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ANTI-MICROBIAL RESISTANCE
—an overlooked adverse event

Latin American initiatives • SCOPE project • Device safety
Patient perspectives on PV • Annual meeting • New comic book
Jordan’s health sector • Vigi updates
I like doing practical things and producing tangible results, and I enjoy working on my own – but when I look back at what I consider the happy moments of my life, they almost invariably are the good times I have shared with other people – the good meetings with good conversations. The food we ate, the clothes we wore, the ambiance of the room, all that is important – but what I remember afterwards is what we talked about, how I got to know other people a bit better and how the interaction between us influenced and touched me. And how good I felt!

So why am I going on about this? What’s so important about people, conversations, the good meeting? Well, I have a feeling that many of the problems in the world today, small and big, have their origin in an inability to connect with other people, understand them and find a way forward, together. When we stop trying to understand other points of views than our own, winning an argument becomes more important than resolving a problem, and dialogue is replaced by debates. This leads to something far worse than simple misunderstandings: a rejection of the other. That’s how conflicts start. Resolving conflicts, to me, is never a pleasure in itself, but it is a necessity, and when a resolution has been reached I do feel some sense of achievement. But to be really content I’d much rather spend my time involved in good conversations and productive dialogues that solve problems and prevent conflicts from occurring in the first place.

As it takes two to tango – it takes two to talk. Let’s engage in open, honest and constructive dialogue wherever and whenever possible. Start the good conversation before it’s too late!

Marie Lindquist, Director
Updates

**APEC knocks down on Asia Pacific medicines safety**

To achieve regulatory harmonisation in pharmacovigilance in its member economies, the Asia-Pacific Economic Cooperation (APEC) organised a medicines safety workshop in South Korea in September 2016.

The APEC Harmonization Center (AHC) Pharmacovigilance Workshop and Training Centres of Excellence (CoE) Pilot took place in Seoul, South Korea, in early September 2016. These events were arranged as part of the on-going activities of the APEC Regulatory Harmonization Steering Committee Roadmap to promote regulatory convergence in pharmacovigilance in the APEC economies by 2020.

APEC consists of 21 economies located around the Pacific Rim, of which 18 – all but Papua New Guinea, Hong Kong, and Taiwan – are full members of the WHO Programmes for International Drug Monitoring. At the Seoul gathering, the APEC Harmonization Center held a workshop, while the Korea Institute of Drug Safety and Risk Management (KIDS) hosted the three-day CoE Pilot programme. This workshop was organised as a part of the AHC’s ‘Roadmap to Promote Regulatory Convergence on Pharmacovigilance and Medical Device Vigilance’. Similar workshops have been organised in 2012, 2013, and 2015. This year, the workshop included 12 speakers and panellists from a variety of countries and organisations, including US Food and Drug Administration, the Ministry of Food and Drug Safety (MFDS) in Korea, national pharmacovigilance centres (NCs) in the APEC region, as well as WHO, UMC, and the Dutch pharmacovigilance centre Lareb. It was attended by approximately 200 people, largely representing Korean professionals working within the industry, MFDS, and KIDS. Over the course of three sessions, there were presentations on pharmacovigilance activities within and beyond the APEC region, the collection and reporting of adverse events, and approaches to benefit-risk assessment. The CoE Pilot training was attended by approximately 60 persons, both regulators and pharmacovigilance experts from countries within the APEC region: Taiwan, Japan, Malaysia, the United States, Singapore, Indonesia, Chile, Thailand, Peru, Philippines, and the Republic of Korea (MFDS, KIDS, AHC). Each day of the training course was composed of morning lectures followed by afternoon small-group sessions, which allowed for cooperative work on the lecture material, as well as providing opportunities for sharing information on how different NCs function and how they deal with safety concerns.

**Reporting adverse events in published and unpublished studies**

The recent article “Reporting of Adverse Events in Published and Unpublished Studies of Health Care Interventions: A Systematic Review” aims to quantify the under-reporting of adverse events (AEs) in published medical literature, compared with unpublished sources. The article, published in PLOS Medicine and written by Su Golder, Yoon K. Loke, Ruth J. Walker, and Gill Norman, reviewed 28 studies that provided a comparison of information on AEs according to whether the study was published or unpublished.

The researchers found that fewer published studies reported information on AEs compared with unpublished studies, that both a lower number of AEs and a narrower range of named AEs are reported in published studies compared to unpublished studies, and that the inclusion of unpublished data in meta-analyses leads to more precise conclusions on harms. There is a growing movement calling for full disclosure and unrestricted access to clinical trial data, as exemplified in campaigns such as AllTrials. Given the potential for unpublished data to be an important source of information on harms from medicines, UMC fully supports the authors’ call for a new policy and action to make adverse event data readily accessible to the public.

**New educational offering on the epidemiology of vaccine safety at ICPE**

Vaccines are key tools for global public health. Increasingly, pharmacoepidemiological studies are providing the critical evidence needed to risk-benefit assess-ment to inform immunisation policy. This is true both for mature immunisation products with successful control and elimination of the targeted vaccine-preventable diseases (VPD), as well as for low- and middle-income countries (LMIC) where innovative vaccines against challenging diseases such as HIV/AIDS, Dengue, Ebola, malaria, etc. are under development.

The annual International Conference of Pharmacovigilence (ICPE) has had a vaccine-specific session for more than 10 years, and a Vaccine Special Interest Group (VAXSIG) was formed in 2014. One of the goals of the VAXSIG is to offer educational activities together with the ISPE Education Committee on vaccine-related epidemiology. The VAXSIG pre-conference course on vaccine safety was offered for the second time at the 31st ICPE in Dublin in August 2016. This beginner-to-intermediate level half-day course aims to establish an understanding of some of the ways in which vaccine safety is monitored post-licensing, including passive surveillance methods, common observational vaccine-safety study designs and methods, active vaccine-safety surveillance using sequential analysis, and how to investigate signals that arise from active surveillance.

The faculty of this year’s course was a mixture of experts from the United States, representing government, academia, and industry. The five topics covered were introduction to vaccine safety and policy overview by Dr Robert Chen of the US Centers for Disease Control and Prevention (CDC); passive vaccine-safety surveillance in practice by Dr Steven Bailey from Pfizer; common observational vaccine study designs and methods by Dr Patricia Saddier from Merck; near real-time surveillance methodology by Dr Martin Kudolf from Harvard University; and active vaccine-safety surveillance in practice by Dr Katherine Yi, also from Harvard. The course was directed by Dr Syed Rizwanuddin Ahmad, currently a pharmacovigilance consultant and a former safety reviewer at the U.S. Food and Drug Administration (US-FDA).
VigiBase: Embracing the new & strengthening the established

In less than a year, the number of individual case safety reports (ICSRs) in VigiBase, the WHO global ICSRs database, has increased from 12 million to over 14 million reports.

Within the scope of drug safety surveillance, collecting ICSRs is a fundamental prerequisite to detecting signals of adverse drug reactions (ADRs). Countries who are members of the WHO Programme for International Drug Monitoring (WHO PIDM) are always strongly encouraged to share their reports with VigiBase.

