



Reflections on Publication and Dissemination of DHPCs

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Direct healthcare professional communications

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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.

National competent authorities may **adapt the text** agreed at EU level to their specific situation, so the final letter a healthcare professional receives may differ slightly from the version published on the EMA website.

Categories

☒ Human

Medicine name

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

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Medicine

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Relevance



Direct healthcare professional communication (DHPC): Tecentriq (atezolizumab): Risk of Severe Cutaneous Adverse Reactions (SCARs)

Active substance: atezolizumab, DHPC type: Adverse event, Last updated: 25/03/2021

Direct healthcare professional communication (DHPC): Brivudine: potentially fatal toxicity of fluoropyrimidines if administered shortly before or at the same time with brivudine or used within 4 weeks after the end of treatment with brivudine

Active substance: Brivudine, DHPC type: Periodic safety update single assessment, Last updated: 12/05/2020

Direct healthcare professional communication (DHPC): Ondexxya (andexanet alfa): Commercial anti-FXa activity assays are unsuitable for measuring anti-FXa activity following administration of andexanet alfa

Active substance: andexanet alfa, DHPC type: Safety signal, Last updated: 17/06/2020

Direct healthcare professional communication (DHPC): Ondexxya (andexanet alfa): Avoid use of andexanet prior to heparinization

Active substance: andexanet alfa, DHPC type: Adverse event, Last updated: 04/11/2020

Direct healthcare professional communication (DHPC): Metamizole: Risk of drug-induced liver injury

Active substance: metamizole, DHPC type: Periodic safety update report, Last updated: 15/12/2020

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	https://www.basg.gv.at/gesundheitsberufe/sicherheitsinformationen-dhpc 
 Belgium	https://www.afmps.be/fr/humain/medicaments/medicaments/pharmacovigilance/dhpc_s_-_direct_healthcare_professional_communications  (FR) https://www.fagg.be/nl/MENSELIJK_gebruik/geneesmiddelen/geneesmiddelen/geneesmiddelenbewaking/dhpc_s_-_direct_healthcare_professional_communications  (NL)
 Bulgaria	https://www.bda.bg/bg/лекарствена-безопасност-съобщения/преки-съобщения-до-медицинските-специалисти 
 Croatia	http://www.halmed.hr/Farmakovigilancija/Pisma-zdravstvenim-radnicima/ 
 Cyprus	No online register available yet
 Czechia	http://www.sukl.cz/leciva/informacni-dopisy-lekarum 
 Denmark	https://laegemiddelstyrelsen.dk/da/bivirkninger/direkte-sikkerhedsinformation/udsendte-meddelelser/ 

INFOMED - Base de dados de medicamentos de uso humano



O Infomed tem uma nova versão. Para aceder utilize o endereço: <https://extranet.infarmed.pt/INFOMED-fo/>.



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COVID-19 Vaccine Janssen: Contraindication in individuals with previous capillary leak syndrome and update on thrombosis with thrombocytopenia syndrome [Share](#)

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About

This direct healthcare professional communication (DHPC) contains important information for healthcare professionals prescribing, dispensing or administering the medicine(s). It also includes a communication plan with details of intended recipients and the dissemination date.

Documents



Direct healthcare professional communication (DHPC): COVID-19 Vaccine Janssen: Contraindication in individuals with previous capillary leak syndrome and update on thrombosis with thrombocytopenia syndrome (PDF/136.25 KB) [\(new\)](#)

First published: 19/07/2021



Contiene información sobre seguridad de medicamentos.

Apreciado/a socio/a,

Se adjunta a este correo una carta remitida por los laboratorios Janssen-Cilag S.A. de la vacuna frente a la COVID-19 de Janssen: **Riesgo de trombosis en combinación con trombocitopenia.**

- Aquí puedes leer el [CARTA AUTORIZADA](#) [+]

Contiene información sobre seguridad de medicamentos.

Carta revisada por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS). También está disponible en el siguiente enlace de la página web de la AEMPS.

Carta autorizada en la página web de la AEMPS

"Circular Informativa N.º 080/CD/550.20.001 Data: 07/07/2021"

09/07/2021

COVID-19 Vaccine Janssen: Contraindicação em pessoas com história de síndrome de transudação capilar

"Circular Informativa N.º 082/CD/550.20.001 Data: 09/07/2021"

09/07/2021

Comirnaty e Spikevax: possível ligação a casos muito raros de miocardite e pericardite

"Circular Informativa N.º 081/CD/550.20.001 Data: 09/07/2021"

09/07/2021

 **Contacte-nos**

Communication on Safety of Medicines in Europe: Current Practices and General Practitioners' Awareness and Preferences

Communication on Safety of Medicines in Europe

735

Table 3 General practitioners' awareness of DHPCs, NCA communications, and EMs, and preferences on format and repetition

