteurs or MAH may request/propose a DHPC
- 'EMA lead' (e.g. PL, PM, SML, RMS) and S-PH-MHI provide guidance and lead the drafting and review process
- DHPCs and communication plans are adopted by PRAC/CHMP/CMDh
- DHPCs are disseminated by MAH to target HCPs in EU MS (in line with comms plan)
- DHPCs are published on EMA and NCAs websites



## Useful links

- <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/direct-healthcare-professional-communications>
- [https://www.ema.europa.eu/en/medicines/field\\_ema\\_web\\_categories%253Aname/field/Human/ema\\_group\\_types/ema\\_dhpc\\_document](https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname/field/Human/ema_group_types/ema_dhpc_document)
- <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/direct-healthcare-professional-communications#national-registers-section>
- [https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-xv-safety-communication-rev-1\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-xv-safety-communication-rev-1_en.pdf)



# Any questions?

## Further information

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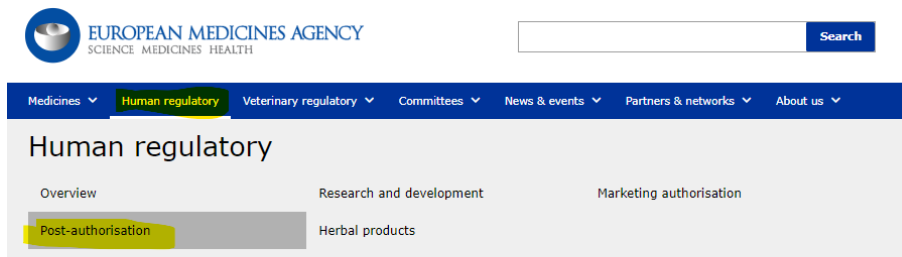
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# Back up slides



# EU DHPCs are published on EMA website (since Jan. 2020)



- Advanced therapies
- Availability of medicines
- Certifying medicinal products
- Changing the (invented) name of a medicinal product
- Changing the labelling and package leaflet (Article 61(3) notifications)
- Classifying post-authorisation changes
- Compliance
- Contacting EMA: post-authorisation
- Data on medicines (ISO IDMP standards)

## Direct healthcare professional communications

### Table of contents

- [DHPCs published by EMA](#)
- [National registers](#)



**A marketing authorisation holder may send a direct healthcare professional communication (DHPC) to healthcare professionals to inform them of important new safety information about a medicine and any actions they should take. The European Medicines Agency (EMA) publishes DHPCs agreed at European Union (EU) level and links to national registers of DHPCs, as of February 2020.**

DHPCs serve to inform healthcare professionals of, for example:

- a suspension, withdrawal or revocation of a [marketing authorisation](#) for safety reasons;
- an important change, for example a restriction of [indication](#), a new contraindication or a change in the recommended dose;
- a medicine supply shortage;
- quality problems with a medicine.

DHPCs agreed at EU level **include a communication plan** specifying the intended recipients and the dissemination date.



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Categories

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Medicine name

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Active substance / international non-proprietary name (INN) / common name

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Medicine

Direct healthcare professional communication

European public assessment reports (EPAR) (1842)

Summaries of opinion (62)

50 results

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MEDICINE Direct healthcare professional communication

Sort by Last updated date (new to old)

Direct healthcare professional communication (DHPC): RoActemra (tocilizumab): Temporary supply shortage for 162 mg solution for subcutaneous injection and RoActemra 20 mg/mL concentrate for solution for infusion (IV) & recommendations to manage potential risk of disease flare in patient (new)

Active substance: tocilizumab, DHPC type: Medicine shortage, Last updated: 02/09/2021

Direct healthcare professional communication (DHPC): COVID-19 Vaccine Janssen: Contraindication in individuals with previous capillary leak syndrome and update on thrombosis with thrombocytopenia syndrome





Active substance: adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein (Ad26.COV2-S), DHPC type: Safety signal, Last updated: 19/07/2021



## National registers

National competent authorities publish DHPCs in their official languages.

Please note that the information in these national registers may not be available in English.

EU Member State	Medicine register
 Austria	<a href="https://www.basg.gv.at/gesundheitsberufe/sicherheitsinformationen-dhpc">https://www.basg.gv.at/gesundheitsberufe/sicherheitsinformationen-dhpc</a>
 Belgium	<a href="https://www.afmps.be/fr/humain/medicaments/medicaments/pharmacovigilance/dhpc_s_-_direct_healthcare_professional_communications">https://www.afmps.be/fr/humain/medicaments/medicaments/pharmacovigilance/dhpc_s_-_direct_healthcare_professional_communications</a> (FR) <a href="https://www.fagg.be/nl/MENSELIJK_gebruik/geneesmiddelen/geneesmiddelen/geneesmiddelenbewaking/dhpc_s_-_direct_healthcare_professional_communications">https://www.fagg.be/nl/MENSELIJK_gebruik/geneesmiddelen/geneesmiddelen/geneesmiddelenbewaking/dhpc_s_-_direct_healthcare_professional_communications</a> (NL)
 Bulgaria	<a href="https://www.bda.bg/bg/лекарствена-безопасност-съобщения/преки-съобщения-до-медицинските-специалисти">https://www.bda.bg/bg/лекарствена-безопасност-съобщения/преки-съобщения-до-медицинските-специалисти</a>
 Croatia	<a href="http://www.halmed.hr/Farmakovigilancija/Pisma-zdravstvenim-radnicima/">http://www.halmed.hr/Farmakovigilancija/Pisma-zdravstvenim-radnicima/</a>