First ACTO symposium

Improving medication adherence: tailored solutions for success

24 November 2016

ABSTRACT BOOK

Contents

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Improving medication adherence: tailored solutions for success

24 November 2016 – University of Namur, Business & Learning Center, rue Godefroid, 5 – 5000 Namur

Programme

08:30	09:00	Welcome (1st floor)	
09:00	09:15	Introduction	Prof. Yves Poullet, Rector, University of Namur

Morning chairs : Micky FIERENS (Director, LUSS) & Bernard VRIJENS (Director,Espacomp)

Session I: Setting the scene

09:30	10:15	Therapeutic adherence: state-of-the-art	Prof. Bernard Vrijens, Espacomp
10:15	11:00	Medication to take or not to take: a shared-decision making process	Prof. Marc Tomas, University of Namur
11:00	11:30	Coffee break (1st floor)	

Session II: Patients experience

11:30	12:30	Patient adherence in Europe: the view from the patient European platform	Marc Greco, EPF President
		The Belgian patient experience	Mr André Krajewski, GIRTAC, VIBAST
12:30	13:30	Walking lunch (1st floor)	

Afternoon chairs : Prof. Valérie FLOHIMONT & Prof. Jean-Michel DOGNE, University of Namur

Session III: Patients' rights

13:30	14:15	Patients' rights, autonomy and adherence	Prof. Valérie Flohimont, University of Namur

Session IV: The ways to improve adherence

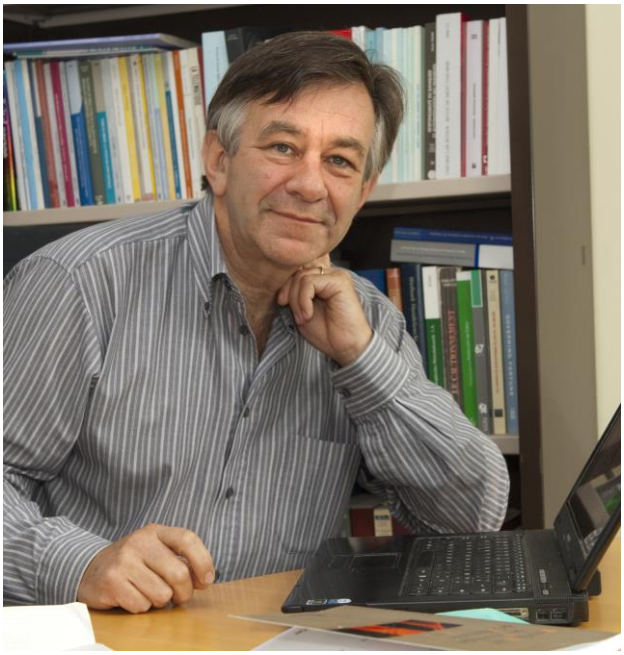
14:15	15:45	Patient educational materials: insights from EMA activities	Prof. Jean-Michel Dogné, University of Namur
		Initiatives of the Pharmaceutical Industry	Dr Ann Adriaensen, General secretary, Pharma.be
		The pharmaceutical dossier and good medication usage	Dr Jan Saevels, Scientific Director, APB
15:45	16:00	Coffee break (1st floor)	

Session V: Round table

16:00	17:00	Call for action	Moderated by Frédéric Deborsu, RTBF
17:00	17:15	Concluding words and drink (1st floor)	

YVES POULLET

CURRICULUM VITAE



After having obtained a master in philosophy and a doctorate in legal studies, Yves Poullet has created in 1979 and has been director of CRIDS (UNamur Research Center Computer Law and society) since its creation in 1979 until August 31, 2010, he conducted various researches in the field of Internet law with a special emphasis on privacy issues, on individual and public freedom and on legal aspects of electronic commerce.

Moreover, he was full professor at the Faculty of Law at the University of Namur (UNamur) and part time at the University of Liège.

He has conducted more than twenty doctoral researches, been nominated as expert in different international organization (UNESCO, European Commission, Council of Europe…) and chaired a lot of European and international associations in the field of his research.