There are many aspects that play a role in the quantity and frequency of reports submitted by each member country. One aspect could be the global change in the culture of ADR reporting, as pharmacovigilance gains popularity and recognition among healthcare professionals and patients. Another aspect could be the overcoming of a technical obstacle in the ICSRs submission process, which can result in a surge of reports received by VigiBase. The increase could equally be due to the growing number of countries participating in the WHO PIDM or the addition of three new countries in 2016, bringing the total to 125 full members.

Nevertheless, as we welcome and introduce the newest member countries to UMC and VigiBase, it is important that the pre-existing relationships with other member countries are strengthened and maintained. One of the key elements contributing to the strengthening of these relationships is the diverse language skills available at UMC, the recent addition of Arabic, French and Portuguese language support for UMC staff and the recently released pharmacovigilance network’s guidelines for adverse drug reactions in the Arabic language.

To be compliant with international standards and to utilise the enhanced functionalities in VigiFlow, MedDRA is required as the medical terminology. Conversion of WHO-ART and ICD to MedDRA is necessary, and to facilitate this process Uppsala Monitoring Centre will provide mapping suggestions from WHO-ART and ICD to MedDRA terms; a manual review will then be required by each national pharmacovigilance centre (NC). Some of the entries from ICD might have a corresponding term in MedDRA, which may result in manual reassessment of the coding.

The enhanced VigiFlow will be released during 2017. UMC will contact each NC to decide a roll-out schedule for their country. The goal is to have all NCs using the enhanced VigiFlow by the end of 2018.

UMC has engaged a reference group consisting of current VigiFlow users who will be asked to provide input, for example on how to optimise the user interface.

SCOPE shares insights into European Union pharmacovigilance practices

Representatives from 20 EU countries assembled in the United Kingdom in October to attend training sessions on adverse drug reaction reports and different methods for collecting them.

The strengthened Collaborations to Operate Pharmacovigilance in Europe (SCOPE) Joint Action project has now been running for three years, and the core activities are nearing completion. SCOPE recently held a number of training sessions to share the findings of the past years’ work with the pharmacovigilance network, focused on information gathering and analysis of how EU member states conduct pharmacovigilance activities and what good practice looks like.

SCOPE has project teams concentrated on five aspects of pharmacovigilance activities: adverse drug reaction (ADR) reporting, signal management, risk communication, quality management systems, and lifecycle pharmacovigilance.

The project team focusing on adverse drug reaction (ADR) reporting, led by Halmed – the medicines agency in Croatia, held a two-day training session in London on October 2016. It was attended by 70 pharmacovigilance staff from 20 countries. Topics covered included telephone reporting; web-based reporting; how to carry out comparisons of data from different reporting sources; and how to handle ADRs and AEFI reports; additional monitoring, duplicate detection; measuring and auditing quality of reports; and how to effectively raise awareness of ADR reporting systems through campaigns.

Dr Julià Pallós, head of Biomedical Division and Pharmacovigilance and a PRAC delegate for the National Institute of Pharmacy in Hungary, said: “The scale of presented subjects and discussion was very large, covering both methodological and practical aspects of ADR reporting. The workshops connected to each item gave further benefit to the audience, which consisted of mainly pharmacovigilance assessors.”

The participants were taken through the different methods of ADR reporting, with a particular focus on telephone reporting and how to deal with difficult calls, with practical examples being provided. They also heard how SCOPE has developed a web-based form that is EUDR compliant and available for member states to adopt.

The presenters from the national ADR centres in Croatia, UK, Romania, and Latvia in the Netherlands were joined by Sieta de Vries, a postdoctoral researcher from the University of Groningen, who spoke about ADR reporting in the context of the opportunities and preferences of patients. She said: “As a researcher, it was very useful to hear about the current practices and experiences of national centres in dealing with suspected ADR reports.”

Sieta de Vries said: “To further improve reporting by patients, it is important to increase awareness among patients about how they can report ADRs to the national centres and to provide patients with information about what happens with their reports.”

This project was complemented by François Houyet from the patient organisation Rare Diseases Europe (EUBORDIS), who provided further information on patients’ needs when reporting side effects.

The audience were also taken through the stages of planning, running, and evaluating ADR awareness campaigns. SCOPE has reviewed a number of campaigns run at a national level, as well as the materials and methods used. This helped in the development of a guidance document on how ADR centres can adopt the methods for increasing reporting levels in their countries.

The presenters explained that the training being delivered is derived from a series of “Best Practice” guidance documents that will soon be available on the SCOPE website. There will also be e-learning modules for National Competent Authority (NCA) staff and e-learning packages for healthcare professionals.

In addition, there are a series of animated or interactive posters that were used in an EU-wide social media campaign in November 2016 to raise awareness about national ADR reporting systems. The idea was that each NCA that joined the campaign should use Facebook, Twitter, and other social media platforms to inform people about the importance of reporting, and point them towards their national ADR system.

More information can be found on the SCOPE project website, www.scopejointaction.eu.

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AMR REMAINS UNCHECKED, the progress achieved by modern medicine in the past 70 years is at serious risk of coming undone. Already today more than half a million deaths annually are attributable to antimicrobial resistance – a number projected to rise to 10 million in 2050 if no action is taken.

Solutions to contain this issue need to reflect the broad ecological nature of AMR, which require a multi-sectoral response, including management of the medicines’ pathway from the manufacturing facility to the patient’s bedside. Assuring quality, safety, and effectiveness of antibiotics need to go hand-in-hand with data generation on antibiotic use, resistance levels, and patients’ access to effective antibiotics. All of this is needed to ensure the highest possible attainable health standards for everyone, and to inform policymakers on which interventions to prioritise in order to better manage AMR.

As more data is generated to reveal the magnitude of the problem, it shows that the post-antibiotic era may already have begun. Every year, 214,000 newborn sepsis deaths are estimated to be directly attributable to bacteria that are resistant to available antibiotics. That is roughly one third of all neonatal sepsis deaths. In the last years, antibiotic resistance has started to compromise the effectiveness of carbapenems – a last-line class of antibiotics used against serious bacterial infections. According to a study from the Southeast Asian region, more than 75% of Acinetobacter isolates, 30% of Klebsiella isolates, and 30% of E. coli isolates displayed resistance to carbapenems. Of particular concern is the increasing prevalence of carbapenem-resistant Enterobacteriaceae (CRE), as mortality rates in patients with CRE infections are high.

Another study done in health facilities in the African region detected 100% resistance to ampicillin in Klebsiella sepsis isolates. High-income countries likewise are being affected, as exemplified by at least 28,000 people dying each year as a direct result of infections caused by bacteria that are resistant to antibiotics solely in the United States.

CROSS-CUTTING NATURE OF AMR NEEDS BROADER SET OF ACTORS

AMR has been neglected for many years, but it has finally begun to attract the necessary attention by the general public and among decision makers. AMR reaches beyond health and healthcare and is equally a serious concern in agriculture, animal health, and for the environment. This cross-cutting nature of the issue means that it has direct consequences for our social and economic development.

In 2015, countries adopted the Global Action Plan on Antimicrobial Resistance at the World Health Assembly, as a blueprint and guideline for the development and implementation of National Action Plans on Antimicrobial Resistance. Recognition of the threat AMR poses to the successful fulfilment of the Sustainable Development Goals propelled the topic to the level of Heads of States at the United Nations General Assembly in September 2016. Following HIV/AIDS, non-communicable diseases, and Ebola, AMR is only the fourth health issue to ever be brought up at the General Assembly as a matter of urgent consideration. The Political Declaration that all UN Member States subsequently adopted calls for coordinated, global action and includes a proposal to establish an ad hoc inter-agency coordination group.

