SD COLLECTION

2023 SPECIAL

PHARMACOVIGILANCE

SafetyDrugs
PHARMACOVIGILANCE SOLUTIONS

SUMMARY

DRUG SHORTAGES: THE MEASURES FOR EMA TO TACKLE THEM

THANKS TO AN EU REGULATION, THE EUROPEAN MEDICINES AGENCY HAS NOW THE MEANS TO STRENGTHEN THE TOOLS AGAINST SHORTAGES OF MEDICINES AND MEDICAL DEVICES. HERE ARE ALL THE NEWS.

The shortage of medicines is a problem that has afflicted all European countries for several years. With the advent of the pandemic situation from Covid-19 the question has become even more dramatic. To remedy this, the European Parliament and the European Council issued the Regulation (EU) 2022/123 aimed at strengthening the tools of the EMA (European Medicine Agency) to fight the shortage of medicines and medical devices.

THE REGULATION (EU) 2022/123

Published on 31 January 2022 and became applicable from 1 March 2022, the **Regulation's main objective is to strengthen the EU's role in monitoring shortages of both medicines and medical devices, through the establishment of new structures inside EMA**. In this way, it will be possible to avoid supply problems even in the event of future health emergencies.

INNOVATIONS INTRODUCED BY REGULATION (EU) 2022/123

In order to manage the shortage of medicines and medical devices, the new Regulation brought about the **introduction of two steering groups (Medicines Shortage Steering Group and Medical Device Shortage Steering Group), the implementation of a platform for collecting shortage and the activation of an operational task force.**

Medicines Shortage Steering Group

A new introduced by the regulation is the Medicines Shortage Steering Group (MSSG). It is a steering group made up of representatives from each Member State plus one from EMA and one from the Commission. **Its aim is to monitor and prevent medicines shortages in each Member State.**

A working group made up of representatives from each state's drug agencies was also established to support the MSSG.

The task of the MSSG is to provide the EU Commission, the Member States, the companies and others, including representatives of healthcare professionals and patients, **with recommendations to prevent or mitigate shortages of medicines.**

The MSSG also takes care of drawing up the list of critical drugs, that are those medicines necessary for emergency treatment. In the event of an emergency or serious event, the MSSG may require pharmaceutical companies to provide information about these medicines and for pharmacies and wholesalers to provide evidence of actual or potential shortages.

Medicines Device Shortage Steering Group

In parallel to the MSSG, the MDSSG, that is the group for the monitoring and management of specific deficiencies of medical devices, was also established.

Supporto da parte di SPOC

The EU's network of Single Points of Contact (SPOC), a system used by EMA and national competent authorities to exchange information on deficiencies, is now in charge of supporting the MSSG and providing it with recommendations on:

- monitoring and managing shortages and/or availability issues during a crisis and beyond
- update of the EMA plan for emerging health threats
- definition of the main medicines needed for emergency care, surgery and intensive care, in order to help prepare the lists of essential medicines to respond to public health emergencies or serious events
- guidance for businesses on the Industry SPOC Network (i-SPOC).

European Shortage Monitoring Platform

With the Regulation, **the European Shortage Monitoring Platform (ESMP) was introduced, a platform for collecting data on drug shortages.**

The ESMP, **which must be fully operational by 2 February 2025,** will be fed with information from MAHs and national medicines agencies. In the Italian case, given that AIFA, the national competent authority, does not have such information, it is necessary to involve pharmacies and wholesalers in monitoring at the distribution level. This information can also be used to possibly declare a state of emergency or a serious event.

Emergency Task Force

An Emergency Task Force (ETF) was also implemented with the aim of simplifying clinical trials of drugs intended to treat, prevent or diagnose diseases responsible for public health emergencies.

Its duties include reviewing scientific data, making recommendations on the use of unauthorized drugs, coordinating independent studies on vaccine efficacy and safety monitoring, as well as providing scientific advice for the development of medicines intended for use during a public health emergency.

EDQM STANDARD TERMS: MANDATORY FROM 30 JUNE 2022 FOR DOSAGE FORMS AND ROUTE OF ADMINISTRATION

THE EDQM STANDARD TERMS WILL BE MANDATORY STARTING FROM 30 JUNE 2022 FOR THE INDICATION OF DOSAGE FORMS AND ROUTES OF ADMINISTRATION IN PHARMACOVIGILANCE REPORTS. HERE'S THE NEWS.

EDQM STANDARD TERMS: WHAT THEY ARE

The EDMQ standard terms are identifying terminology established by the European Directorate for the Quality of Medicines & Healthcare at the request of the European Commission.

These terms identify the routes of administration and pharmaceutical forms, but also presentation units and containers, closures and delivery devices for products intended for both human and veterinary use.

They are used in adverse reaction reports, but also in marketing authorisations, electronic communications, drug labels and Summaries of Product Characteristics (SmPCs), the document in which information about the medicinal product is collected such as pharmaceutical form, parameters clinical and pharmacological properties.