	Total	Mean of country percentages	DK	ES	HR	IE	IT	NL	NO	SE	UK
Awareness											
Aware of DHPCs	1652 (94)	91	24 (96)	816 (96)	81 (95)	138 (96)	165 (90)	62 (86)	89 (85)	88 (81)	189 (96)
Aware of NCA com.	1571 (89)	79	20 (80)	820 (97)	56 (66)	136 (94)	151 (83)	15 (21)	100 (95)	93 (86)	180 (91)
Aware of EM	995 (64)	65	14 (56)	533 (63)	56 (66)	110 (76)	121 (66)	49 (68)	^a	^a	112 (57)
Format preference ^b											
Hardcopy	389 (22)	29	5 (20)	112 (13)	23 (27)	63 (44)	48 (26)	28 (39)	23 (22)	50 (47)	37 (19)
Electronically	1116 (63)	56	15 (60)	610 (72)	41 (48)	66 (46)	113 (62)	33 (46)	69 (66)	38 (36)	131 (67)
No preference	258 (15)	16	5 (20)	123 (15)	21 (25)	15 (10)	22 (12)	11 (15)	13 (12)	19 (18)	29 (15)
Repetition seen as useful ^c	1565 (89)	87	21 (84)	768 (91)	80 (94)	129 (90)	177 (97)	58 (81)	86 (82)	89 (82)	157 (80)

<https://pubmed.ncbi.nlm.nih.gov/28540672/>

Table 1 Current (2014) risk communication practices

	BE	BG	CZ	DK	EE	ES	FI	FR	GR	HR	HU	IS	IE	IT	LV	LT	MT	NL	NO	PL	PT	RO	SE	SK	SI	UK
DHPCs																										
-NCA allows companies to distribute DHPCs by email without sending a hard copy	-	-	+	-	+	+	+	+	-	-	-	-	-	-	+	+	+	-	-	+	+	+	-	-	-	-
-DHPCs are published on the NCA's website	+	-	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	+
-NCA disseminates DHPCs via electronic means in addition to distribution by companies	-	-	-	-	-	-	-	-	+	-	+	+	-	+	-	-	+	+	-	-	+	-	-	-	-	-
-NCA uses patient organizations and professional bodies to distribute DHPCs	-	-	+	+	-	+	-	+	+	-	-	-	+	+	+	-	-	+	-	-	-	+	-	-	-	+
NCA communications																										
-NCA publishes bulletin / safety newsletter	~	+	~	+	~	~	-	~	-	+	~	-	+	+	+	-	~	~	~	~	+	-	+	~	~	+
-Bulletin/newsletter on NCA's website	+	+	+	+	-	-	-	+	-	-	+	-	+	+	+	-	+	-	+	?	+	-	+	+	-	+
-NCA distributes bulletin via post to HCPs	-	+	+	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	+	-	-	-	-
-NCA distributes bulletin via email to HCPs	-	-	+	+	+	-	-	+	-	+	-	-	+	+	+	-	+	+	+	-	+	-	+	-	-	+
-NCA distributes bulletin to HCPs indirectly via professional bodies using emails	-	-	-	-	-	+	-	+	-	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-	-
-NCA reproduces safety communications from EMA press releases on its website	+	+	+	~	~	-	~	+	~	+	-	+	+	+	~	+	~	~	~	+	+	+	~	~	+	~
-NCA publishes own press releases	+	+	+	-	+	+	+	+	+	+	-	+	+	+	+	+	+	+	-	-	+	+	+	+	?	+
-Direct contact with interest groups	~	~	~	~	-	-	~	~	-	~	~	~	~	~	~	-	~	~	~	-	~	+	~	~	~	+
Educational materials																										
-Available on NCAs website	+	-	+	-	+	+	+	+	-	-	-	-	-	-	-	-	+	+	-	?	+	-	-	-	-	+
-Link on NCA website to external webpage	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	?	-	-	-	-	-	+

BE = Belgium, BG = Bulgaria (BG), CZ = Czech Republic, DK = Denmark, EE = Estonia, ES = Spain, FI = Finland, FR = France, GR = Greece, HR = Croatia, HU = Hungary, IS = Iceland, IE = Ireland, IT = Italy, LV = Latvia, LT = Lithuania, MT = Malta, NL = Netherlands, NO = Norway, PL = Poland, PT = Portugal, RO = Romania, SK = Slovakia, SI = Slovenia, UK = United Kingdom
+ Yes always / yes; ~ Yes, occasionally / Yes, on a case by case basis / Sometimes, depending on the topic; - No; ? Country did not complete web-portals survey / Missing
NCA = National competent authority; DHPC; Direct Healthcare Professional Communication; HCP = Healthcare professional; EMA = European Medicines Agency

<https://pubmed.ncbi.nlm.nih.gov/28540672/>

- Observations:

- GP's across Europe seem largely aware of DHPCs
- GP's prefer the electronic format of DHPCs
- There are important differences between Member States on how DHPCs are disseminated
- DHPCs are largely present in the websites of NMA, but are poorly disseminated by electronic means
- However, we do not know the uptake and if GP's read DHPCs.

- My personal experience:
 - I do not receive DHPCs through my NMA by email or other means and I could not find them on the respective website (only press releases from PRAC)
 - It seems difficult to find DHPCs on my NMA's website if i actively look for them
 - I have only received DHPCs by email through a Spanish Scientific Society I happen to be a member of
 - I would not know about DHPCs if I wasn't reviewing them through the HCPWP!

- Take-home messages:
 - Do not expect that GP's will actively look for DHPCs.
 - DHPCs should be disseminated directly to GP's by email, post and/or social media
 - DHPCs should be easy to find in the websites of NMAs
 - More research is needed on awareness and uptake of DHPCs among European GPs