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COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

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Uppsala Monitoring Centre

Making medicines safer for patients everywhere

This is the fourth of a series of special newsletters that describe the context of CIOMS activities and the work of its member organizations and partners. It describes what the Uppsala Monitoring Centre (UMC) is doing to support and promote patient safety through effective and global pharmacovigilance practice.

CIOMS thanks the UMC Team for their collaboration and support in producing this newsletter. For more information about the UMC and its activities, please contact: info@who-umc.org.

Quick links

The vision of the Uppsala Monitoring Centre (UMC) is a world where all patients and health professionals make wise therapeutic decisions in their use of medicines.

*UMC uses the science of **pharmacovigilance** to explore and understand the risks and benefits of medicines. Pharmacovigilance covers everything to do with noticing, assessing, understanding, managing and preventing adverse effects of medicines for individuals and populations. The Centre's mission is to support and promote patient safety through effective and global pharmacovigilance practice.*

Images by Brian Merrill , Kimthecoach, Ernesto Eslava, Sabar M.Pd., Tuhin Khamaru and Gerd Altmann from Pixabay

Editorial

Uppsala Monitoring Centre (UMC) was established in 1978 to support the WHO Programme for International Drug Monitoring (PIDM), which began in 1968 as a global response to the thalidomide tragedy. The programme sought to collect information about adverse effects of medicines from as many sources as possible around the world, to ensure that the first signs of possible danger from medicines would not be missed.

Today, most countries have active, well established systems for monitoring the safety and use of medicines. UMC has played a major role in creating, developing, and supporting those systems. As of October 2021, 172 countries are members of the WHO-PIDM. Of these, 149 are full members sharing individual case safety reports (ICSRs) within the WHO global database, VigiBase, which is maintained at UMC. At the time of writing, VigiBase contains close to 30 million ICSRs, almost half of which were reported in the last five years. Since the introduction of the COVID-19 vaccines around 2 million ICSRs related to the vaccines have been submitted.

As pharmacovigilance is facing new challenges, the UMC is changing to meet the current demands. A new organizational structure has been implemented, and a new project will be developed to ensure adequate support and expertise to the WHO and member states of the PIDM. The goal of UMC in the next five years is to become a centre of excellence for all stakeholders involved in pharmacovigilance.

Hervé Le Louët *(left) took over from Marie Lindquist as CEO of UMC in November 2020. He is also the President of CIOMS.*

Christian Rausch *(right) is special advisor to the CEO..*

A word from the Chair of the Board

During these beautiful autumn days here in Sweden, we are slowly going back to a ”next-to normal” society thanks to a successful COVID-19 vaccination program. However, the public sector has never been in greater need of substantial, correct information sources concerning drugs and vaccines. It is becoming increasingly clear how disinformation can cause a threat and can harm both the individual and society as a whole, and how large the need is for trustworthy, scientific-based information about drugs. To be agile and relevant in these demanding circumstances, a complete makeover of our organisation was necessary and is ongoing with impressive pace driven by our new CEO, Hervé le Louët, and by the dedicated staff at UMC.

The message from the ”new UMC” is that the task is not only to identify risk, but to move to risk management and prevention in cooperation with other public health actors. Ultimately the goal is to support health care workers to deliver only the right drug to the right person for the right reason. Every prevented case of adverse event sums up to less suffering for thousands of patients globally each year. We are proud to be part of this important work, including the renewal of the WHO Collaborating Centre status from 2021, to eventually save lives, health and costs for society and patients.

Filippa Nyberg, *Senior Consultant, Karolinska University Hospital and Associate Professor at the Karolinska Institutet, has been chairing the UMC Board since 2019.*

UMC as a WHO Collaborating Centre

As a WHO Collaborating Centre, UMC maintains the world's largest repository of adverse effects from medicines and supports countries in establishing and managing their pharmacovigilance systems. A new UMC department is dedicated to the Collaborating Centre role.

Pinelopi Lundquist, *Head of the new WHO CC department. Pinelopi has worked at Swedish government agencies for more than 10 years before joining UMC in August 2020.*

Strengthening UMC's WHO Collaborating Centre role

UMC was established in 1978 to support the WHO Programme for International Drug Monitoring (PIDM), which began in 1968. UMC's ambition is to be a centre of excellence in medicines safety, providing technical and scientific support to key stakeholders. As a WHO collaborating centre, UMC aims to empower the pharmacovigilance centres belonging to WHO PIDM to support the safe use of medicines. Activities and deliveries from UMC in the capacity of a WHO Collaborating Centre were recently updated and are defined in a 4-year-agreement with WHO.

