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Pharmacovigilance in the 2030 Sustainable Development Agenda

On 1 January 2016 the United Nations (UN) resolution entitled "Transforming our world: the 2030 Agenda for Sustainable Development" came into force. This agenda is based on 17 Sustainable Development Goals (SDGs) broken down into 169 targets.

In the words of the then UN Secretary-General Ban Ki-Moon, the 17 SDGs are "a list of things to do on behalf of people and planet". Turning this vision into reality is essentially the responsibility of governments of countries, so the 2030 Agenda assumes the integration of the SDGs into policies, processes and actions developed at national, regional and global levels, and requires new partnerships and international solidarity. Additionally, ordinary citizens must also contribute individually to the pursuit of the SDGs. We all have a role to play!

Pharmacovigilance is no exception. According to the World Health Organization (WHO), this area of knowledge aims to improve the safety of medicines, in defence of the user and of Public Health, through the detection, evaluation and prevention of adverse drug reactions (ADRs). The information collected through spontaneous reporting of suspected ADRs is vital to identify potential unknown adverse reactions, quantify and/or better characterize previously identified adverse reactions and implement measures to minimise the risk of their occurrence.

It is globally accepted that ADRs are a relevant Public Health problem, so monitoring the safety of medicines is an essential element for the promotion of their rational use, as well as for the provision of high quality medical care, aiming at reducing morbidity and mortality rates, decreasing the number of hospitalizations due to failures in pharmacotherapy and, consequently, reducing overall costs related to health and to the burden of disease.

As a field of knowledge, Pharmacovigilance is characterized by its strong technical-scientific component. It is an unequivocal motor for the continuous generation of knowledge and information about medicines, but also an indispensable tool to guarantee the safe use of medicines.

Although present in all phases of the life cycle of a medicine, surveillance and risk management achieve their greatest purpose in post-marketing monitoring, which focuses on the evaluation of the relation of benefit-risk of medicinal products from the moment they begin to be used by various populations, when exposed to an infinitely greater diversity of inter-individual differences (at biological, psychological and even socio-cultural levels) than those observed in clinical trials.

Pharmacovigilance is an extremely relevant component in the daily activity of health professionals, its most visible face

INDEX CARD

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being the spontaneous reporting of suspected adverse reactions to medicines.

To be more comprehensive, the spontaneous reporting of suspected ADRs should not be an exclusive responsibility of health professionals, but also of patients. For pharmacovigilance to be effective, it is essential to inform and raise awareness of its importance to the common citizen, as well as more specifically for the use of the RAM Portal (ADR reporting portal), thus fulfilling the aim of the 2030 Agenda 2030 that concerns the involvement of civil society.

Figure 1 shows the main areas where Pharmacovigilance can contribute towards the SDGs of the 2030 Sustainable Development Agenda.

