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Editorial
National Pharmacovigilance System Restructured

The Portuguese National Pharmacovigilance System (NPS) is coordinated by Infarmed. Its role includes monitoring the safety of medicinal products through collection and assessment of adverse drug reactions (ADRs), identifying and assessing risks associated with the use of medicines, implementing risk minimization measures, and communicating with healthcare professionals, patients, consumers and the general public.

Until the end of 2016 the NPS included four Regional Units (North, Midlands, Lisbon and Tagus Valley, and South). These were overseen by the Medicines Risk Management Department (DGRM) which is also responsible for processing reports from the archipelagos of the Azores and Madeira islands. However, the contribution of major healthcare organizations has consistently been almost nil. Reduced participation from professionals from those organizations could be ascribed to relative isolation and communication difficulties between healthcare providers and the Regional Pharmacovigilance Units (RPUs). This has led to a decision to double the number of NPS RPUs. The aim is to develop pharmacovigilance activities closer to professionals, to widen population catchment areas and to reduce geographical dispersion.

Adding four new RPUs is also a measure to further allow Infarmed to fulfil its commitments with the European Medicines Agency (EMA). In fact, marketing authorizations are in some cases being processed under conditional provisos or with incomplete clinical data, which calls for greater vigilance over the use of medicines. With a total of eight RPUs it will be possible to make pharmacovigilance more dynamic by getting healthcare professionals proactively involved in selective monitoring of medicinal products, newer ones in particular.

The ongoing restructuring process is aiming for closer links to universities and/or research centres to allow for the development of the critical mass that is essential for research in pharmacovigilance and pharmacoepidemiology. Cooperation among RPUs in this field is one of the objectives in view.

The relaunch of the pharmacovigilance delegate role as facilitator of ADR reporting is part of the decentralization process at a national level. These delegates will be professionals working in hospitals and community health centres. They will hopefully bring the RPUs closer to the healthcare professionals and more efficiently promote the NPS and ADR reporting by ensuring a more adequate coverage of the whole of the country.

This model is therefore based on concentrating medicinal product safety monitoring efforts, especially for new molecules. It can only succeed through proactivity and bringing pharmacovigilance closer to people.

No effective medicinal product is without risk. The benefits of any given medicine must always be weighed against its risks. There is a challenge to ensure a balance between timely availability of new medicines and limited knowledge of their safety profile at the moment they are first marketed.

The location, catchment areas and population coverage of each one of the new regional units can be found on the table overleaf.

Fátima Canedo, Henrique Luz Rodrigues

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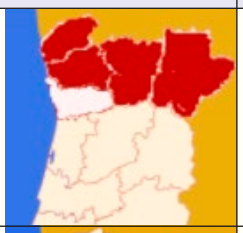
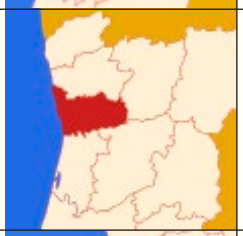
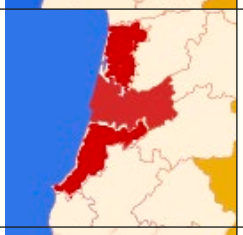
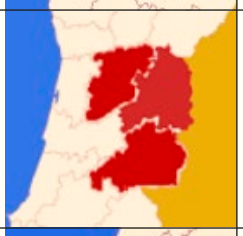
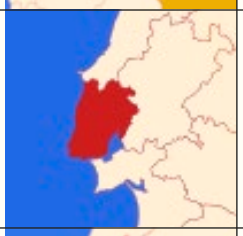
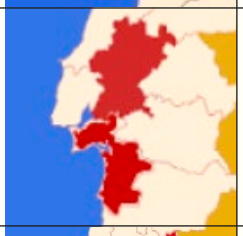
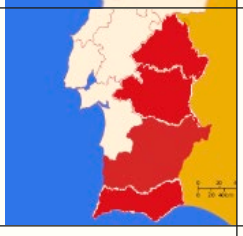
Regional Pharmacovigilance Units

Pharmacovigilance Unit	Location and contact details	Catchment area	Population covered No. inhabitants***
Guimarães Unit	**Hospital da Senhora da Oliveira – Guimarães EPE** Rua dos Cutileiros, Creixomil – 4835-044 Guimarães Ph: 253 775 479 / 910 337 505 Fax: 253 513 592 E-mail: farmacovigilancia@hospitaldeguimaraes.min-saude.pt	**Braga, Bragança, Viana do Castelo e Vila Real** 	**1,437,034**
Porto Unit**	**Faculdade de Medicina Universidade do Porto** Rua Doutor Plácido da Costa – 4200-450 Porto Ph: 220 426 952/220 426 943 – Fax: 225 513 682 E-mail: ufn@med.up.pt Site: www.ufn.med.up.pt	**Porto** 	**1,816,045**
Midlands Unit**	**Aibili** Azinhaga de Santa Comba, Celas – 3000-548 Coimbra Ph: 239 480 138/111 – Fax: 239 480 117 E-mail: ufc@aibili.pt Site: http://www.ufc.aibili.pt	**Aveiro, Coimbra e Leiria*** 	**1,510,383**
Beira Interior Unit	**Universidade da Beira Interior** Faculdade de Ciências da Saúde – UBI Av. Infante D. Henrique – 6200-506 Covilhã Ph: 275 329 070 E-mail: ufarmabi@ubi.pt	**Guarda, Castelo Branco e Viseu** 	**735,046**
Lisbon Unit**	**Faculdade de Medicina Universidade de Lisboa** Laboratório de Farmacologia Clínica e Terapêutica – FML Av. Prof. Egas Moniz – 1649-028 Lisboa Ph: 217 802 127 / 0 (ext. 44136 / 7) – Fax: 217 802 129 E-mail: uflvt@sapo.pt	**Lisbon*** 	**1,823,357**
Setúbal and Santarem Unit**	**Faculdade de Farmácia Universidade de Lisboa** Av. das Forças Armadas – 1649-019 Lisboa Ph: 217 971 340 – Fax: 217 971 340 E-mail: ufs@ff.ulisboa.pt Site: http://ufs.ff.ul.pt	**Setúbal e Santarém** 	**1,304,298**
Alentejo and Algarve Unit	**Universidade do Algarve** Departamento de Ciências Biomédicas e Medicina (DCBM) Campus de Gambelas, ala norte do edifício 2, sala 2.52 8005-139 Faro Ph: 289 800 900 (ext: 7420) E-mail: falgarvealentejo@gmail.com	**Portalegre, Évora, Beja e Faro** 	**889,576**
Infarmed DGRM (Medicines Risk Management Dept)	**INFARMED, I.P.** Direção de Gestão do Risco de Medicamentos Ph: 217 987 140/1 Fax: 217 987 397 E-mail: farmacovigilancia@infarmed.pt	**Azores, Madeira and the following Lisbon and Leiria local municipalities:** Alenquer, Arruda dos Vinhos, Azambuja, Bombarral, Cadaval, Caldas da Rainha, Lourinhã, Mafra, Óbidos, Peniche, Sobral de Monte Agraço, Torres Vedras, Vila Franca de Xira	**1,040,114**