The combination of the cross-cutting nature of AMR and recent political developments underline the need to involve actors that previously haven’t been directly engaged with the topic. The increasing political and technical attractiveness of AMR can be helpful for this broader engagement, but that may not be enough. Means of implementation to turn words into action are essential. A few AMR-specific initiatives have been announced, such as the Fleming Fund set up by the UK government, but none are yet in operation.

ENSURING SUSTAINABLE ACCESS TO EFFECTIVE ANTIBIOTICS

Since 1987, no new class of antibiotics has been discovered. Lack of profitability and major scientific bottlenecks has meant that pharmaceutical companies have withdrawn in big numbers from the anti-infectives research and development (R&D) field. Moving away from the current patent-based innovation model and designing new incentives and investment strategies that can help overcome the scientific and financial bottlenecks is urgently needed, but is currently subject of intense debate by key stakeholders.

New approaches are needed not only in R&D, but also in the way we manage antibiotics. Environmental pollution from antibiotic production sites, substandard quality of antibiotics, and unnecessary use

Antimicrobial resistance (AMR) – one of the greatest threats to achieving UN’s Sustainable Development Goals – is increasingly being recognised as an issue of global concern that requires global collective action.

“Already today more than half a million deaths annually are attributable to antimicrobial resistance – a number projected to rise to 10 million in 2050 if no action is taken.”
Embedding human medicine and livestock production in the context of antibiotic stewardship is crucial. In human medicine and livestock production, there is a need to understand how antibiotics are used, how resistance spreads, and how to measure changes in antibiotic use over time. This requires a system that balances the need for surveillance against the need for effective antibiotic stewardship.

The challenges for challenges for human medicine and livestock production are complex. Resistance patterns can emerge quickly, and new antibiotics may not always be available. In human medicine, the availability of antibiotics is crucial, but resistance levels and antibiotic use also need to be balanced carefully against the need to do the necessary benefit-risk assessment.

Data generation on antibiotic resistance is still the core method for reporting. However, more sophisticated and electronic data capture is needed. This can be achieved through pharmacovigilance tools such as ReAct - Action on Antibiotic Resistance, which can utilise existing standards to improve data exchange.

The "Simplified E2B Guide for Primary Reporters" aims to overcome some of the barriers that health authorities may face in submitting adverse drug reaction reports to the global database VigiBase. This guide can help any user, including those in low- and middle-income countries, to submit reports electronically in a structured format, improving the ability to efficiently exchange, process, and analyse drug safety data.

Advantages with ICH E2B format:
- Improves the ability to efficiently exchange, process, and analyse drug safety data
- According to predefined business rules
- Facilitates sharing of pharmacovigilance information to organisations who need it (i.e. pharmaceutical companies, public health programmes, regional pharmacovigilance centres, WHO Global ICH database etc.)

The document "Simplified E2B Guide for Primary Reporters" can help any electronic reporting solution to create and transfer safety data in a harmonised way, using the International E2B standard. "The guide is a very comprehensive and focused document on the main concepts of E2B R2," Stephanie Bodin-Parsinnen said after reviewing the document. Bodin-Parsinnen, director of the QPPV office at UCB Biopharma SRL, Quality Assurance and one of the partners in the WEB-RADR project, continued: "The xml structure, code lists, formats et cetera are illustrated through graphical representations and very valuable examples."

"This constitutes a fantastic introduction to the ICH E2B R2 standard for IT personal or vendors unfamiliar with pharmacovigilance safety reporting and also for pharmacovigilance staff willing to know more about the technical aspects of the ICSR transmission," she said.

Most NCs are already capable of handling ICSRs according to these standards, either through a vendor, or home-built systems, or through the widely adopted VigiFlow system. The NCs’ needs are different and international standards can be utilised in several different ways. There is no one-size-fits-all solution in place, and standards can be introduced by step by step, starting with simple primary co-reporting scenarios and continuing all the way to fully fledged data-exchange workflows with pharmaceutical industry.

Taking into account the international dimension of ADR reporting and the need to achieve harmonisation and high quality between all parties involved, ICSRs should be submitted electronically as structured data with the use of controlled vocabularies. In respect of the content and format of electronic ICSRs, all involved parties are encouraged to adhere to internationally agreed ICH-guidelines and standards. To interpret and implement these comprehensive guidelines and standards is, however, complex and time consuming.

The aim of the guide is to make the essential parts of these complex standards reachable for everyone, thereby facilitating international data exchange.

Please feel free to contact UMC in an early planning stage when developing data-capture systems to avoid non-compatibility of data sharing.

**Harmonising global sharing of patient safety data**

**NE MIGHT THINK THAT UNDER-REPORTING FROM HEALTH AUTHORITIES, i.e. NATIONAL CENTRES (NCs), TO VigiBase, THE WHO GLOBAL INDIVIDUAL CASE SAFETY REPORTS (ICSRs) DATABASE, IS DUE TO A LACK OF WILLINGNESS TO SHARE PATIENT SAFETY DATA GLOBALLY. IT IS QUITE THE OPPOSITE. NCs ARE STRIVING TO ADD THEIR OBSERVED-TO-EXPECTED RATIOS OF REPORTED CLUSTERS OF ADVERSE EVENTS CAN BE AN ENABLING FACTOR IN IDENTIFICATION OF RESISTANCE SPREAD PATTERNS IN THE RESPECTIVE AREA. USE OF POOR QUALITY MEDICINES CONTAINING PHARMACEUTICAL INGREDIENT CAN EXPRESS ITSELF IN SUB-THERAPEUTIC DOSES OF THE ACTIVE PHARMACEUTICAL INGREDIENT CAN EXPRESS ITSELF CLINICALLY WITH EXPECTED ANTIEPYRETIC EFFECT WHILE PROLONGING THE ILLNESS PERIOD. SUCH MEDICINES OF POOR QUALITY CAN BE UNDETECTED IF THEY ARE ALLERGIC MEDICATIONS. PHARMACOVIGILANCE DATA COLLECTION AND REGULATORY STRENGTHENING THEREFORE HAS A CRUCIAL ROLE TO PLAY TO ESTABLISH THE UPTAKE NEEDED SYSTEMIC AND CULTURAL CHANGE IN HOW WE CAN MANAGE AND USE ANTIBIOTICS TO ENSURE THEIR EFFECTIVENESS AND LONGEVITY FOR GENERATIONS TO COME.**

**THE ROLE OF PHARMACOVIGILANCE IN AMR MANAGEMENT**

Dr. Sandor Lajoský, Policy Associate, ReAct - Action on Antibiotic Resistance

Dr. Helle Aagaard, Policy Advisor, ReAct - Action on Antibiotic Resistance

Dr. Anna Zorzet, Head of ReAct Europe, ReAct - Action on Antibiotic Resistance

Dr. Dušan Jasovský, Policy Associate, ReAct - Action on Antibiotic Resistance

Dr. Helena Wilmar, Senior Advisor, Pharmacovigilance Consulting, UMC

Dr. Magnus Wallberg, Technical Fellow, Evgeni.e., UMC

Dr. Magnus Wallberg, @CMWallberg, Magnus.wallberg@who-umc.org

Dr. Helena Wilmar, Senior Advisor, Pharmacovigilance Consulting, UMC

Dr. Helena Wilmar, @CMWallberg, Helena.wilmar@who-umc.org
How concerned are European patients about side effects?

