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The Pharmacovigilance Risk Assessment Committee – PRAC

The PRAC (Pharmacovigilance Risk Assessment Committee) is the European Medicines Agency (EMA) committee in charge of assessing and monitoring the safety of medicinal products for human use. It was created in 2012 with a remit encompassing medicines for the whole of the European Union.

The **PRAC is in charge of** assessing all aspects concerning medicinal product risk management, including adverse reaction detection, risk assessment, minimisation and communication. The PRAC also assesses post-authorisation safety studies (i.e., when medicines are already being marketed). It issues recommendations and monitors the effectiveness of pharmacovigilance activities and of risk management systems.

The PRAC **includes** one chair, who is elected from within the committee's members, one member and one alternate that is nominated by each member state (including Iceland and Norway), six independent experts designated by the European Commission, one member and one alternate from patient organisations, as well as one member and one alternate from healthcare professional representative bodies.

The committee meets **monthly**. Highlights of its meetings are published at EMA's website **here**. These highlights have included, since October 2020, more in-depth information regarding medicines for the treatment/prevention of COVID-19. This website feature is planned to be extended to other procedures as well.

Cont'd overleaf ▶

The Portuguese National Pharmacovigilance System is counting on healthcare professionals to keep reporting any ADRs that may occur with medicinal products used in the treatment of COVID-19 – see infografic (in Portuguese)

▶ *Cont'd from previous page*

October PRAC meeting highlights

Start of a safety signal review concerning Velkury® (remdesivir)

The PRAC has started an assessment regarding a possible risk of acute kidney injury in some COVID-19 patients treated with remdesivir. Renal toxicity is an important potential risk that has already been identified in the product's Risk Management Plan and which is under intensive monitoring.

At this stage it is not yet possible to determine whether there is a causal nexus between reports of acute kidney injury and remdesivir. Acute renal injury can indeed be associated with various other factors, such as diabetes or COVID-19 itself. The **Summary of the Product's Characteristics (SmPC)** already alerts to the need for monitoring renal function before and during therapy.

Should a causal relation come to be determined, the necessary regulatory measures will be taken, namely SmPC and Patient Information Leaflet updates.

EMA Guidance on Risk Management Plans for COVID-19 vaccines

The PRAC has reviewed the EMA guidance for pharmaceutical companies on how to put together their COVID-19 vaccine **Risk Management Plans (RMPs)**.

Whenever marketing authorisation is applied for any medicinal product, its corresponding RMP also needs to be submitted for assessment. This supplementary EMA Guidance intends to help companies to monitor COVID-19 vaccine risks and to implement measures to manage risks associated with vaccination. RMPs are dynamic documents – they are updated throughout the medicinal product's life cycle.

Márcia Silva

What do they mean?

ADR	Adverse Drug Reaction
EMA	European Medicines Agency
MA	Marketing Authorization
PIL	Patient Information Leaflet
PRAC	Pharmacovigilance Risk Assessment Committee (EMA)
SmPC	Summary of Product Characteristics

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ADRs in the Literature

Motivating factors versus hurdles for direct patient ADR reporting

Relatively little is still known about the factors affecting patients' decisions whether to report an ADR. This qualitative study looked at how adult patients experienced ADR reporting in the Canadian context.

Through social media and patient associations, subjects were invited to participate in interviews conducted by the study's researchers. Both **motivating factors** and deterrents for direct patient reporting were identified in the fifteen interviews undertaken. Intolerable side effects with an impact on daily life activities and encouragement from third parties, such as family and work colleagues, were the main promoting factors.

Factors discouraging direct reporting were normalisation or minimisation of adverse effects by a physician, confusion about what to report, lack of feedback from the system, and pre-existing experience with adverse reactions.

- ***Dweik RA et al. Patients' experiences on adverse drug reactions reporting: a qualitative study. Eur J Clin Pharmacol. 2020 Dec;76(12):1723-1730.***

HPV vaccination not associated with autonomic dysfunction syndromes

This case series from the Danish national clinical registries included 869 patients with autonomic dysfunction syndromes, out of a cohort of over 1.3 million females between 10 and 44 years of age, during the period from 2007 to 2016. The authors aimed to assess a possible association between **quadrivalent human papillomavirus immunisation** and the occurrence of autonomic dysfunction syndromes, such as **chronic fatigue, complex regional pain and postural orthostatic tachycardia syndromes**. These syndromes present with non-specific symptoms including tiredness, headache, nausea and dizziness.

The data analysed suggest that the appearance of those adverse events in temporal proximity with HPV vaccination is pure coincidence. A causal association has not been supported.

- ***Hviid A et al. Association between quadrivalent human papillomavirus vaccination and selected syndromes with autonomic dysfunction in Danish females: population based, self-controlled, case series analysis. BMJ. 2020 Sep 2;370:m2930.***

Communications to Healthcare Professionals published in the Infomed product information webpage

Click on the links.

INN Medicinal product	Target	Communication? Online publication date
Dimethyl fumarate Tecfidera	**Physicians:** neurologists who treat patients with multiple sclerosis	Updated risk minimisation recommendations regarding the risk of progressive multifocal leucoencephalopathy in a setting of mild lymphopoenia 12-11-2020

Compiled by Patrícia Catalão

Educational Materials published in the a Infomed product information webpage

Click on the links.

INN Medicinal product	Target	Communication? Online publication date
Axicabtagene ciloleucel Yescarta	**Healthcare professionals:** multidisciplinary teams at qualified centres in charge of managing patients being treated with this product	Guide on management of serious neurological adverse reactions and cytokine release syndrome Handling and administration guide 12-11-2020
Ravulizumab Ultomiris	**Physicians:** haematologists	Prescribing physician's guide – PNH
	Physicians: nephrologists	Prescribing physician's guide – aHUS
	Physicians: haematologists (indication: PNH) and nephrologists (indication: aHUS)	Vaccination certificate – PNH and aHUS
	Patients	Patient guide – PNH Patient guide – aHUS Parents' guide – aHUS Adult patient safety alert card (PNH or aHUS) Paediatric patient safety alert card (aHUS) 04-11-2020
Rituximab Truxima	**Physicians:** rheumatologists and internists (potential prescribers)	Important safety information – non-oncological indications
	Physicians: oncologists, haematologists, rheumatologists and internists (potential prescribers) **Nurses:** day hospitals **Pharmacists:** hospital	Information on the medicinal product
	Patients	Important safety information - non-oncological indications 17-11-2020

Compiled by Patrícia Catalão