He is member of the Belgian Royal Academy and, since 2010, rector of the University of Namur.

INTRODUCTION

Le groupe de recherche ACTO, acronyme de « access to care & therapy optimisation » a vu le jour au sein de l'Université en 2015. Il s'agit d'un groupe de recherche trans-facultaire regroupant dans un premier temps des membres de la Faculté de Médecine et de Pharmacie ainsi que de la Faculté de Droit.

Ce groupe s'est fixé comme domaine d'activité :

- d'une part l'accès des patients aux soins de santé au sens large, en Belgique mais pas exclusivement ;
- d'autre part l'optimisation thérapeutique ;
- plus en détail, l'accès aux soins comprend les dimensions d'accès aux traitements innovants mais aussi les composantes socio-économiques, éthiques et légales.

La collaboration avec les associations de patients est à cet égard un domaine- clé d'exploration.

Parmi les activités qui seront potentiellement développées figurent :
- Le développement de programmes éducatifs en collaboration avec les associations de patients ;
- L'évaluation de modalités pour les patients de participer aux décisions en matière de santé ;
- L'étude de la synergie entre l'expérience des patients et le savoir des soignants au travers de partenariat de formation et de recherche.

En ce qui concerne l'optimisation thérapeutique, les activités de recherche couvrent :
- L'amélioration de la santé des malades chroniques au travers de la simplification des traitements ;
- Le développement de solutions susceptibles d'optimiser la littératie en santé, l'empowerment des patients et l'adhésion aux traitements.

Les premiers travaux ont fait l'objet de publications scientifiques à des congrès européens et le développement d'une collaboration avec l'Association Belge du Diabète et la société pharmaceutique MSD.

Yves Poullet

BERNARD VRIJENS

CURRICULUM VITAE

Bernard Vrijens is Chief Science Officer at WestRock Healthcare. He was General Manager of the AARDEX Group, prior to AARDEX becoming part of WestRock Healthcare. He is also Associate Professor of Biostatistics at the University of Liège, Belgium.

Dr. Vrijens holds a PhD from the Department of Applied Mathematics and Informatics at the University of Ghent, Belgium.

Dr Vrijens currently leads a research program investigating (a) the most common errors in dosing using a simple but robust taxonomy, (b) particular dosing errors that can jeopardize the efficacy of a drug, and (c) the optimal measurement-guided medication management program that can enhance adherence to medications and maintain long-term persistence.

Dr. Vrijens is a co-author of five book chapters, over 75 peer-reviewed scientific papers, and named as inventor on two patents. He is a founding member and managing director of the European Society for Patient Adherence, Compliance, and Persistence, and an active member of several EU- and US-funded collaborative projects around the theme of adherence to medications.

Medication Adherence: state of the art

The advent of reliable means to measure medication adherence have brought patient non adherence into clear view. Poor adherence to chronic-use drugs is a long-neglected worldwide problem of striking magnitude that occurs in 3 different forms: (a) non-initiation of dosing; (b) episodic omissions of single or sequential doses; (c) short persistence with dosing meant to continue indefinitely. The relative importance of these deviations varies with the therapeutic context and results repeatedly in: biased clinical study results, poor outcomes of drug treatment, emergence of drug resistance, added costs of health-care. The complexity of adherence-related sciences, as well as its richness, results from the fact that it operates across the boundaries between many disciplines; i.e. economics, pharmacometrics, medicine, pharmacy, nursing, psychology, sociology.

In practice, given the economic burden of poor adherence, health systems must evolve to meet the challenge of achieving satisfactory adherence to therapeutic drug regimens. There is an urgent need for an interdisciplinary approach to monitor and support patient's adherence to achieve the best use of appropriately prescribed medicines in order to maximize the potential for benefit and minimize the risk of harm for each individual patient. The recent uptake of mobile-health, big data analysis, and personalized medicine, if well integrated into the care system, should facilitate patient-tailored intervention required to achieve optimal exposure to therapeutic drug regimens.