Safety issues are probably the main concern for patients starting a new treatment. There are patients who differ from the general patient population, who have such a severe disease that the risk they take with the medicine may be less important than the expected benefit, given what happens if their condition is left untreated. But even in this population I think side effects is a main concern. For example, in 1997 patients who had started an highly active antiretroviral treatment for HIV several years prior discovered in large numbers that they’d undergone body-shape changes and gained weight. It was later called HIV-related lipodystrophy, but when it was first discovered nobody knew what it was. It hadn’t been detected in clinical trials, because it takes time before it occurs. And then many patients started to interrupt their treatments even though they knew it was life-saving, because they didn’t know what was happening to them. So they made their own benefit-risk assessment; the benefit was to control HIV replication, but the risk was completely unknown because the doctors didn’t even know what these body-shape changes were.

So I think that the risk can become the main concern, even with these life-saving medicines. It’s a permanent re-evaluation by the patient of their own benefit-risk, depending on how they feel and what condition they have.

How do the priorities of regulators and healthcare programmes differ from those of patients?

What we’ve learned from working with regulators and healthcare professionals is that they’re not people working in isolation who are indifferent towards what happens to the patient. On the contrary, they’re too obsessed by the possible harm to patients, and sometimes there’s a risk that a potentially effective medicine is not authorized due to the perception the regulators may have of the side effects. This is why we welcome the efforts by regulators to elicit patient preferences, to consult with more patients, and use techniques where patients themselves weigh the benefit and risk of a new medicine. How patients work through these issues can inform the regulator’s actions the day they make a decision.

We did an interesting exercise at the European Medicines Agency (EMA) where we used one of these techniques to say what we thought of an anti-cancer product. The healthcare professionals sat in one room, and patients and consumers in the other room, and both groups did the same exercise. The patients were discussing one of the side effects, which was the risk of sudden death. The cancer in question emerged in a quite old population, and the representatives for the elderly said that this risk isn’t really a problem in very old populations; the risk of sudden death is easier to live with than drawn-out agony and a lot of pain. So they graded this adverse drug reaction as very low. In comparison, the healthcare professionals spent the entire exercise discussing sudden death, because for them it was horrible, and they couldn’t even finish the exercise because they were still debating the sudden-death risk. This highlights the need to have different opinions to make the best decision.

“I think that the risk can become the main concern for patients, even with these life-saving medicines.”

Who is François Houÿez

... director of Treatment Information and Access, and policy advisor at the European Organisation for Rare Diseases (EURORDIS). Mr Houÿez has been working as a patient advocate since the early 1990s. Among other things, he’s also involved in the MEDES-RADAR project, and is a advisor to the SCOPE Joint Action Advisory Group.

Patient perspectives on pharmacovigilance

When do patients accept more risk than regulators, and what are the communication barriers between healthcare professionals and consumers of medicines? Uppsala Reports sat down with the European patient advocate François Houÿez for a Q&A on patients’ concerns regarding pharmacovigilance.
“If we don’t change this cultural dilemma, then the boring package leaflet will never become a document that patients will want to read.”

Better communications between healthcare professionals and patients is needed.

WHAT CAN PATIENTS DO TO CONTRIBUTE TO BETTER MEDICINES SAFETY DATA?

In the same way that Marketing Authorisation Holders have to have a QPPV, we would like to see a contact person for pharmacovigilance in all patient organisations – someone who’s been appointed on request from the regulator. That person should be the one to, for example, receive safety alerts, press releases or copies of the healthcare professional letters – and then be responsible to work with a communications colleague to disseminate the information to others in the organisation. But they should also prepare reports, queries, and research questions to pass on to pharmacovigilance experts, when they’ve received questions, concerns, reports or analysis of social media results within their group. We think that this could be an interesting way to engage these organisations, officially and with an official recognition. We need to make these interactions more visible to the population, so that others will want to get engaged in pharmacovigilance as well.

WHAT ARE THE BARRIERS TO PROVIDING THE PUBLIC WITH BETTER INFORMATION?

In general, the national competent authorities don’t have the necessary expertise in communication and how to target a population. To just post a message on their own website cannot be considered real communication. If once shared UMC’s information music video Take&Tell at workshop for qualified persons for pharmacovigilance (QPPVs). Someone made an interesting comment – she said that: “This video is excellent, it does what it wants to do, it engages the public, and there are many other messages where we need to create such tools. But as soon as we propose easy-to-read material with a nice graphic design that appeals to patients, regulators reject it, because it looks too nice then it becomes promotional material.”

I don’t know to which extent this is true, but I’ve heard and I’ve seen very nice and well-developed educational material submitted to regulatory authorities and rejected because it was too nice. If we don’t change this cultural dilemma, then the boring package leaflet will never become a document that patients will want to read.

IS THERE ENOUGH INFORMATION ABOUT PHARMACOVIGILANCE AND ADVERSE SIDE EFFECTS AVAILABLE TO PATIENTS?

There is a lot of information, the problem is how to bring it to those who need it, and that’s where we need to be very imaginative. There is a lot of information on the EMA website and on the websites of the national competent authorities. There are tools where patients can receive warnings, and some communication campaigns on specific issues. Sometimes there are campaigns that invite people to report adverse drug reactions. But these efforts are usually not continued, the campaign runs only one time and it’s not repeated. They need to be repeated again, and again, and again.

We hope that new tools, like for example the WEB-RADR mobile application – where people can sign in and receive information on the medicines they’ve listed – can establish a two-way communication with regulators where the public can be informed when there is a recall, a new warning, or any new information regarding safety. And this is what we’re starting to see with the first users of the mobile app, where only a few people are using the app to report side effects, but all downloaders are using it to receive safety information on the medicines they’ve listed.

WHAT IS VIGIMATCH AND WHY WAS IT DEVELOPED?

vigiMatch is a new tool that was developed by TNO in the Netherlands and is ready for routine use. It is a new algorithm for automatically detecting duplicates in the VigiBase database of individual case safety reports (ICSRs). The aim of VigiMatch is to support the quality assurance of the VigiBase database and to help identify patterns in adverse drug reactions that might not be obvious from the analysis of routine data. VigiMatch is a complex computational method used for signal screening and time wasted in manual work; the new algorithm vigiMatch helps to reduce duplicates.

Automatic detection of suspected duplicates in VigiLyze using vigiMatch

Duplication of adverse drug reaction reports in VigiBase causes several problems, such as interference with complex computational methods used for signal screening and time wasted on manual work; the new algorithm vigiMatch helps to reduce duplicates.

A NEW ALGORITHM developed by UMC researchers in help in the detection of duplicates in VigiBase is now ready for routine use. vigiMatch will be implemented in VigiLyze in January 2017, and it will mean that all reports that are suspected duplicates are hidden by default, and only the reports with the highest vigiGrade completeness score are shown.

The suspected duplicates are also excluded from the statistics view and the data mining tab. Reports that have support for a suspected duplication are indicated by a double arrow in the list of individual case safety reports (ICSRs). In the user settings however, one can select to use the full dataset, which includes suspected duplicates in the statistics and data mining tabs.