WHO-CC Department

UMC has several outward-facing departments led by managers working both strategically and hands-on to direct day-to-day operations and support staff. But up until now we haven't had one department dedicated to our role as a WHO Collaborating Centre for International Drug Monitoring. Before the summer UMC changed its organisational structure to create a new department that will support and coordinate our WHO-related activities and deliveries. The WHO Collaborating Centre department (WHO CC) will also serve as an interface between UMC and WHO headquarters. Regular monthly meetings will be held with WHO where project issues and strategic questions will be on the agenda. Working groups will be set up to undertake specific tasks as needed.

Department responsibilities

WHO CC is the first point of contact for questions related to UMC's role as a WHO Collaborating Centre for International Drug Monitoring. Other UMC departments will contribute directly or indirectly to WHO CC-related tasks as needed. Working closely with other UMC departments, WHO CC will contribute to the development and maintenance of VigiBase by providing technical solutions and support for national centres to submit, access and explore safety data. The department is divided into three **teams** working with:

- Signal Management,
- Education & Training, and
- Global Communication.

Signal Management

WHO CC supports WHO and members of WHO PIDM with ongoing signal detection, assessment, and analyses. Close collaboration with a new group of multidisciplinary clinical experts bringing together specialists from around the world contributes to signal generation and management through exchange of experience, guidance, and peer review.

Education & Training

WHO CC is looking to offer customized training to meet current and anticipated needs. Training builds on the concept of learning paths, where users can navigate and complete courses, and integrates the teaching of cognitive, process and tools skills. UMC will seek to collaborate with WHO and CIOMS in developing and delivering training.

Global Communication

WHO CC strengthens communications capacities within the global pharmacovigilance community by raising awareness of the WHO PIDM and UMC's work through multiple media channels. For example, the Uppsala Reports magazine is required reading for anyone interested in the latest issues in medicines safety. Country updates, tools and technology, exciting new research – online and in print, from UMC and members of the WHO Programme for International Drug Monitoring.

(Above) The member countries of the WHO Programme for International Drug Monitoring (PIDM). ***Together, they represent close to 99% of the world's population.*** *(Image from UMC website, as at 21/10/2021)*

A new organization for a new era

Developing the science behind the practice of pharmacovigilance has always been a key priority for UMC. New technologies give opportunities to test and evaluate both old and new scientific discoveries and speed up the signal assessment process. UMC is now reshaping its organization, building a new platform to become a body of excellence and support centre.

***Birgitta Lindner**, Chief Operating Officer and Deputy CEO of UMC*

UMC offers a range of products, tools and services for collection of data and signal assessment:

VigiBase is the database of individual case safety reports submitted by member countries. Its purpose is to ensure that early signs of previously unknown medicines-related safety problems are identified as rapidly as possible. VigiBase is UMC's starting point for the journey from data to wisdom about safer use of medicines.

VigiLyze is an online search and analysis tool that gives an overview of the data in VigiBase. It can provide a national, regional and global view of the suspected adverse effects of a medicine, and can recalculate disproportionality for any chosen country or region background within seconds. For any given search based on a drug or reaction it also offers related investigations to identify signals, which can then be shared with other programme members. VigiLyze supports assessments of emerging issues, including qualitative assessments, enabling health professionals to propose wise therapeutic decisions to their patients.

UMC offers powerful tools for recording, processing and sharing data in line with common coding principles, supporting global analysis.

VigiAccess makes high-level, aggregated data from VigiBase available to the public.

New tools and functionalities

As a WHO Collaborating Centre, UMC will work in close collaboration with WHO to release the full potential that comes with VigiBase and its associated tools and services. The database and its tools will be developed further to support scientific use as well as signal assessment. VigiLyze for the new era will be enhanced to facilitate communication and collaboration between experts. It will be a complement to existing information-sharing.

Shaping the organization

UMC is building competence and processes, adjusting the organization and its internal infrastructure, and the ways in which it interacts with its stakeholders. A competence-sourcing strategy will be the basis for building a strong organization, with capacity to develop and maintain advanced data-related tools and functionalities.

Focus on the future

Building on the information-sharing platforms we have today, the new focus will be on communication, creating resources for collaborations that will benefit all parties.

We are now shaping the organization that will take on the projects and challenges of tomorrow, taking projects into routine use. Building a focused organization for the future has started.

CIOMS and UMC: Advancing medicines safety together

Pharmacovigilance is at the core of the UMC's work, and is one of the three main working areas of CIOMS. The two organizations have a long track record of working together in complementary roles in advancing medicines safety globally.

The beginnings

International drug monitoring

The WHO International Drug Monitoring Programme was set up in 1968 by Jan Venulet, long-standing CIOMS advisor and member of several CIOMS Working Groups.