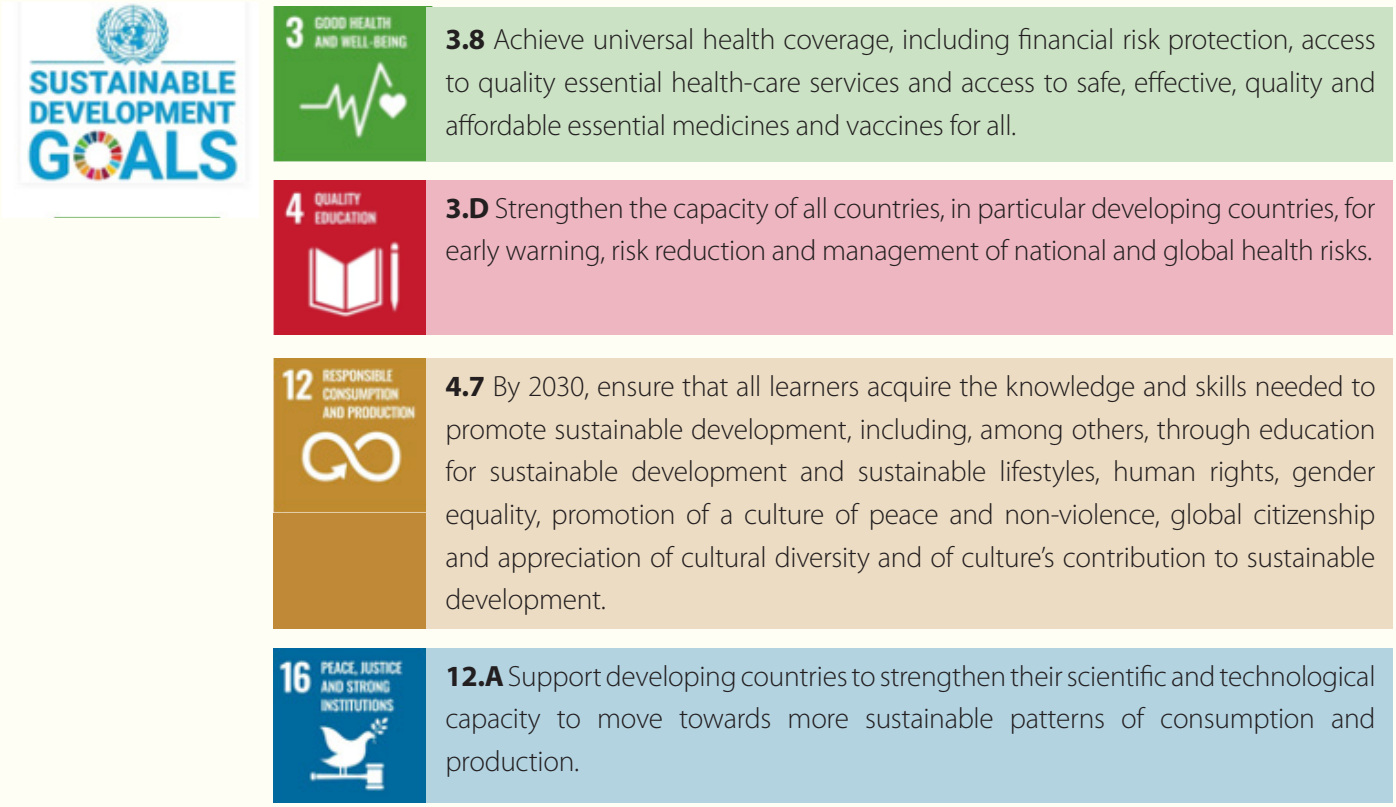

Figure 1. Main areas where Pharmacovigilance can contribute to the SDGs and related targets of the 2030 Agenda for Sustainable Development (adapted, with due acknowledgment, from https://unric.org/en/united-nations-sustainable-development-goals/)

Pharmacovigilance has been providing unquestionable benefits to human health and it is easy to see that its action will continue to be essential to ensure the safe use of medicines, thus promoting healthy lives and the well-being of the population. Medicines are one of the most important health technologies and are primarily responsible for improving people's quality of life and for increasing life expectancy. Pharmacovigilance stands out therefore as having a very important role in health, as it represents a system capable of identifying potential ADRs through a set of active and routine methodologies, in order to prevent and minimize potential risks to patients' health. So-called Proactive Pharmacovigilance also plays an increasingly important role in health systems, since awareness on the part of both patients and health professionals enables them to anticipate risks, develop strategies and/or determine medicinal product monitoring actions, in order to avoid, minimize or treat potential future ADRs.

Let's all never hesitate and always report. Let's contribute to a Sustainable Development!

"You can reduce the suffering and save thousands of patients by doing this one thing: report suspected adverse drug reactions." OMS, 2002

Cristina Galacho, Margarida Perdigão, João Valente Nabais, Ana Margarida Advinha

Communications to Healthcare Professionals published on the Infomed product information webpage

Click on the links.

INN Medicinal product	Target	Materials Online publication date
Electrolytes + Hidroxyethylamide *Tetraspan, Volulyte, Voluven Fresenius*	**Healthcare professionals:** in charge in hospitals that qualify for use of this medicine	Marketing authorizations suspended 04-08-2022
Verteporfin *Visudyne*	**Healthcare professionals:** ophthalmologists, hospital pharmacists **Patients:** patient organizations for eye conditions	Information on limited undisrupted availability until the end of 2023 12-08-2022

Compiled by Patrícia Catalão

Portal **RAM**

Notificação de Reações Adversas a Medicamentos

Report an adverse drug reaction here.
Find answers to your questions about the ADR Portal here.

Educational Materials published on the Infomed product information webpage

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INN Medicinal product	Target	Materials Online publication date
Valproic acid / valproate semisodium *Ácido Valpróico Generis Ácido Valpróico Ratiopharm 300 mg, Ácido Valpróico Ratiopharm 500 mg, Depakine, Depakine Chrono 300, Depakine Chrono 500, Depakine Chronosphere, Diplexil, Diplexil 150, Diplexil 300, Diplexil 500, Diplexil 1000, Diplexil-R, Epixival, Valproato de sódio Altan*	**Physicians:** neurology, psychiatry, general/family medicine, child psychiatry, neuropaediatrics **Patients**	Prescriber's guide Annual risk awareness form Guide 12-08-2022
Etanercept *Erelzi*	**Patients**	Patient card 12-08-2022
Lenalidomide *Lenalidomida Tecnigen*	**Physicians:** haematology, oncology **Pharmacists:** hospital service directors **Patients**	Safety information for healthcare professionals **Advice for:** female patients with childbearing potential female patients without childbearing potential male patients Pregnancy reporting form Adverse event reporting form **Booklet for:** female patients with childbearing potential female patients without childbearing potential male patients 19-08-2022
Mosunetuzumab *Lunsumio*	**Patients**	Patient card 08-08-2022

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	Patients	**Patient booklet – information for:** female patients with childbearing potential female patients without childbearing potential male patients 12-08-2022

Compiled by Patrícia Catalão

What do they mean?

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