With over 14 million reports currently in VigiBase, the WHO global ICSRs database, a manual approach to weeding out duplicates is not feasible. vigiMatch uses a statistical model that scores pairs of reports, taking into account the amount of matching and mismatching information:

- Blank fields are ignored, matches are rewarded, and mismatches are penalised.
- For numerical fields, vigiMatch rewards a close match, although with a lower score.
- The algorithm takes into account how likely it is to get a match by pure chance, so that a match on a very common drug yields a lower score than a match on a more unusual drug.

The same principle applies for all other fields.

Correlations are considered so that if, for example, two drugs are usually reported together, the score is reduced if a report pair matches on those two drugs.

The scores received for each individual field are added together to obtain a total score for the report pair. For a report pair to be automatically flagged as suspected duplicates, the score needs to reach above a certain threshold based on the expected number of duplicates in VigiBase.

There are several reasons why a report could be duplicated. Reports could be sent by multiple caregivers of the same patient as well as by the actual patient. Often the pharmacovigilance companies are required to submit a report for any adverse reaction they learn about, and reports often contain drugs from different companies, which can result in many duplicates of a single underlying case. Duplication can also arise due to errors when transferring the reports between different systems and databases.

Since reports of the same underlying case can come from multiple different sources, it means that the reports are usually not identical. Differences can arise from typos, variability when coding drugs and adverse reactions, as well as uncertainty in the available case information. This makes it harder to detect if two reports actually describe the same underlying case.

vigimatch does a good job at identifying possible duplicates; it has even been shown to outperform rule-based duplicate detection. However, reports that are not duplicates but otherwise related (e.g. a same patient, different issue) are difficult for the algorithm – and even humans – to handle. It can also miss some duplicated reports. vigiMatch is an aid to reduce duplicates, but in the end it is up to each national centre to determine which suspected duplicates should be officially merged.
Jordan’s medical sector grows despite regional instability

In spite of long-lasting geopolitical unrest in the region and the resulting influx of migrants to Jordan, the country has managed to create strong growth in its pharmaceutical and healthcare sectors.

THE FIRST INTERNATIONAL congress arranged by the Jordan Food and Drug Administration (JFDA) took place in the country’s capital Amman in October 2016, covering topics on how to mobilise investments in a medical sector facing complex challenges, and characterising the role of regulatory institutions in the Middle East and North Africa region.

The two-day conference attracted around 600 participants from 27 countries. They shared their perspectives and presented future directions for a pharmaceutical industry and healthcare sector that are complicated by the unstable political situation in the region.

Bordering Syria, Iraq, Israel, the West Bank and Gaza Strip, and Saudi Arabia, Jordan has remained one of the few stable countries among its neighbours. Being located in the midst of a region plagued by conflicts has impacted the country’s economy in different ways and has shaped its various industries to adapt to the waves of migration from the West Bank and Gaza Strip, Iraq, and Syria.

Over the last few years, Jordan has coped with these external strains and managed to maintain economic stability despite rising socio-economic tensions and the hosting of a large number of people displaced from neighbouring countries.

TO COME TO TERMS with the challenges that political instability and its effect on the economy poses, authorities have undertaken significant adaptations in policies to cope with the current conditions and enhance financial growth, through improving competitiveness and to stimulate good governance. In particular, the pharmaceutical industry has become a strategic sector for investments and with its continued good outlook for growth it has become a key sector in the country’s economy.

The unique role of the pharmaceutical industry and the healthcare sector in Jordan and in the region was evident at the opening session of JFDA’s 1st International Congress in Amman. The conference highlighted the medical requirements of current and future generations living in Jordan, and the need for an efficient pharmaceutical and healthcare sector.

Harmonisation between the neighbouring countries to manage the shift to a more specialised healthcare that focuses on post-conflict care is also needed, as is the ability to adequately respond to changes arising from the political context in the region.

The first Jordanian pharmaceutical industry has expanded rapidly over the past 50 years, and to date there are 16 registered local pharmaceutical companies in the country. The sector has developed into an export-driven industry delivering 81% of production to markets in more than 60 countries at an affordable cost, out of which 90% of the production is delivered to other Arab countries, underlining the need to establish a harmonised pharmaceutical regulatory framework for the industry.

Economically, Jordan has benefitted from being a geographical hub for trade between Europe and the Middle East. The country also has an advantage in its highly educated labour force, which provides the neighbouring Gulf countries with human capital through Jordanian migrant workers. The influx of displaced people settling and working in the country also provides a larger population that could contribute to the domestic work force.

Decades of migration have increased demand on the pharmaceutical sector, and the regional lack of access to medicines and healthcare presents challenges in meeting those demands.

As many of the displaced people from neighbouring countries often come from a middle-income background, the proportion of chronic, non-communicable diseases increases. This also calls for a shift in the type of healthcare that’s provided. There is an increased demand for long-term care in areas such as cardiac and hypertensive treatment, diabetes, psychiatric disorders, and war trauma rehabilitation.

A key survival characteristic of the Jordanian pharmaceutical industry and health sector has been to respond quickly to external conditions and having a proactive, agile regulatory and legislative framework to stimulate cooperation and mobilise capital in a region facing novel healthcare needs in a time of political turbulence.

Afifa Trad
Specialist, Pharmacovigilance Consulting, UMC
afifa.trad@who-umc.org

Hayel Obeidat, Director General of Jordan FDA, speaking during the opening session panel. Photo: JFDA
The changing faces of device safety

Many aspects of device regulations are under revision globally. The status of revision implementation varies between regions, but increased expectation for manufacturers to be more proactive than reactive when marketing safe and effective devices remains constant.

Manufacturers are obliged to provide evidence of the safety, efficacy and benefit throughout the device lifecycle. This includes data from clinical trials prior to marketing, and establishing Post-Marketing Surveillance (PMS) systems to monitor device performance, data from published literature are required.

At first glance this may appear to be just an increased burden to manufacturers. But proactive literature monitoring for evidence of device performance in the real world is more than just regulatory compliance. Effective data-gathering may help reduce time and costs to market and improve technical design, the likelihood of reimbursement, and overall reputation as a responsible manufacturer. Collectively, this may help gain an edge in this competitive and innovative industry.

Regulation essentially protects the market from ill-designed, inadequate or unsafe devices, and encourages production of good quality products that fulfill a medical need. Real-world data are important because they are created in less restricted environments than in clinical trials, and are gathered from wider patient populations. Real-world data also provide an insight into the performance of a device in the hands of consumers with a range of skills. Demonstrating device performance based on expert opinion is no longer acceptable; it is crucial to provide evidence, some of which is found in the scientific literature.

Gathering real-world data during the research stage provides a landscape view to help designers identify market gaps and appropriate predicate devices; the latter also determines what regulatory pathway needs to be followed (e.g. with or without predicates).

PMS systems require manufacturers to gather evidence for own and similar devices. These data are used to update various regulatory reports including, the technical document, Periodic Safety Update Reports, and can also be used for ongoing signal detection and risk mitigation.

Literature monitoring can provide performance data to help demonstrate device benefit-risk over existing treatments. If positive, the likelihood of market entry is increased. If negative, it will save the time and costs of pursing a fruitless project. Proving superior benefit will ensure a device remains on the market and enhances reimbursement potential, an important aspect of marketing success.