This was a daunting task at the time, that he described as follows when addressing the 27th CIOMS round table conference on Drug Surveillance, held in 1993: "*Hoping to find among this mass of reports cases of medical significance amounted to … looking for nuggets of gold in a huge pile of garbage. It took me some time to convince myself that it was possible.*"

VigiBase

UMC has been managing the global database of adverse drug reactions on behalf of WHO since 1978. In the mid-1990s, work started on a new database system, for which the main inspiration was the then-ongoing CIOMS 1A working party on *Harmonization of data fields for electronic transmission of case-report information internationally*, chaired by UMC Director Ralph Edwards. The CIOMS 1A report later informed the deve–lopment of the ICH E2B guideline. In 2003 UMC launched its upgraded, E2B-compatible database: VigiBase was born.

2004 visits to UMC:

(Top) Jan Venulet, looking at the latest UMC signal work.

(Bottom) Judith Jones, long-standing member of the former CIOMS MedDRA Working Group, discussing data-mining methodology with Andrew Bate.

Images from : Uppsala Report #26

A long track record

Over the years, UMC has been an active contributor to many CIOMS publications. Some of the past and present UMC staff and collaborators who have participated in CIOMS Working Groups (WG) are pictured below.

*(Top row, from left) The three UMC founding members **Sten Olsson** (WG XI on Patient involvement); **Marie Lindquist**, UMC Director 2009-21 (WG XI) and **Cecilia Biriell** (Standardized MedDRA Queries–SMQ WG); **Ralph Edwards**, UMC Director 1990-2009 (CIOMS pharmacovigilance WGs III, IV, V and VIII).*

*(Middle row, from left) UMC staff **Andrew Bate** (CIOMS VIII), **Rebecca Chandler** (Vaccine Safety WG), **Ola Caster** (WG XII on Benefit-Risk) and **Qun-Ying Yue** (WG XII); UMC Board alternate and WHO Medicines Safety Lead **Shanthi Pal** (WG on Drug-Induced Liver Injury–DILI, XI, and XII).*

*(Bottom row, from left) Past UMC Board members **Gunilla Sjölin-Forsberg** (past CIOMS Secretary-General) and **Lembit Rägo** (current CIOMS Secretary-General); UMC CEO **Hervé Le Louët** (CIOMS President)—all three have contributed to multiple WGs—and UMC Board Chair **Filippa Nyberg** (CIOMS WG on Severe Cutaneous Adverse Reactions to Drugs–SCARs).*

Sources of images: click names

The journey continues …

Information on this page from Uppsala Reports No. 15, 19, 22, 24, 47, 49, 66 and 75. Find the Uppsala Reports archive here.

Opportunities and perspectives

The COVID–19 pandemic has shown once more how important pharmacovigilance is to maintain public confidence in medical products, and has exposed some gaps in the global systems. The role of the UMC is to support the efforts of WHO to address these. *Images by Wilfried Pohnke , Teja Klinar , VGC-Group , Markus Winkler , 정훈 김 and David Mark from Pixabay*

UMC is a strong and recognized centre since 1978. Nevertheless, as times are changing, some updates in the global strategy are necessary for the Centre to stay on course. Anticipating upcoming challenges, UMC is implementing structural and strategic changes to ensure that the Centre will be able to respond adequately.

Training and education

UMC will provide a consolidated platform for education and training. The aim is to avoid redundancies, provide a gateway to available resources, and facilitate access to validated knowledge on pharmacovigilance for WHO-PIDM member states.

Collaboration

UMC will promote collaboration between all stakeholders involved in drug risk management and will support harmonization, good pharmacovigilance practice and the dissemination of new guidelines. CIOMS is an important partner in this regard. New working groups on pharmacovigilance topics will be considered, for example to explore the link between pharmacovigilance practices and public health, or the role of pharmacoepidemiology as a tool to assess the impact of emerging adverse effects.

Methodology

Reporting to VigiBase has accelerated in the last ten years, and has increased further since the introduction of COVID-19 vaccines. Together with academia, UMC is exploring new methods — including pharmacoepidemiological ones—to detect and assess signals, and additional tools to estimate the risk associated with signals in different countries. The findings will help countries across economic settings to make the best possible use of their resources, and will guide health professionals in identifying the safest treatments for their patients.

Bringing experts together

Internally, the UMC is changing so that it can position itself in the global landscape as a centre of excellence and support. The aim is not to compete with regulatory centres, but to provide them with the best scientific evidence and methodology, access to knowledge, and a platform for collaboration, coordination and capacity-building.

Externally, UMC is looking to strengthen its links with academic networks, forge new relations with patient associations around the world, and increase its exchanges with WHO, large regulatory agencies and ICH. The connections with low- and middle-income countries will be renewed and strengthened, and UMC will then act as a facilitator, linking up authorities across economic settings.

UMC is envisaging new projects to respond to the challenges of the future. The strong commitment of its staff gives reason for confidence that these goals will be expertly met.

Hervé Le Louët
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