The terms are more than 900 in 35 languages and are collected in the Standard Terms Database, from where it is also possible to view the changes made to the terms, an explanation of the different possible states of a standard term, technical information such as object identifiers (OIDs) for the different lists of deadlines, ongoing requests and the latest decisions of the Commission for the European Pharmacopoeia.

Access to the database is available free of charge for users registered on the EDQM Publications registration site.

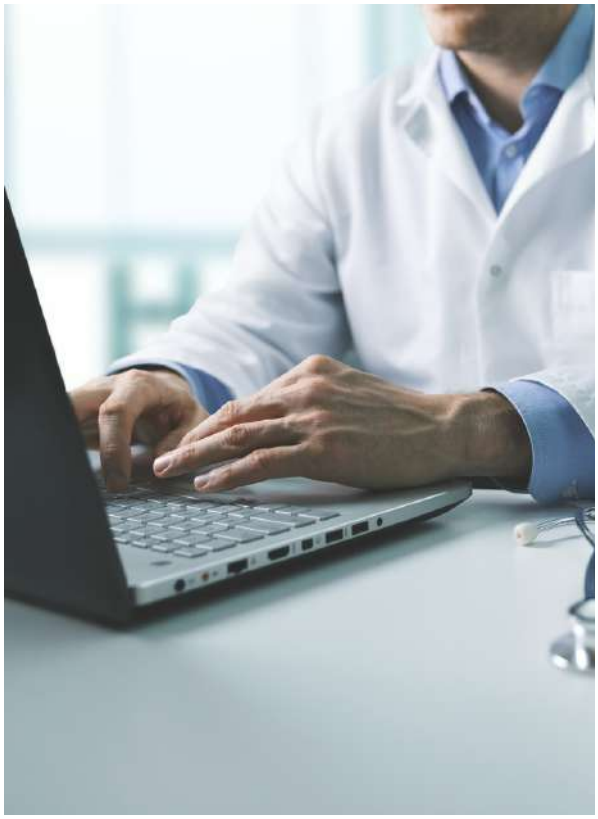
EDQM STANDARD TERMS: WHAT CHANGES

From 30 June 2022 it will be mandatory to use the EDQM standard terms for the indication of Dosage Forms (DF) and route of administration (RoA) of drugs in the ICSR(s).

The European Directorate for the Quality of Medicines & Healthcare (EDQM) will periodically issue updates to the terms. As soon as these are approved, they will be uploaded to the SPOR RMS portal.

Every Sunday, EudraVigilance, the European database for pharmacovigilance reporting, will synchronize with SPOR RMS to update its terms.

For companies that carry out pharmacovigilance activities, it is therefore necessary to keep the EDQM terms constantly updated in their safety database to avoid failures in submitting a report.



WHAT HAS CHANGED IN SAFETYDRUGS

Max Application, the software house developer of SafetyDrugs, has promptly worked to implement the EDMQ standard codes in the safety database and to make some improvements that are useful for the user.

First of all, the fields dedicated to the Route of Administration and Dosage Forms have been converted from free text fields to list of values, so that the user can simply choose the right option without worrying about entering it correctly. However, the possibility of manually entering the values remained.

Alerts have also been added, both in the import phase and in the case management phase, to signal the presence of any TERMID codes that are no longer in use or EDQM codes that are invalid or out of date.

Finally, a new table has been inserted which lists all the EDQM codes, both valid and not, with an indication of the relative class they belong to. Furthermore, after adjusting the tables relating to the Route of Administration and the Formulation, a mapping was created between the old TERMIDs and the new EDQM codes, so that the user can update the codes based on the periodic updates released by the institution.

ITALIAN MEDICINE AGENCY (AIFA): NEW NATIONAL PHARMACOVIGILANCE NETWORK

AIFA, THE ITALIAN MEDICINES AGENCY HAS ANNOUNCED IN JUNE THE NEW NATIONAL PHARMACOVIGILANCE NETWORK ADAPTED TO EUROPEAN STANDARDS. HERE'S THE NEWS.

NEW AIFA NATIONAL PHARMACOVIGILANCE NETWORK

On 20 June 2022, the new National Pharmacovigilance Network was activated, the system with which reports of adverse reactions from the use of drugs in Italy are collected, processed and analysed. The new RNF (National Pharmacovigilance Network) uses the standard ISO format (ICSR) ICH E2B(R3), essential for the exchange of reports with Eudravigilance, the European database. This format entered into force in 2017, when the transition period began, and which became fully applicable on 30 June 2022.

NEW ONLINE REPORTING METHOD

At the same time, again on 20 June 2022, a new online reporting method was also made available through a platform available directly on the AIFA portal. Also compliant with the international standard, it replaced the well-known Italian reporting portal "Vigifarmaco", which was discharged from 6 pm on 8 June 2022.