* Some local municipalities in these regions are included in the DGRM catchment area.
** Units which were already part of the National Pharmacovigilance System but whose catchment area has changed.
*** Source: PORDATA (Contemporary Portugal Database) www.pordata.pt

Methylphenidate:
Priapism

Quick Read

Methylphenidate, like many other drugs, can be associated with the occurrence of priapism. Its incidence is unknown. An erection lasting longer than two hours, especially when painful, should prompt medical attention.

Methylphenidate is a central nervous system stimulating agent indicated in the treatment of attention deficit hyperactivity disorder (ADHD). Its effects are thought to be due to stimulation of the cortex and possibly also of the reticular activation system, involving norepinephrine and dopamine reuptake into the presynaptic neuron and an increase in their release into the extraneuronal space.
Priapism is a condition defined by persistent or prolonged penile erection. It is frequently idiopathic but can be a complication of various conditions or of exposure to pharmacological agents. In children, five percent of cases of priapism are drug-induced (Donaldson JF et al, 2013). In adults in the western world the agents used in the treatment of erectile dysfunction are the commonest pharmacological cause of priapism.

In November 2016 the PRAC at EMA concluded the assessment of a safety signal concerning priapism and the use of methylphenidate. Taking into account the cases in the literature [1,2] and the European ADR database EudraVigilance, PRAC agreed on the following changes to the the SmPC (sections 4.4 and 4.8) and PIL (sections 2 and 4) as risk minimization measures:

Summary of Product Characteristics

Section 4.4 Special warnings and precautions for use

Priapism. Prolonged and painful erections have been reported in association with methylphenidate products, **mainly in association with a change in the methylphenidate treatment regimen**. Patients who develop abnormally sustained or frequent and painful erections should seek immediate medical attention.

Section 4.8: Undesirable effects

Reproductive system and breast disorders

priapism, erection increased and prolonged erection

Frequency: unknown

Patient Information Leaflet

2. Warnings and Precautions

During treatment, boys and adolescents may unexpectedly experience prolonged erections. This may be painful and can occur at any time. **It is important to contact your doctor straight away if your erection lasts for longer than 2 hours, particularly if this is painful.**

4. Possible side effects

Prolonged erections, sometimes painful, or an increased number of erections.

Frequency: unknown

NB: Highlights in bold have been added in this article; they are not part of the published texts.

References:
[1] *Eiland LS et al (2014) Priapism associated with the use of stimulant medications and atomoxetine for attention-deficit/hyperactivity disorder in children. Ann Pharmacother 48; 1350-5*
[2] *Schwartz R, Rushton H. Stuttering Priapism Associated with Withdrawal from Sustained-Release Methylphenidate. The Journal of Pediatrics. 2004; 144: 675-676*

Sílvia Duarte

Educational Materials published on the Infomed product information webpage

Medicinal product (DCI)	Click on the links (in Portuguese)
Humira (adalimumab)	***Educational materials for healthcare professionals*** Informação de segurança importante – 3.ª versão *For rheumatologists, dermatologists, internal medicine specialists, gastroenterologists, and paediatricians.* Published on 31-01-2017
Kadcyla (trastuzumab emtansine)	***Educational materials for healthcare professionals*** Informação de segurança muito importante para os profissionais de saúde que prescrevem, dispensam e administram Kadcyla – 2.ª versão *For oncology and radiotherapy specialists, general surgeons, gynaecologists and internal medicine specialists in charge of senology services and with experience in the use of anti-HER2 therapies; for hospital pharmacists and hospital nurses.* Published on 01-02-2017
Lixiana (edoxaban)	***Educational materials for healthcare professionals*** Guia do prescritor – 1.ª versão *For cardiologists, internal medicine specialists, neurologists, haematologists, immunohaemotherapy specialists, general surgeons, vascular surgeons and family medicine specialists.* Published on 02-02-2017
Quetiapina Sandoz (quetiapine)	***Educational materials for healthcare professionals*** Informação importante de segurança para médicos prescritores – 1.ª versão *For psychiatrists, neurologists, internal medicine and family medicine specialists.* Published on 01-02-2017

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