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Valproate / Valproic Acid
Use in pregnancy and in women of childbearing age

INFARMED has issued a **public notice online** concerning the use of medicinal products containing valproate / valproic acid in pregnancy and in women of childbearing age. An infographic has been developed (right) to disseminate this information in a format and language more suitable **for patients and the general public**. The objective is to reinforce warnings and restrictions due to the risk of malformations and developmental problems in babies who have been exposed to those products in utero. The information is given in a condensed, simple and attractive way, and makes for easy reading with key messages clearly highlighted.

INDEX CARD

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Social media for the detection of adverse drug reactions

Current pharmacovigilance methods focus on collecting and assessing safety data from adverse event reports and ADR monitoring of marketed medicinal products. It is highly dependent on the spontaneous communication of adverse events[1]. This type of reporting however, has been associated to a number of limitations that contribute towards significant underreporting of ADRs[2]. Regulatory authorities and the pharmaceutical industry have extensively used these traditional systems but in the last few years novel safety techniques and tools have been developed to communicate and monitor ADRs. In particular, there has been growing interest in the potential use of social media as safety tools for ADR reporting and signal detection.

Although posting in social media is unlike traditional forms of communication of human adverse drug reactions, specialists in pharmacovigilance have been researching to find out whether this type of public information on Twitter, Facebook and patient forums and blogs, may help regulators and pharmaceutical companies to monitor the safety of marketed medicines.

The potential of digital media in pharmacovigilance

According to the coordinator of a project involving pharmaceutical companies and called Web-RADR (Recognising Adverse Drug Reactions), ADRs are usually underreported by all parties, including healthcare professionals, but especially by patients themselves[3]. Data from social media provide greater opportunities to capture ADRs patients would probably not tell their doctor or nurse about. Doctors are excellent at diagnosing diseases and picking up objective signs, but patients are great at describing reactions and subjective feelings.[3]

Social media and health related websites are being widely promoted and adopted by patients as means to facilitate discussions on health topics. Many patients actively use those media to share their experiences and possible drug-related adverse events. This creates an opportunity for such information to be explored for ADR signal detection and drug safety monitoring.[4]

Up to now, studies on the use of social media in pharmacovigilance have mostly focused on data mining techniques, which are necessary to sieve large scale safety data from those websites. The results of those studies point to the potential triage of information related to adverse events as a means of ADR signal detection. In spite of the many limitations, quick accessibility to those websites could eventually allow for the detection of ADRs in real time[5].

Advantages and challenges of ADR monitoring via social media

Various advantages and challenges regarding the use of social media in ADR monitoring have been described in the literature. Monitoring huge quantities of data on social media has the potential to shed light on new safety data from people's daily practice. This could even be a useful way to detect safety data that are of very low incidence and which cannot be picked up before or during clinical trials. Moreover, data from patients on the internet may be used to collect information on off-label uses or the use of medicines by specific population or age groups, such as pregnant women, children or the elderly[6].

However, ADR monitoring via social media platforms also raises challenges, such as:

- Patient data quality may be less reliable;
- Identifying a given patient who can be singled out and traced back can be a problem for privacy protection reasons (there are meanwhile other sources available for demographic analysis of data from social media);
- Data can be less remarkable due, for instance, to the limited number of characteristics that can be used (e.g., Twitter)[7].

Furthermore, only a small proportion of health related data from social media really includes any actual safety information. In addition, it can be hard to retrieve information from social media with text recognition techniques, if one considers spelling mistakes and the use of non-clinical terms to describe health problems and adverse reactions.

Underreporting and the role of healthcare professionals in pharmacovigilance

Scanning social media for drug safety information or even effectiveness data raises significant legal and ethical issues for both companies and regulators, such as who can use the data and how should patients who post their data online be approached. Not to mention the technical challenges that need to be overcome so that great volumes of non-structured and frequently low-quality data can be processed into useful information.

Post-marketing drug safety and pharmacovigilance are embedded in healthcare professionals' roles and their duty of care. Though MA Holders may under certain circumstances have to face criticism and even legal action concerning ADRs, it is ultimately the healthcare professionals' responsibility to prescribe, dispense and administer medicines. Doctors, nurses, dentists and pharmacists all play a very important role in monitoring and communicating the serious adverse events they observe. This is even enshrined in national law[8].