Historically, some medical devices have not performed as expected (e.g. transvaginal mesh and metal-on-metal hip prostheses). These devices were originally considered “not high risk”, so the regulations at the time did not require comprehensive clinical evidence of safety prior to release, or strict post-market performance monitoring. Consequently, several similar devices with fault potential were released in relatively rapid succession into a wide patient population. Decades later, some manufacturers still have to budget for million-dollar payouts in lawsuits and litigation fees.

It could be easy to look back and blame, but it is more appropriate to take responsibility and look forward to successful, reliable medical devices that will enhance the lives of many. Taking responsibility includes establishing robust, auditable PMS systems; this means searching public literature, which is a huge task if the processes are unfamiliar. Searches need to be broad enough not to miss pertinent information; this introduces an exaggerated triaging task. Identified, relevant articles require globally recognised, uniform tagging to allow appropriate, efficient analyses of the data.

If devices follow the same trend as drugs, it is highly likely that the amount of publically reported device safety data will increase over the next few years. According to the AdisInsight Safety database, the number of drug safety reports published has doubled between 2008 and 2015.

Consumer expectations are also increasing. They demand value; commonly, a low-cost or a discounted product. As a result, manufacturers outsource and offshore production, and encounter a greater number of authorities to gather data for. Alternatively, device designers may “de-innovate” a product (i.e. produce a subsequent more basically designed device) with the functionality required by healthcare professionals and patients, but delivered at a lower cost. Being aware of real-world performance and user experiences for own and competitor devices may assist improvement of design iterations resulting in a device that will satisfy the functional requirements and financial constraints of consumers.

There is no doubt that the revised regulations for medical devices are for the good of the industry, nor that this increased demand for responsibility in proving the benefit clinically and economically of a device will increase the workload of the manufacturer and potentially require additional resource. However, being proactive and sensitive to consumer needs and experiences could lead to opportunities for the release of additional devices, and wider global market penetration. Importantly, it demonstrates responsibility and a willingness to act in the best interest of patient safety, and this can only enhance the reputation of the devices industry as a whole.
The 39th annual meeting of the WHO Programme for International Drug Monitoring drew around 150 pharmacovigilance experts from nearly 60 countries to Oman in 2016. With the Minister of Health of the Sultanate of Oman and other senior dignitaries present, the Director-General of Pharmaceutical Affairs & Drug Control, Dr Mohammed Hamdan Al Rubaie, opened proceedings by setting out his centre's achievements.

In the Eastern Mediterranean region, there are 11 member countries, where Morocco was the first to join in 1992 and Afghanistan the latest in 2016. Oman is a member country since 1995 and has made great progress in strengthening their safety surveillance system in the last few years, for example by transforming their organisational structure, adding resources, arranging training workshops for healthcare professionals, and raising public awareness. Oman is currently contributing the highest number of reports per million inhabitants of all countries in the Eastern Mediterranean region.

The ANNUAL NC MEETINGS provide a unique opportunity to share information, exchange experiences and to learn from each other. Depending on its location, the meeting naturally attracts staff from centres nearby, so this year Arabic countries and those in the Eastern Mediterranean region came out in force – including fresh faces from Libya and Qatar, and old friends from Morocco. At the closing session the Iraqi representative reported to everyone from a productive round-table, where representatives from the regional countries that were present at the meeting had explored potential regional collaboration in patient safety.

While the WHO PIDM meeting invites its members to a face-to-face gathering only once a year, the programme's work continues even when colleagues are far apart. Ideas floated during the few days of the meeting are fleshed out and explored by the WHO Collaborating Centres and individual NCs in the intervening months. Exchanging ideas and comparing day-to-day issues with colleagues from other countries is always a vital formal – and informal – function of the meeting; many of the barriers to improved monitoring and better patient safety are similar all over the world.

At the close a special tribute was paid to UMC’s WHO programme expert Sten Olsson, who attended his last WHO PIDM meeting before his retirement in early 2017; he has attended as a UMC spokesperson all but once since the first meeting in 1978. In 2017 the meeting will land a few degrees south in Uganda. Until then all the project work – as well as the routine work – will continue behind the scenes at NCs worldwide, at WHO headquarters in Geneva, at UMC in Uppsala, and at the other WHO Collaborating Centres in pharmacovigilance.
Latin America

Uppsala Monitoring Centre embarked on a multi-destination tour to Latin America in September 2016, visiting the FIP congress in Argentina, the ISO-UMC training course in Peru, and the International Pharmacovigilance Meeting of the Americas in Panama. The team also visited national pharmacovigilance centres (NCs) of the WHO Programme for International Drug Monitoring (WHO PIDM) and other institutions in these countries, as well as in Costa Rica, Guyana, and Uruguay.

Costa Rica’s “Good pharmacovigilance practice” regulation

The “GOOD PHARMACOVIGILANCE PRACTICE” regulation was announced in January 2016 in Costa Rica and sets out the functions and responsibilities that must be fulfilled by each of the stakeholders in the national pharmacovigilance system. Despite the short time since the release it has garnered great interest and attracted involvement, especially from pharma companies. The rate of individual case safety reports (ICSR) sent by different stakeholders has increased. Training and dissemination has been performed at several sites, including the Medical Sciences School (UCIMED) and the University of Costa Rica (UCR).

In September 2016, UMC’s Elki Sollenbring was invited to talk about the WHO PIDM during the launch of the new regulation, and to speak at a pharmacovigilance training course for healthcare professionals.

Reviewing reporting methods in Uruguay

UMC visited the Ministry of Health in Uruguay in September 2016, to attend a meeting focusing on the WHO PIDM and Take&Tell. The visit also focused on the national centre unit’s pharmacovigilance work in the country, and its challenges and objectives. The possibility to better utilise VigiFlow and the use of eReporting were explored during the visit. These tools would allow the fulfillment of two fundamental objectives: the reporting to the centre following the current regulations, and the transfer of reports on to VigiBase, so that all countries in the WHO PIDM can access this critical information.

Xiomara Vega
Head, National Pharmacovigilance Centre Costa Rica

UMC’s Elki Sollenbring with pharmacovigilance training course participants in San José.
Guyana aims join the WHO PIDM in 2017

**Guyana**: the UMC team also visited Guyana in September. The delegation had in-depth discussions with the local pharmacovigilance experts about challenges and solutions to issues that they may face in their work.

**World congress in Argentina**

**TEN OLSSON**, UMC’s WHO programme expert, gave a presentation at the 76th FIP World Congress of Pharmacy and Pharmaceutical Sciences in Buenos Aires in late August 2016. Mr Otisson’s talk opened a half-day session on the role pharmacovigilance may play in improving and better understanding patient adherence.

**INSPIRE ENGAGE TRANSFORM**

**The first ISoP–UMC course in Latin America**

The first ISoP–UMC Pharmacovigilance Training course took place in Lima in early September. It was not only the first time an ISoP–UMC course was organised in Latin America, but also the first time UMC was involved in such a course in this part of the world. 69 participants from 11 countries in the region took part in the three–day course, which focused particularly on regulatory oversight on prescription drugs in the country. The process of establishing and maintaining an effective NC will be an ongoing exercise, so the Guyana centre foresees a future need to gain and enjoy the invaluable support of various stakeholders. Moreover, the need for capacity building and ongoing training of GA-FDD staff cannot be overstated. Employing a quality management reporting system to run the centre is important, as is the need to ensure that a monitoring and evaluation system to measure the impact of the centre’s activities over time is created.