TRANSITIONAL REPORTING PHASE TO AIFA

To remedy the gap between the discharge of Vigifarmaco and the activation of the new platform, from 9 to 20 June, healthcare professionals and patients were able to report suspected adverse reactions by filling in the appropriate form, sending it by e-mail to the Manager pharmacovigilance department of your facility or the Marketing Authorization Holder (MA) of the medicinal product that is suspected to have caused the adverse reaction.

NEW AIFA REPORTING FORMS

In addition to the new platform, the possibility of making reports by filling in and sending the forms to the pharmacovigilance manager or to the MA holder has remained active: AIFA has made available, in replacement of the existing ones, reporting forms updated to the ISO standard (ICSR) ICH E2B(R3), therefore including the additional fields required by the new format, and graphically updated for better usability.

61ST AFI SYMPOSIUM: THE PROGRAM

THE AFI SYMPOSIUM RETURNS TO THE PALACONGRESSI IN RIMINI FROM 8 TO 10 JUNE 2022. AS USUAL, THERE WILL BE 3 DAYS OF SCIENTIFIC SESSIONS ACCOMPANIED BY WORKSHOPS AND ROUND TABLES. HERE IS THE PROGRAM.

After the stop caused by the covid pandemic, the AFI symposium returned home to the Palancongressi in Rimini, from 8 to 10 June 2022.
The title of the 61st edition is: The Pharmaceutical World: the paradigms of a New Era.
"The event will focus on the Copernican revolution through which the scientific world has passed, an irreversible revolution that projects us beyond the New Normal, into a new era for the Pharmaceutical World." can be read on the event website.

Here is the agenda of the topics discussed in 2022.

Wednesday 8th June
10:00 – 13:00: Workshops
14:00 – 15:00: Lectio Magistralis
15:00 – 19:00: The Scientific Sessions

- Session I – Supply Chain: The safety of the drug supply chain: European legislation and Italy
- Session II – Biotech: The Value of Research for the Patient: the role of Biotech
- Session III – Clinical Research: Evolution of clinical research: how to adapt the context to generate data to support new therapies?
- Session IV – Food Supplements: Quality food supplements amidst doubts and technical and regulatory certainties.

Thursday 9 June
08:45 – 16:00: The Scientific Sessions

- Session V – **API**: The API sector: regulatory compliance and new development strategies
- Session VI – **Technological Innovation**: Technological Innovation: instructions for correct use
- Session VII – **Quality**: Change management as a fundamental process for compliance and continuous improvement
- Session VIII – **Pharmacovigilance**: 360 ° Vigilance
- Session IX – **AFI / CRS / ADRITELF**: Research, development of new drugs and new technologies: Chronotherapy and new personalized regimens for controlled drug release
- Session X – **HTA & Market Access**: The new scenarios of the HTA process in Italy in the post-Covid era19

13:00 – 14:30: Pharma women's square

- Round table: Journey into the female world of pharma-biotech through experiences of know-how, passion, will and dedication

13:00 – 14:30: Start up square

- Round table: Making Start-ups in Italy, an impossible mission? System actions, opportunities and changes in the post-pandemic era

14:00 – 15:30: The Poster Session

16:30 – 18:30: The Plenary Session

Friday 10th June
09:00 – 13:00: The Scientific Sessions

- Session XI – **Production**: Pharmaceutical Production 2022: New Challenges and New Responses
- Session XII – **Medical Devices**: The world of Medical Devices: the paradigms of a new era

AFI SYMPOSIUM 2022: THE VIGILANCE AT 360°

HERE IS WHAT EMERGED FROM THE SESSION ON PHARMACOVIGILANCE AT THE AFI 2022 SYMPOSIUM, HELD FROM 8 TO 10 JUNE.

The AFI 2022 Symposium, aimed at its 61st edition, was held from 8 to 10 June. As per tradition, it took place at the Rimini conference center. The 12 scientific sessions touched on the most diverse topics: from clinical research, to technological innovation, from APIs to supplements, from regulatory affairs to quality, from drugs to medical devices.
We went to follow the session of Thursday 9 reserved for pharmacovigilance for you. Here's what we talked about.