Bernard Vrijens

MARC TOMAS

CURRICULUM VITAE

Marc Tomas obtained a Medical Degree from the Free University of Brussels, Belgium. He is Board Certified in Cardiology, Sports Medicine and in Pharmaceutical Medicine and obtained a Master in Coaching from the International Coaching Institute, Geneva.

He has 25 years Pharma experience, holding senior Medical management positions in Belgium and Europe in companies such as UCB, Bristol Myers Squibb, GSK, AstraZeneca, MSD and more recently Merck.

He conducted several Patient Support Programmes for the Pharma industry in the field of adherence.

He is currently the Managing Director of the Health Access company, committed to deliver competent medical advices and training to public and private life science organizations.

Marc is also a visiting professor at the Faculty of Medicine of Namur (Belgium) and at the International Coaching Institute (Switzerland), teaching communication in health and wellness coaching for health care professionals and Vice-President of the International Health & Wellness Coaching Federation (IHWCF).

Medication to take or not to take:

a shared-decision making process

Predictive factors for non-adherence to prescribed treatment are well identified by healthcare experts: patient-, medication-, medical professional- and environment are the main categories.

Main reasons for poor adherence mentioned by non-compliant patients are also well known: low level of health literacy and difficulties to endorse changes in lifestyle in parallel to medication initiation, execution and persistence.

With the explosion of health technologies able in theory to constantly monitor our health and support both partners in making appropriate decisions, the health care professionals will have now to make choices and to letting go some of their skills: medical knowledge, diagnosis, prescribing, caring, monitoring… to be able to become an efficient patient partner. Ensuring scientific background and at the same time encouraging patient empowerment will be the future challenge for medical professionals.

In this particular context, there is a bright future for innovative professional functions that will support activated patients to set their goals in health and life and manage emotional impact of health concerns.

The recently established International Federation of Health & Welness Coaching (IFHWC) will collaborate with the other healthcare bodies to ensure this new vision of integrated healthcare is implemented for the benefit of patient health & wellness and for healthcare team well-being.

Marc Tomas

MARC GRECO

CURRICULUM VITAE

Marco Greco is the President of the European Patients' Forum (EPF). He has been chairman of the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) from 2008 till 2016. He has also been the founder of the EFCCA Youth Group, and its leader from 2003 till 2007.

He is actually working as attorney in his law firm, focusing on litigation, commerce and consumers' protection legislation. He is the patients' representative in the Pharmacovigilance Risk Assessment Committee at the European Medicines Agency (EMA) and a member of the EMA Patients and Consumers Working Party (PCWP).

After an LL.MM in Law, he graduated as a Ph.D in Law and Religion, religious freedom and discrimination and canon law at Università Cattolica del Sacro Cuore in Milano, where he still collaborates with the Chair of History and Systems of Church-State relationships. As a scholar, his main area of research focuses on the relationship between law and religion in the healthcare system.

ANDRE KRAJEWSKI

CURRICULUM VITAE

Ingénieur chimiste depuis 1972, Andre Krajewski travaille chez Boehringer Mannheim diagnostic en 1975 (leader mondial en chimie, immuno, sérologie).

Spécialisé dans le domaine des tests de diagnostic en hémostase depuis 1990.

Retraité depuis 2012 et président du Girtac depuis 2012.

GIRTAC

(gestion individuelle responsable de son traitement anticoagulant)

- Apporter un support continu aux patients tout au long de leur thérapie
- Echanger des points de vue, des expériences, des doutes mais aussi des victoires
- Apprendre aux patients à bien respecter leur traitement
- Tenir informé des nouvelles possibilités de surveillance et de thérapie
- Mutualiser les échanges entre médecins, patients, infirmiers
- Etre actif pour le remboursement des nouvelles molécules et de l'automesure
- Informer le secteur médical et paramédical des interférences aux traitements

3 missions

- Information
- Adhérence au traitement
- Carte patient

André Krajewski

VALERIE FLOHIMONT

CURRICULUM VITAE

- docteur en droit
- thérapeute spécialisée en thérapie brève
- professeur à la faculté de droit de l'UNamur, à l'Ecole royale militaire et à l'UC Lille
- pratique de la relation d'aide en entreprise ou à titre privé
- présidente du conseil scientifique de l'observatoire wallon de la santé
- co-présidente de l'association belge de droit du travail et de la sécurité sociale
- nombreux projets de recherche interdisciplinaires qui allient l'approche juridique et l'approche relationnelle

Plus de détails : https://directory.unamur.be/staff/vflohimo

Patients rights, autonomy and adherence

Comment favoriser, dans un cadre juridique précis, l'adhérence thérapeutique des patients tout en respectant leur autonomie et leur liberté de choix ?