**Panama City**

**Three stops in Panama**

**The journey to Panama in September took the UMC team to several destinations, most notably the three–day International Pharmacovigilance Meeting of the Americas, organised by ISoP. The meeting’s first day opened its doors to around 120 participants, both from Panama’s regional pharmacovigilance centres and representatives from 14 countries in the Regional Network of Pharmacovigilance Focal Points in the Regulatory Authorities. The second and third day of the meeting was open only for members of the regional network. The University of Panama invited UMC’s Elki Sollenbring to give a lecture about the WHO PIDM to over 100 pharmacist students, while the UMC team were in the country.**

**The UMC delegation** also visited the national centre in Panama City – a relatively young centre that became a full member of the WHO PIDM in 2016, after joining as an associate member in 2005. While there, UMC’s Elki Sollenbring and Heloísa Conesa showed the NC team how to use VigiLyze and other important tools provided by UMC.
The growth of drug safety networks in Latin America

Since 2012, the Regional Network of Focal Points in the Regulatory Authorities, moderated by the Pan American Health Organization (PAHO), has worked on the dissemination of safety communications, alerts, and other information generated within and outside the Americas. Additionally, through a permanent communication scheme, monthly virtual meetings, and at least one annual face-to-face meeting, the network has developed multiple initiatives to strengthen medicines regulation that benefits the safety of patients in the region.

Moving forward, countries will work towards cancelling marketing authorisations for specific products that are still available in the Latin American and Caribbean markets, despite being withdrawn globally for serious safety reasons. In addition, following a pilot coordinated by Canada, Chile, and Brazil, an initiative on the joint assessment of Periodic Safety Update Reports (PSURs) has been reinforced, and agreements have been made for further evaluations to be conducted by other countries. The network’s members also agreed on the arrangement of two multi-collaborative projects on active surveillance of new medicines for the treatment of hepatitis C and multidrug-resistant tuberculosis (MDR-TB). Finally, an important initiative is also in progress regarding the electronic bridging of national adverse drug reaction (ADR) databases and Vigibase, the WHO global ICSR database; currently, Chile is working on the transmission of their reports of adverse events following immunisation (AEFI).

Another Significant Initiative – the Latin-American Network of Pharmacovigilance and Technovigilance (RedLaFarTec, Red Latinoamericana de Farmacovigilancia y Tecnovigilancia A.C.) – began in 2015. It’s a non-profit organisation created in Mexico by healthcare professionals working at universities, hospitals, and pharmaceutical industries throughout Latin America, for the promotion of pharmacovigilance and technovigilance through specialised training and continuing education. The network aims to join forces with the health authorities of Latin American countries to promote patient safety.

“The existence of different partnerships adds meaning to the will of collaboration and harmonisation in pharmacovigilance in Latin America.”

More recently, during the 3rd Symposium of the RoP Latin-American Chapter in Bogotá in August 2016, the Colombian Pharmacovigilance Association (Asociación Colombiana de Farmacovigilancia) led an initiative to create a space to discuss solid actions to further their main concern: the safer use of drugs and the development of pharmacovigilance in Latin America.

The participants concluded that the strategic areas to integrate within the countries should be: unifying and promoting a culture of safe use, risk communication and medicines safety training for all stakeholders; and creating room for patients and the public to participate in pharmacovigilance and medicines safety programmes.

The formal document, named the Bogotá Declaration, was signed by representatives from Brazil, Chile, Mexico, Colombia, and Central American countries, and it will give impetus to unify different players such as regulatory and health authorities, healthcare professionals, healthcare service providers, pharmaceutical industry, healthcare organisations, academia, and most importantly patients and the public.

“The goal is to be able to count on organised working groups, with multiple participants working together to achieve specific improvements that demonstrate the importance of pharmacovigilance, both in patient safety and in the optimisation of resources”, said Dr Carlos Maldonado, president of the Colombian Pharmacovigilance Association.

Anyone who is interested in contributing to the proper and safe use of medicines, and the development of pharmacovigilance, can join the Bogotá Declaration published on the website of the Colombian Pharmacovigilance Association in both Spanish and English. Anyone can demonstrate their interest in participating, choose a strategic area in which they want to collaborate, and start to actively work on concrete actions to solve the different problems in the use of medicines in Latin American countries.

The existence of different partnerships adds meaning to the will of collaboration and harmonisation in pharmacovigilance in Latin America. Hopefully, through these initiatives more healthcare professionals will be reached and engaged as a reflection that pharmacovigilance is not only a regulatory requirement, but a vital means to improve patients’ treatments worldwide.

Thanks to Heloisa Conesa and Elvis Solé Benítez, both pharmacovigilance specialists at UMC, for contributing to this article.
Local needs in focus at ISoP’s Latin American symposium

Pharmacovigilance training at universities, medication errors, and risk management plans took centre stage when ISoP’s Latin American chapter gathered for its third symposium in Colombia in August 2016.

G LOCAL DEVELOPMENTS IN safer use of medicines should be adapted to local population’s characteristics and drug markets. Pharmacovigilance must be locally performed and implemented, strategies for preventing drug-associated risks should take each country’s health system features into account, as well as population’s medical, environmental, and cultural characteristics.

Pharmacovigilance concepts and tools should be expressed in local languages in order to be accurately and effectively communicated to specific or wider public audiences; Latin American countries need at-home pharmacovigilance meetings and trainings to allow participants to frequently express their thoughts and experiences. In addition, as many clinical practitioners, pharmacists, and academics in the region have low incomes, these activities – especially the educational ones – should ideally be free of charge or affordable for academics and independent health professionals.

On this basis, the International Society of Pharmacovigilance’s (ISoP) Latin American chapter, under the chairmanship of its president Prof Luis Alesso, has been organising regional symposia since 2014. The third symposium of the chapter was held in Bogotá, Colombia, in August 2016 with a scientific agenda coordinated by Raquel Herrera Comoglio.

Aiming to promote exchange and discussion between professionals, students, regulators, and industry around local realities and challenges, the scientific programme focused on three important topics for patients and public health: pharmacovigilance teaching at universities, medication errors, and risk management plans.

Academics from Colombian, Brazilian, and Argentinean universities shared their vision about the central role educating healthcare professionals can play in increasing spontaneous reporting and raising awareness about the magnitude of adverse drug reactions. Educating healthcare professionals is also one of the key strategies to diminish the occurrence of medication errors, which cause a substantial part of all adverse drug reactions.

Pharmacovigilance development and regulations around the world are largely driven by the most influential regulatory agencies – for example the European Medicines Agency, the US Food and Drug Administration, and others requiring risk management plans (RMPs) or minimisation strategies from marketing authorisation holders (MAHs). In order to get reliable results, these activities must take each country’s particular needs, drug utilisation patterns, and healthcare system into account. Latin American national centres require RMPs – both in national and transnational companies – which should be designed and implemented according local features, not merely be a replica of those issued in Europe and the US. As has been shown for example with isotretinoin, measures proposed by RMPs cannot reach its objectives even in countries where they are originally conceived. In regions or countries where it’s difficult to implement such controls or the drug market is not completely regulated, the efficacy of these strategies may be reduced, and its assessment can be impracticable or unreliable.