PHARMACOVIGILANCE: FROM THE RISK MINIMIZATION PLAN TO INFORMATION MATERIAL

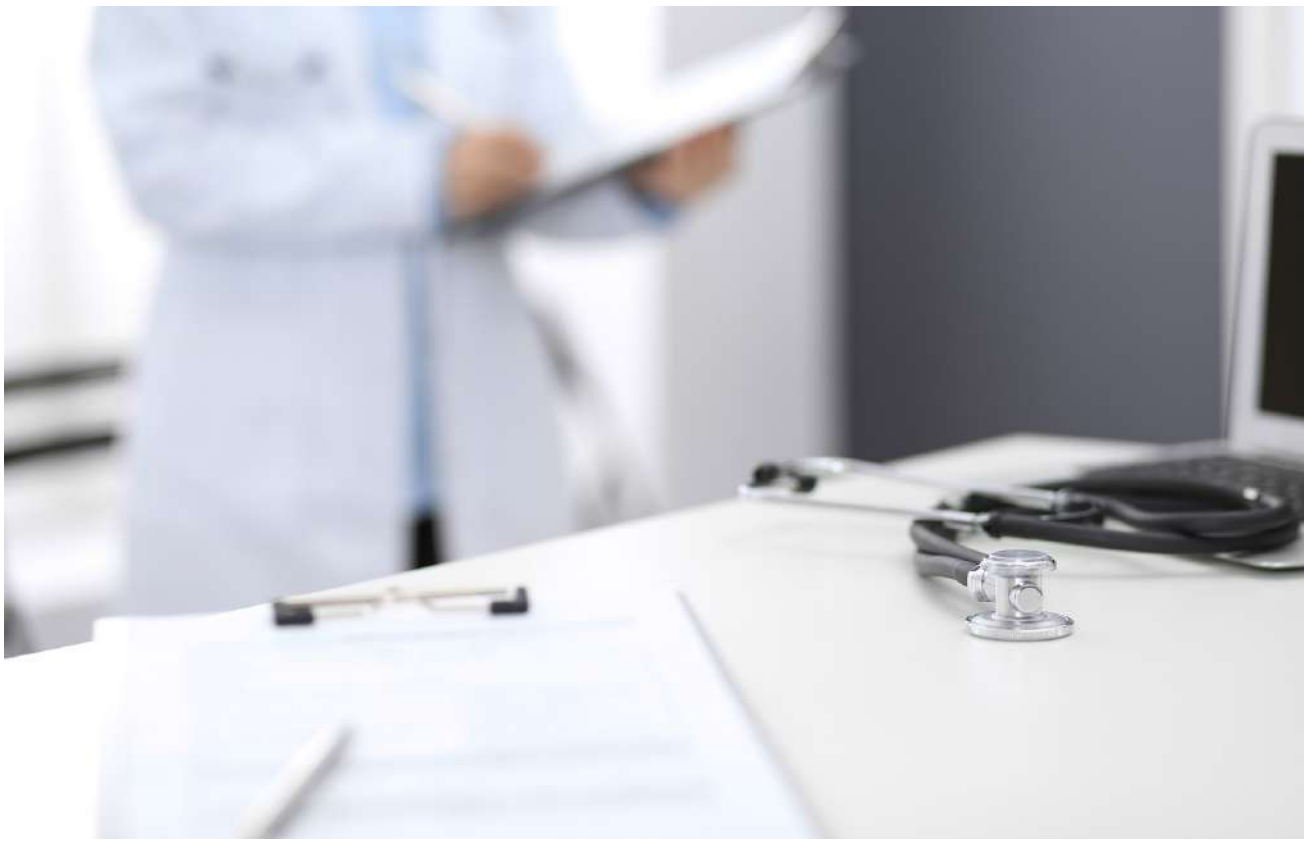
The AFI Symposium 2022 title was "The Pharmaceutical World: the paradigms of a new era". Therefore, the sessions could only turn on the return to normality. For pharmacovigilance, one of the most challenging activities now is the implementation of the "additional Risk Minimization Measures – aRMM". The session, therefore, dealt with the risk minimization activity in all its aspects, from the point of view of all the stakeholders involved: the pharmaceutical company, the authority, the healthcare worker and the patient.

The session started with an introduction by dr. Oliva di Mylan, who dedicated the session to the memory of Dr. Pimpinella, manager of the AIFA Pharmacovigilance Office, recently deceased.

After to speak was Dr. Cagnato of DOC Generici. She explained how the Risk Management Plan activity is carried out by her pharmaceutical company. To follow, dr. Diana of AIFA exposed the approach of the Regulatory Authority.

To evaluate the point of view of the pharmaceutical company with respect to that of the patient, there was an interesting double interview. It was held by Veronica Franchina of A.O. Papardo, to Dr. Pappalardo of AUSL Romagna and to Dr. Patrucco di Sofar and experienced patient Eupati. She asked them questions about the importance of the information material.

To conclude the session there was a round table. Here all the exponents of the various sectors discussed the issues of the individual interventions and answer questions from the public.



RISK MANAGEMENT AND EDUCATIONAL MATERIAL AS AMMR

IN THE SESSION DEDICATED TO PHARMACOVIGILANCE OF THE AFI SYMPOSIUM, DR. CAGNATO OF DOC GENERICI SRL, DEEPENED THE THEME OF RISK MANAGEMENT AND EDUCATIONAL MATERIAL.

