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Pharmacovigilance *eBook*

First launched in hard copy format at the Infarmed Innovation in Pharmacovigilance Symposium on 10th December last, this practical pharmacovigilance manual (*Farmacovigilância em Portugal: 25 anos*) is now also available in digital form.

Knowledge on adverse drug reactions, their causality, epidemiology and prevention, as well as risk minimization and mitigation strategies, are clearly essential in healthcare professionals' pre and post-graduate training. This reference work can be used as a tool for **teaching, research** and medical **decision making**.

The manual is very accessible – in Portuguese, for free and online **here**.

The ***eBook*** can be browsed based on index and page numbers. You can also choose to download it and do keyword searches on your personal computer.

INDEX CARD

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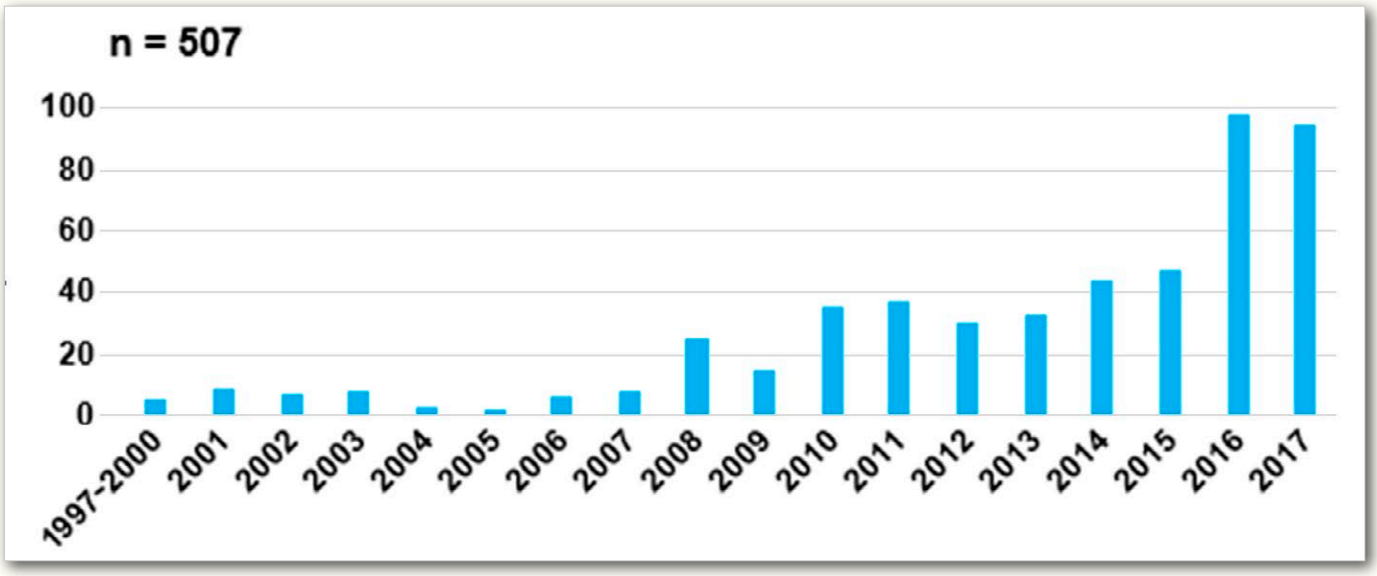
Adverse reactions to radiographic contrast media:
Allergy vs dose and administration-dependent reactions?

Radiographic contrast media (CM), namely intravascular, are associated with various serious and even fatal adverse reactions (ARs). The World Health Organization (WHO) considers CMs to be one of the drug groups most prone to medication errors.

SPCs state doses for an average 70-kg adult. However, the dose to be administered should be calculated based on the patient's actual rather than estimated weight. The CM solution should be warmed up to 37ºC to decrease viscosity and minimize the chance of occurrence of ARs.

The Figure below shows the evolution of the number of cases of ARs to CM reported annually to the Portuguese National Pharmacovigilance System between 1992 and 2017.



A total of 507 cases were reported and the reporting frequency in 2016 and 2017 was twice as high as in previous years. Females were affected in 56% of cases. Peak incidence was seen in the 50-69-year-old group, which is possibly related to a greater number of diagnostic exams undertaken in that age group.

In over one third of cases reported (36%) both the patient's weight and the dose used were known, though not the perfusion rate and/or the type of ancillary exam for which the CM was employed.

Respiratory and cardiac ARs were observed in 107 cases (21% of total), eight of which had a fatal outcome. None occurred with skin manifestations which leads one to suspect they were possibly not allergic reactions but rather dose or mode of administration related.