Moreover, in order to be effective, communication strategies should be tailored to patients’ culture and social contexts, and conveyed in the most effective and locally suitable way. This complex and multiple-level topic was discussed by representatives from three national regulatory agencies of the region – Colombian INVIMA, Brazilian ANVISA, and COFEPRIS in Mexico – Health Canada. An active round-table discussion on communication strategies – focusing on reaching the right audience with the right information in a timely fashion, measuring effects, and challenges – closed the session.

Besides patients’ suffering, adverse drug reactions cause a wide range of illnesses, and even disabilities and deaths, impacting the health system’s economic burden. Awareness of health professionals is central, and all partners – academia, regulators, industry representatives, media, and patients – should actively contribute to a safer use of medicines.

Meet Annie and Mac - the new pharmacovigilantes on the block

The Pharmacovigilance comic book – Uppsala Monitoring Centres (UMC) new communication project – was developed to reach young minds and give children important information about medicines safety.

“Children are great teachers and have the capacity to influence their communities. By giving them early access to information we are tapping into their capacity to drive change,” Paula Alvarado, the head of Global communications at UMC, said.

Through the pages of the comic’s first issue, we’re taken through an action-packed chapter where Annie and Mac set out to stop the evil Count Erfeit from producing and selling fake medicines. This is followed by a history chapter that explains such a chapter where Annie irritates her entire family as she explains how side effects happen by pretending that her parents and brother are different body parts.

The project’s lead writer is Fredrik Brönéius, pharmacist and author, who has written several books for children and young adults. Including Drug and Bugs – a small book about medicines.

“We went through quite a few protagonists and side-kicks before Annie and Mac stepped into the picture. She is inquisitive and brave, and Mac is an eagle in the body of a hummingbird. Together they make the perfect team to tackle important medicines safety issues,” Mr Brönéius said.

The illustrator is Paul Crompton, a designer and artist from the US who lives in Wuhan in central China.

“It was very fun to get to know Annie and watch her grow and change throughout designing and drawing her. I can’t wait to see what she does in the future,” he said.

UMC plans to test the comic in different countries and then discuss a distribution plan with those interested. After an initial pilot phase, UMC will translate the comic into a few other languages, and expand the cast of heroes to include lead characters from different parts of the world, in order to properly reflect the diversity of the global pharmacovigilance community. In 2017, a second issue of the comic will be published.
Join the conversation on social media!

In brief

Sten Olsson elected new president of ISoP

At ISoP’s annual meeting in India in October 2016, it was announced that UMC’s WHO Programme Expert Sten Olsson has been elected to the post of president.

M R OLSSON, ONE OF THE THREE original founders of UMC, is set to retire from UMC in early 2017, after 39 years in the organisation. “Instead of preparing for a quiet retirement from UMC, I’m now fully charged with the challenge of making the International Society of Pharmacovigilance (ISoP) a dynamic, supportive, and visible organisation,” he said.

“As pharmacovigilance expands geographically and in its scope, it is essential that ISoP also expands its coverage and membership services, while maintaining its essence of minimising the risk of harm for individual patients,” he said.

Besides his responsibilities at ISoP, Mr Olsson will also run a consultancy firm focusing primarily on matters relating to the establishment of pharmacovigilance systems and how to assess them, particularly in resource-limited settings. He can be reached on stenolssonpv@gmail.com or on Twitter at @StenOlssonPV.

Maldives 125th member of WHO PIDM

IN OCTOBER 2016 the national pharmacovigilance centre of the Maldives submitted their first batch of individual case safety reports (ICSRs) to VigiBase, using VigiFlow. The Ministry of Health and Family of the Republic of Maldives applied for membership of the WHO Programme for International Drug Monitoring (WHO PIDM) in March 2011, and have now become the 125th full member country of the programme.

In October 2016 a group of specialists from the Russian regulatory agency Roszdravnadzor visited UMC. During a two-day seminar UMC covered data processing tools, statistical methods of signal detection, coding of ADR reports, causality assessment, and other topics of interest. The Russian team also gave a presentation on the state and future of their pharmacovigilance system. The country is preparing to implement a new Eurasian Economic Union pharmacovigilance regulation, which is harmonised with the EU GVP guidelines. This mandates the participation in the WHO PIDM, which will help to increase Russia’s contribution to VigiBase and assure regular interaction with UMC.

Coloursful UMC bike helmets were produced for participants in the 2016 Uppsala Forum. They’ve found their way all over the world and one of them is to been seen frequently on the roads of the northern Thai province of Chiang Rai, on the head of Nana Yaw Osei Bediako, a Ghanaian student at Mae Fah Luang University.

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Pharmacovigilance Meetings 2016

16-27 January 2017
3rd Asia Pacific Pharmacovigilance
Training Course
Mysore, India · JSS University & Uppsala Monitoring Centre (UMC)
www.jsspharma.org
@UMCGlobalSafety

23-25 January 2017
DIA Pharmacovigilance and Risk
Management Strategies Conference
Washington D.C., USA · Drug Information Association (DIA)
www.diaglobal.org
@DrugInfoAssn

15-16 February 2017
Back to Basics in Pharmacovigilance
 Fareham, UK · Drug Safety Research Unit
www.dsru.org/trainingcourses
@DSRUDrugSafety

22-23 February 2017
Towards Professional Excellence in
Pharmacy Practice
Muscat, Oman · Ministry of Health
www.pharmacareconference.om
@7hpcc

6-8 March 2017
Advanced Pharmacovigilance
London, UK · Management Forum Ltd
www.management-forum.co.uk

2-4 April 2017
ISPE Mid-Year Meeting
London, UK · International Society for
Pharmacoeconomics and Outcomes Research (ISPOR)
www.pharmacoepi.org

19-21 April 2017
Congrès annuel de la Société Française
de Pharmacologie et de Thérapeutique
Rouen, France · Société Française de
Pharmacologie et de Thérapeutique
www.congres-sfpt.fr

27 April 2017
An Essential Overview of
Pharmacovigilance
London, UK · Management Forum Ltd
www.management-forum.co.uk

3-5 May 2017
Medical Aspects of Adverse Drug
Reactions
London, UK · Drug Safety Research Unit
www.dsru.org/trainingcourses
@DSRUDrugSafety

8-19 May 2017
19th International Pharmacovigilance
Training Course
Uppsala, Sweden · Uppsala Monitoring Centre (UMC)
www.who-umc.org
@UMCGlobalSafety

8-19 May 2017
11ème Cours Francophone de
Pharmacovigilance
Rabat, Morocco · Centre Anti Poison et de
Pharmacovigilance du Maroc (CAPM)
www.capm.ma

25-26 May 2017
ISoP Mid-Year Training Course
Bangkok, Thailand · International Society of
Pharmacovigilance (ISoP)
www.isoponline.org
@ISoPonline

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Uppsala Monitoring Centre (UMC) is an independent non-profit foundation and centre
for international service and scientific research. Our vision is a world where all patients
and health professionals make wise therapeutic decisions in their use of medicines.
Our mission is to support and promote patient safety through effective global
pharmacovigilance practice.