RISK MANAGEMENT CYCLE

To obtain the Marketing Authorization and keep the product on the market, the pharmaceutical company must monitor the risk/benefit profile of the drug, which must be presented with a positive outcome, that is, the benefits must outweigh the risks. But this is not enough, in fact, the risks must be managed by implementing minimization measures. The process is divided into several phases:

1. Monitoring the effectiveness of data management and data collection measures
2. Identification and analysis of risks and benefits
3. Characterization of the risk/benefit ratio, which must have a positive outcome
4. Identification and planning of minimization measures, which can be routine measures or additional measures
5. Implementation of the aforementioned.

RISK MANAGEMENT PLAN: PURPOSE AND OBJECTIVES

Risk minimization and prevention activities must be reported in the so-called Risk Management Plan (RMP), a document that aims to:

- Identify and characterize the safety profile of the drug
- Indicate any further characterization of the safety profile
- Document the risk prevention or minimization measures
- Document post-authorization obligations

This document must be implemented for each company drug.

RISK MANAGEMENT AND EDUCATIONAL MATERIAL

The identification of risk minimization measures can lead to two results: routine measures or additional measures (aMMR).
The first involves the use of tools such as the Summary of Product Characteristics (SmPC), the Patient Information Leaflet, the labeling and the drug supply regime. These must be applied to all drugs.
The second, on the other hand, are measures that are adopted as supplementary measures to the routine ones if these are not sufficient, at the local level in the country where the drug is marketed. Additional minimization measures include the distribution of educational material, such as information guides or checklists for healthcare professionals or patient diaries and warning cards.
Performing an analysis is essential to understanding the effectiveness of prevention and minimization measures. The most suitable time is between 12 and 18 months from implementation and subsequently during the drug renewal phase. Indices to be analyzed are: reduction in the frequency of the onset of reactions and their degree of severity. Patient surveys are also useful to check whether the content of the educational material has been fully understood.

THE EDUCATIONAL MATERIAL

The educational material is drawn up to prevent or reduce the extent of risk or improving the benefit/risk profile of the drug.
Its content complements that reported in the RCP, in the PIL and the labeling.
Its diffusion can be useful in the prescription phase by a doctor, in the dispensing phase to the patient and, finally, in the phase of use of the medicine by the patient himself.
In the drafting and evaluation of the educational material, there are four figures involved: the company, the regulatory authority, the the healthcare professional and the patient.

RISK MANAGEMENT AND EDUCATIONAL MATERIAL: THE ROLE OF THE COMPANY

With the entry into force of the European legislation on pharmacovigilance, since 2012 pharmaceutical companies are required to have, for each medicinal product, a Risk Management Plan (RMP) that is clear, exhaustive and well articulated: they must be detailed any risks, any risk minimization measures, specifying the rationale, the key messages to be disclosed and the implementation and evaluation methods.

The company has the task of identifying risks and communicating risk mitigation measures. This communication is effective if:

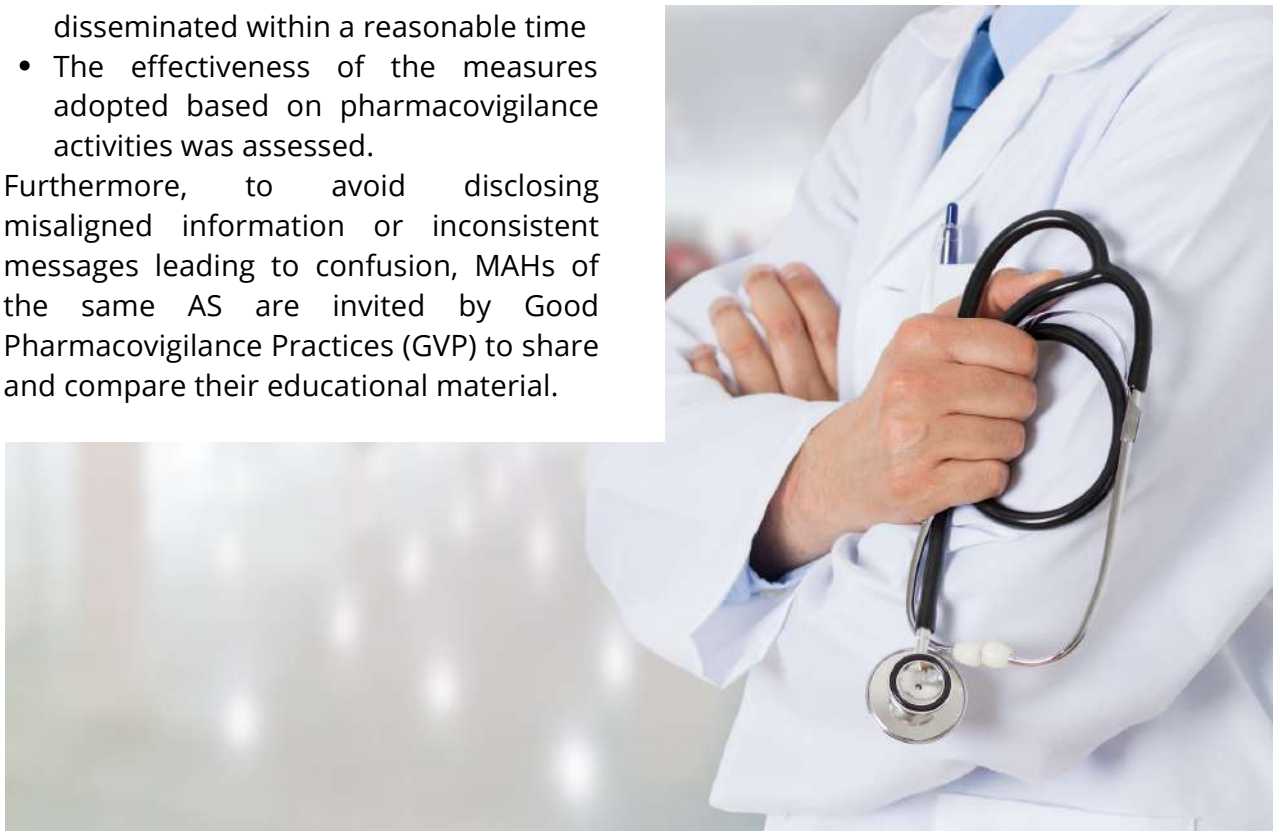
- The target audience has been correctly identified
- The communication lines implemented are based on the target audience, such as healthcare professionals and patients
- The educational material was disseminated within a reasonable time
- The effectiveness of the measures adopted based on pharmacovigilance activities was assessed.