Le législateur a accordé aux patients un certain nombre de droits que tout médecin se doit de respecter et qui, pourtant, ne sont pas toujours facilement conciliables avec la préoccupation de soins et de prise en charge qui anime le personnel médical.

Valérie Flohimont

JEAN-MICHEL DOGNE

CURRICULUM VITAE

Professor Jean-Michel Dogné was born on June 8, 1973, in Liège, Belgium. He obtained his Pharm. D. from the University of Liège (BE) in 1996 and continued his studies in the laboratory of medicinal chemistry at the same university, where he received his Ph.D. in pharmaceutical sciences in November 2000. He was appointed Professor at the University of Namur (BE) in 2005 where he is currently head of the Department of Pharmacy. His teaching activities cover drug development, medicinal chemistry, human biochemistry, drug safety and pharmacovigilance. He is the co-founder of the Namur thrombosis and hemostasis center (NTHC) and the Namur nanosafety center (NNC), and member of the Namur Drug Design & Discovery Centre (NAMEDIC). His research interests include the development and monitoring of the antiplatelet and anticoagulant agents, the hemocompatibility of biomaterials, pharmacovigilance, drug safety, and nanotoxicology. He is the author or co-author of more than 200 papers and abstracts published in peer-review journals, including blood, circulation, trends in pharmacological sciences, journal of medicinal chemistry, thrombosis and hemostasis, and journal of thrombosis and hemostasis (Google scholar November 2016: H-index: 38, citations: 4911).

He also developed a strong and recognized expertise in pharmaceutical regulatory affairs and more particularly drug safety and pharmacovigilance. He is an expert in pharmacovigilance at the Federal Agency for Medicines and Health Products (BE) since January 2006 (Signal management; PSUR, PASS, and RMP assessments). He is the past Belgian delegate at the Pharmacovigilance Working Party (PhVWP) of the EMA (2006-2012). He was appointed Belgian effective member of the Pharmacovigilance Risk Assessment Committee (PRAC) of the EMA in July 2012. His specific areas of expertise in the field of pharmacovigilance cover the safety of medicines for selected systems/organ classes (Hematological and cardiovascular ADRs, medicines affecting the QT interval), vaccine safety, risk management plans, risk minimisation measures, signal detection and signal management, quality in pharmacovigilance, pharmacogenomics and pharmacogenetics of medicines. He actively participated in the EMA working groups of the task force for implementing the new legislation in pharmacovigilance at national and international levels as well as in the development and reviewing of GVP guidelines. He is one of the authors of the concept paper on the conduct of pharmacovigilance for medicines with pharmacogenomics associations at the EMA level.

Patient educational materials: insights from EMA activities

Educational programmes are additional risk minimisation measures (RMM) and usually require educational materials based on targeted communication with the aim to supplement the information in the summary product characteristics (SmPC) and package leaflet (PL). At the EU level, the development and distribution of educational material is recommended by the Pharmacovigilance Risk Assessment Committee (PRAC) and endorsed by the Committee for Medicinal Products for Human Use (CHMP), two committees of the of the European Medicines Agency (EMA). They are usually included as a requirement in the marketing authorisation granted by the European Commission for the medicinal product in question, as applicable, key elements may be agreed at EU level. In this case, draft educational materials should be submitted to the competent authorities of Member States and these educational materials shall implement the key elements. Alternatively, the exact content of educational materials could be agreed at EU level and also become part of the summary of product characteristics (SmPC) and/or the package leaflet (PL), as applicable. The aim of this lecture is to focus the roles of the PRAC in the recommendation of patient educational materials. Recent examples will be provided including direct oral anticoagulants and isotretinoids. The roles and responsabilities of all stakeholders will be highlighted with an emphasis on the patient perspective.