ADR underreporting is still a major concern in pharmacovigilance. Studies undertaken on the attitudes of healthcare professionals regarding ADR reporting have suggested various reasons, including lack of knowledge or understanding about their national pharmacovigilance and ADR reporting system, or even simply about what the process of reporting an ADR entails. Curiously enough, potential latent feelings of guilt for not having "prevented" the ADR has also been suggested as a contributory factor[9-11].The professionals' heavy workload could also partially explain ADR underreporting[2]. It seems therefore unreasonable to further burden them with active searches of social media sites for information on adverse reactions relating to the drugs they prescribe or dispense.

Social media can meanwhile be used to strengthen the healthcare professional-patient relationship. Indeed, patients and the general public often take part in discussions with healthcare professionals on health-related websites, where they share their own personal experiences with medicines.

Vanda Araújo

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Communications to Healthcare Professionals published on the Infarmed website

Medicinal product (DCI)	Click on topic for details (in Portuguese)
Cotellic (cobimetinib)	Risk of haemorrhage and of rhabdomyolysis; new dose modification recommendations. Published on 29-05-2017
Quetiapina Mylan, Quetiapina Teva and Quetiapina ratiopharm, prolonged release tablets (quetiapine)	Safety information on correct dosage, sleepiness, extrapyramidal symptoms, monitoring of metabolic parameters and weight, risks with off-label use and doses different than those indicated. Published on 05-06-2017

Compiled by Magda Pedro

Educational Materials published in the Infomed product information webpage

Medicinal product (DCI)	Click on the links (in Portuguese)
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Enbrel (etanercept)	**Educational materials for healthcare professionals** Guia sobre a técnica adequada para a utilização da caneta pré-cheia de Enbrel – 1.ª versão Registo de Administração – 1.ª versão For rheumatoogists, dermatologists, internists and paediatricians. **Educational materials for patients** Guia sobre a técnica adequada para a utilização da caneta pré-cheia de Enbrel – 2.ª versão Cartão de alerta do doente – 3.ª versão Published on 29-05-2017
Inflectra (infliximab)	**Educational materials for healthcare professionals** Inflectra (infliximab): Informação de segurança importante para médicos prescritores – 2.ª Versão Inflectra(Infliximab): Folha de Triagem – 2.ª Versão For specialists in internal medicine (doctors dealing with automimmune diseases), paediatrics (doctors dealing with automimmune diseases), rheumatology, gastroenterology, and dermatology, and for hospital pharmacists. Published on 07-06-2017

Educational Materials published in the Infomed product information webpage

Medicinal product (DCI)	Click on the links (in Portuguese)
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Quetiapina SR Zentiva (quetiapine)	**Educational materials for healthcare professionals** Minimização e gestão de riscos importantes - 1ª versão For specialists in neurology, psychiatry, internal medicine and family medicine. Published on 16 30-06-2017
Remsima (infliximab)	**Educational materials for healthcare professionals** Brochura educacional para profissionais de saúde sobre o tratamento de crianças com doença inflamatória intestinal – 2.ª versão Informações de segurança importantes para profissionais de saúde - 2ª versão For specialists in gastroenterology, rheumatology, dermatology and internal medicine who treat autoimmune diseases, as well as for nurses in day hospitals and hospital pharmacists who handle biologicals. Published on 09-05-2017
RoActemra (tocilizumab)	**Educational materials for healthcare professionals** Informação de segurança importante sobre o tratamento com RoACTEMRA nos doentes com artrite reumatoide – 7.ª versão For internists and rheumatologists, and for nurses. Published on 09-06-2017
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Tenofovir Sandoz (tenofovir)	**Educational materials for healthcare professionals** Régua de depuração da creatinina – 2.ª versão For doctors who follow up patients with HIV and HVB infection (infectious diseases, internal medicine, gastroenterology and paediatrics specialists). Published on 07-06-2017

Educational Materials published in the Infomed product information webpage

Medicinal product (DCI)	Click on the links (in Portuguese)
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Velcade (bortezomib)	**Educational materials for healthcare professionals** Informação importante relacionada com a reconstituição, dosagem e administração de Velcade – 2.ª versão Poster com informação sobre a reconstituição de Velcade – 2.ª versão For haematologists, hospital pharmacists and nurses. Published on 05-06-2017

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