Furthermore, to avoid disclosing misaligned information or inconsistent messages leading to confusion, MAHs of the same AS are invited by Good Pharmacovigilance Practices (GVP) to share and compare their educational material.

RISK MANAGEMENT AND EDUCATIONAL MATERIAL: THE ROLE OF THE AUTHORITY

Given that the Risk Management Plan is a document drawn up by the company, various Authorities intervene upon its approval:

- Pharmacovigilance Risk Assessment Committee (PRAC): is responsible for assessing the RMP and analyzing the implemented measures
- European Medicines Agency (EMA): publishes summaries of RMPs to disseminate information
- Co-ordination Group for Mutual Recognition and Decentralized Procedures – Human (CMDh): updates the list of risks in the previously approved document
- Italian Medicin Agency (AIFA)'s Risk Management Measures Office, evaluates and approves the educational material in Italy, if required by the RMP.



RISK MANAGEMENT AND EDUCATIONAL MATERIAL: THE HEALTHCARE PROFESSIONAL

The healthcare professional must be properly informed about any risks associated with the administration of a drug. It is his task too, to inform the patient and invite him to read the package leaflet and any other informative brochures.

RISK MANAGEMENT PLAN: CRITICALITY

The most common problems faced by companies are:

1. Identification of risks and their alignment between drugs with the same AS
2. Publication of summaries of RMPs at the European level, which are often not complete
3. Evaluation of the correct dissemination and understanding of the educational material by patients
4. Identification of the method of evaluating the effectiveness of risk minimization measures and consequent decision to implement new measures.

RISK MANAGEMENT: HOPES AND IMPROVEMENTS FOR THE FUTURE

Dr. Cagnato hopes for the future some actions aimed at improving the RMP can be implemented such as the promotion of the importance of knowledge of the MMRs contents, the dissemination of more widespread information to healthcare professionals, greater proactivity by the pharmaceutical companies, the harmonization of RMPs among the various MAHs and the publication of educational materials on all institutional websites for more immediate identification of risks by healthcare professionals and patients.

EDUCATIONAL MATERIAL: THE POINT OF VIEW OF THE PHARMACEUTICAL COMPANY AND THE PATIENT

DURING THE SESSION DEDICATED TO PHARMACOVIGILANCE OF THE 61ST AFI SYMPOSIUM, ALL-ROUND EDUCATIONAL MATERIAL WAS DISCUSSED, FROM THE INFORMATION PRESENT TO ITS DISSEMINATION. HERE'S WHAT TRANSPIRED.

There was a double interview with Laura Patrucco as an EUPATI expert patient and with Francesco Pappalardo of the Romagna AUSL, who respectively represented the patient's point of view and that of the pharmaceutical company. Here's what they answered to the questions of moderator Veronica Franchina of GIDMcrc and A.O. Papardo.

Franchina: ***For the pharmacovigilance responsible, how important is it to receive clear and updated material from pharmaceutical companies?***

Pappalardo: receiving educational material from the pharmaceutical company is of fundamental importance, because this allows the pharmacovigilance responsible to always be updated on what are important safety information, on the events on which the risk must be minimized and consequently on the information that the pharmacovigilance manager or healthcare professional must then pass on to the patient. Specifically, the receipt of the educational material by the pharmacovigilance responsible makes him aware of what are important

information and the use of some classes of drugs that are particularly delicate such as retinoids, such as Isotretinoin, which has high teratogenic effect; to be informed about the risks associated with the use of Valproate in women of childbearing age as it causes delayed effects in both body, psychological and psychic development; or even to be updated and informed on what are the pregnancy prevention programs in patients who take Valproate.