In order to adequately assess whether an ADR was of an allergic nature or arose from an administration problem, it is important to know the type of ancillary diagnostic exam undertaken, the patient's actual weight, the dose and the rate of perfusion of CM used, i.e., all the data necessary to decide whether the CM was given at the indicated temperature and perfusion rate and at the minimum necessary dose for the exam intended and for the subject's weight. These data were not provided in most reports.

In cases without cutaneous manifestations where an allergy to the CM is suspected, the patient should be sent in for allergy tests and the results of the latter fed back to the case reporting person.

Only reports with information of sufficient quantity and quality allow for adequate case assessment and can contribute to improving knowledge on the safety profile of medicinal products and to the implementation of any relevant risk minimization measures that prove to become necessary.

Fátima Pereira de Bragança, Cristina Mousinho, Márcia Silva, Cristina Monteiro

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Educational Materials published in the Infomed product information webpage

Click on the links.

INN Medicinal product	Target	Comunication Online publication date
Eculizumab Soliris	**Patients**	Safety information card
	Parents/caregivers	Safety information card: infants and small children 05/04/2019
Fingolimod Gilenya	**Physicians:** neurologists and neuropaediatricians treating multiple sclerosis	Checklist
	Patients	Information card
	Parents/child caregivers	Information card 23/04/2019
Lisdexamfetamine dimesylate Elvanse	**Physicians:** child psychiatrists, neuropaediatricians, paediatricians	Pre-prescription checklist Ongoing monitoring checklist Ongoing monitoring table 02/04/2019
Medicinal products containing thiocolchicoside Adalgur N, Coltramyl, Relmus Tiocolquicosido Arrowblue, Tiocolquicosido Generis	**Physicians:** general/family medicine, orthopaedics, rheumatology, gynaecology, rehabilitation medicine, internal medicine **Pharmacists**	Healthcare professional guide
	Patients	Patient card 01/04/2019
Micafungin Mycamine	**Physicians:** infectious diseases, intensive care, internal medicine, general surgery, microbiology, transplant unit and paediatrics department directors **Pharmacists:** hospital pharmaceutical service directors	Prescription checklist 01/04/2019

Compiled by Magda Pedro

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

Communications to Healthcare Professionals published on the Infarmed website

Click on the links.

INN Medicinal product	Target	Comunication Online publication date
Alemtuzumab Lemtrada	**Physicians:** prescriber or potential prescriber neurologists, hospital neurology service directors, and Portuguese Society of Neurology	Restriction of use due to serious safety issues (cardiovascular reactions, autoimmune hepatitis and haematophagocytic lymphohistiocytosis) 24/04/2019
Ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, ofloxacin and prulifloxacin Medicinal products containing fluoroquinolones for systemic (oral and injectable) use and inhalation	**Physicians:** cardiothoracic, general, maxillo-facial, paediatric and plastic surgery, dermatology, dentistry, gynaecology/ obstetrics, implantology, infectious diseases, general/family medicine, intensive medicine, internal medicine, tropical medicine, neurosurgery, neurology, orthopaedics, ENT, pneumology, urology, nephrology **Pharmacists:** community and hospital	Restriction of use and risk of long-term, potentially irreversible, incapacitating undesirable effects mainly affecting the musculoskeletal and nervous systems 18/04/2019
Iron hydroxide polymaltose complex Ferrum Hausmann	**Physicians:** internal medicine, nephrology, haematology, immuno-haemotherapy, orthopaedics, anaesthetics, gastroenterology, urology, gynaecology/ obstetrics, general surgery, pneumology, paediatrics, general/family medicine **Pharmacists:** community **Nurses**	Change in the expression of the active substance and dosage: medication error prevention 15/04/2019
Human fibrinogen Haemocomplettan	**Pharmacists:** in charge of hospital pharmacies procuring this medicinal product	Change in preservation conditions 16/04/2019

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New pathway for suspected ADRs in the Lisbon district

The **Lisbon Regional Pharmacovigilance Unit (UFL)** has decided to discontinue its activities in April. This regional unit's collaboration with Infarmed has been one of the core elements for the development and consolidation of the Portuguese National Pharmacovigilance System.

In order to ensure work continuity, and given its geographical proximity, Infarmed has firmed an agreement with the **Setúbal and Santarém Regional Pharmacovigilance Unit (UFS)** starting May 1st 2019.

ADR cases occurring within the Lisbon district and uploaded on to **Portal RAM** by healthcare professionals or patients will from now on be processed by UFS. In addition to the Portal, which is the preferential mode of report communication, cases may also be sent through to:

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