Franchina: ***For the patient, how important is it to be able to receive clear and updated material from pharmaceutical companies?***

Pappalardo: It is necessary to make a premise on the interlocutors involved in the health supply chain, as pharmacovigilance has an impact, as regards clinical studies and above all the patient's daily life: there has been an evolution in the concept of health, especially in this last period with Covid, and in addition to this there has also been an evolution in the role of the patient who started from being a person in need of care to become a patient who wants to get information, to know more about your pathology, up to the path of the EUPATI expert patient, therefore an expert patient, who in some way has certified himself, studying and acquiring skills, up to the 4.0 Patient, who is the trained and aware patient. This awareness is also of fundamental importance for the authorities involved in collecting clinical safety data, as these expert patients are increasingly participating in phase 4 of clinical studies, which in some way are also the most important for the patient because, in addition to efficacy, safety is investigated.

The importance of receiving educational material, but above all correct information becomes a must, precisely because the patient needs to be informed, to also eliminate the risk of fake news. We need to somehow create a single supply chain between all these interlocutors, from the drafting of educational material to dissemination.

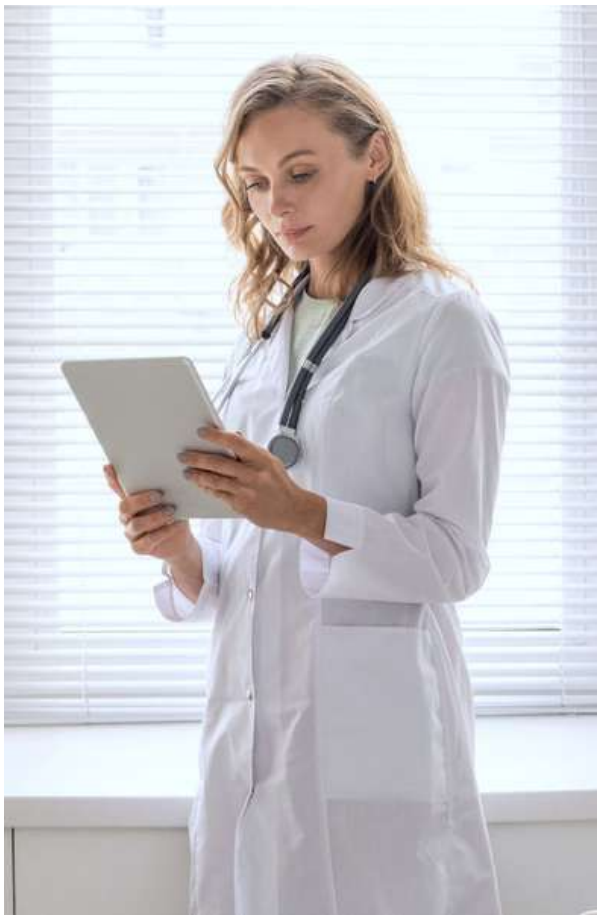
Preventive pharmacovigilance is also of great importance: so far the company has always dealt with pharmacovigilance, but in a way linked to the safety of its drug, lately, thanks to the evolution of the patient, we are starting to talk about pharmacovigilance linked to patient health. Preventive pharmacovigilance is that which, when prescribing therapy to the patient, must inform about what are already known adverse effects, because in this way the patient has a greater ability to intercept those side effects and is urged to report, because also a single data collected through a single patient enrich the database for patient protection.

It is important to talk about tools, which exist and are adequate, but what should be encouraged is the use of these, through a greater culture on how to use them, both for the health of the drug and for the health of the patient.

Franchina: ***do you think the available methods are effective?***
Pappalardo: **I would say yes, the new technologies have benefited the dissemination of educational material both to healthcare professionals and to patients.** A novelty is the fact of being able to use the educational material on computer support, such as the QR code which gives the possibility to scan and be sent directly to the pharmaceutical company website where important information on the safety of drugs can be found, to the possibility of being able to download the material on their devices and we know how much smartphones and tablets are part of our daily life today. So yes, **digital has allowed wider and more widespread dissemination of information material.**

Patrucco: **on the patient side, the best dissemination is given by the empowerment of all these interlocutors who intervene in the health supply chain.**

According to the guidelines of the EMA and the GVP, the collection of safety data is a must for health and is necessary precisely to achieve the goal of pharmacovigilance. It must be said that providing tools that allow us to intercept this security data from real life, therefore through the patient's voice, allows us to enrich the real-world data database, which is a very precious asset, as it contains the data of the patient and somehow transforms the acts into evidence. It must be said that the tools also include the competent authority, which y has taken note of this need for patients who, through associations, have made themselves heard about the need to be pulled on board in this signaling and traceability circuit of safety data.



On the institutional sites, including that of AIFA, we find respectable educational materials; we also find the possibility of making spontaneous reports or, for example, we also have videos on YouTube, which perhaps fewer people know about their existence.

Patient involvement should help a little more to shift attention from what the document, the reporting of the adverse event or side effect is to something that is more patient-oriented and this can happen, for example, by creating greater awareness, greater culture precisely on the importance of not only having the tool but also of sharing it with associations. [...]. There is also the sporadic patient who therefore does not have the habit of intercepting adverse events or simply does not have the awareness of how important this action is. Dissemination as an educational material must somehow help to harmonize the collection of data not only from patients who have chronic or oncological conditions but also from sporadic patients because even a single safety data is precious: many single data are somehow a whole.

Pharmacovigilance must also be a kind of interactive communication: we think of the electronic health record, for example, for patients who have medical devices, such as breast implants, how do they know what the effects are? Or, if they react, how should they go about reporting it? Here we use the collection of safety data through electronic tools such as the electronic health record.

Sooner or later it will also be necessary to talk about Digital Vigilance because it will also protect the security of patient data collected in terms of privacy, all the more so now that we are getting closer and closer to the topic of digital therapies. When there is a cooperation between all these interlocutors, I think it is easier to achieve the goal.

Franchina: ***Could the tools be improved?***
Pappalardo: **new technologies and digital tools can be valid tools to improve dissemination methods, on the other hand, it is also advisable to improve the identification and traceability of educational material** which is very often distributed in the same way as promotional material, not giving due weight on the part of the health worker and consequently the information it contains is not transmitted to the final user who is the patient.

Patrucco: pharmacovigilance has different tools: drug registers, digital archives, the hubs that help to collect adverse events ... There is a tendency on the part of companies to collect these patient prime data: it is precisely this awareness of the role of the patient who has evolved, he has become much more informed, much more experienced. In companies that have an interest in protecting not only the treatment anymore but also the patient who has to do the treatment, they have equipped themselves with patient safety councils, which are co-projects that take place precisely with patient associations, which are the spokespersons of the need, even in the drafting of what may be the most appropriate language to reach the recipient, because the tools must also be designed for the recipients, therefore also the usability of the language must be taken care of.
Having informed patients gives the possibility of having a patient more compliant in intercepting the adverse effect: by making the patient responsible proactively and not only as a simple user of the drug it will be even easier for him to follow you in the adherence to supervision.

We must also think of those citizens who do not yet need to have information on a drug because they are still citizens, but who could be potential patients: it is also important to create a culture of progressive advertising, that advertising that reaches the community directly and not only on patient request. A beginning can also be given by the figure of the pharmacist who must be made responsible for the importance of giving information and empowering the patient by informing him of side effects.

Franchina: ***is the HCP willing to be able to report events concerning the risk to be minimized?***

Pappalardo: The reception of the educational material is part of the health professional, generally he gives knowledge on what is important information on the safety of the drug and on the events of which the risk must be minimized. **He is aware of having to transfer this information and transmit it to the patient and finally, if these should occur, he must report the various suspected adverse events that have occurred.**

The receipt of the educational material by the health professional generates in him greater involvement in what is the reporting activity of these AEs. In recent years, however, the covid 19 pandemic has stolen time from all these health care activities, such as the training of the healthcare professional and the patient and not least the reporting of adverse events, consequently it is necessary to regain possession of these times and spaces. to ensure that the educational material is understood, the information is passed on to the patient and the AEs are reported.

Franchina: ***for the patient, once he has received the educational material, does he reassure him or alarm him because he discovers fears that he otherwise would never have evaluated?***

Patrucco: talking about drug supervision with a patient who does not have technical skills certainly generates many doubts. He needs to receive answers and this is where the need arises to create therapeutic alliance paths between the companies that provide drug safety information and patient associations. The therapeutic alliance can already be that between doctor and patient because when the patient reads a package leaflet, he cannot filter what he reads, as the leaflets are designed more for the protection of the data, not for the protection of the reader of that data, so it is important that these leaflets are rethought in a more user-friendly way and even more important is the figure of the doctor who reassures the patient and who does not leave him alone at the mercy of the package leaflet: he must establish a relationship of trust through constructive dialogue.

It is also important to think about gender pharmacovigilance because the AEs that happen to men are different from those that can happen to women and also in the drafting of protocols, involving an expert patient can also help to find an adequate therapy for women who still today they tend to be excluded from clinical studies and therefore also the safety data are somehow deficient. So we interact with associations, expert patients, companies and competent authorities.

SafetyDrugs
PHARMACOVIGILANCE SOLUTIONS

Via Bertodano 11, Biella (BI) 13900, Italia
Tel: +39 015 324 68

www.safetydrugs.it

marketing@safetydrugs.it