Jean-Michel Dogné

ANN ADRIAENSEN

CURRICULUM VITAE

Ann Adriaensen holds a degree of pharmacist (KU Leuven 1992). After a career of several years in de sector of pharmacists and wholesaler-distributors in different positions, she joined the sector of the pharmaceutical industry in 2010 as Public Health Advisor in the national association of pharmaceutical industry in Belgium, pharma.be.

In July 2012 she becomes Director Public Health and since April 2014 she is the Secretary General of the association. Within pharma.be she has different responsibilities covering the governance of the association and the strategic follow-up of the issues regarding clinical trials, regulatory affairs, pharmacovigilance, distribution, good use and compliance for human medicines. She coordinates different Work Groups and Task Forces. She manages the relationships between the members of pharma.be and the Federal Agency of Medicines and Health Products (FAMHP) with regards to all FAMHP related matters.

She is president of the Transparency Committee (Budget & Strategy Agency) and vice-president of the Audit Committee of the National Competent Authority (FAMHP).

Initiatives of the Parmaceutical Industry

Improving medication adherence is a real challenge to all of us.

Poor adherence to treatment of chronic diseases is a worldwide problem of striking magnitude. A lot more can be done to help patients to improve adherence to their treatment.

Last year the pharmaceutical sector signed an ambitious pact of the future with Maggie De Block, Minister of Public Health. The Pact included several actions contributing to an improved adherence.

Top priority of the pharmaceutical industry is to ensure the maximum effectiveness of medicines. Medicines can only be effective if they are used properly as described by the physician and delivered by the pharmacist.

In this presentation some examples of interesting programs are presented, developed by pharma.be and some of its member companies, to help patients to better adhere to their treatment.

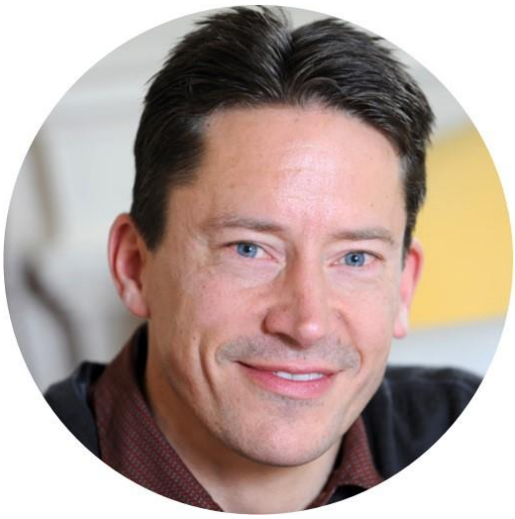
Numerous local initiatives are being taken in Belgium. The creation of a central place is needed, so that patients, healthcare professionals and other concerned parties can easily find information about other people's initiatives, problems, solutions and approaches regarding adherence to treatments of chronic diseases.

The development of a coordinated approach on adherence in Belgium is essential. The professionalization of such cooperation seems the solution for the future.

Ann Adriaensen

JAN SAEVELS

CURRICULUM VITAE



Jan Saevels studied Pharmaceutical Sciences at KU Leuven and obtained his pharmacist degree in 1994.

He obtained a PhD at the same University in 1998. At that time, he started working for APB, the professional body of Belgian community pharmacists.

From 1998 to 2005, he was Department Head of APB's Medicines Control Laboratory.

For the last 10 years, Jan is managing APB's Scientific Department that focusses on the scientific development of community pharmacists. With a team of 15 pharmacists, the Department offers various products and services that help pharmacists in their day-to-day operations. An important part of activities is dedicated to the development of new services, using existing as well as new technology.

The pharmaceutical dossier and good medication usage

Patients, together with healthcare professionals have been looking for a long time how they can improve medication adherence. If we consider the lack of adherence as an “illness”, the first step in finding a cure is off course diagnosis. Is there an adherence issue, where did it go wrong, what are the reasons for non-adherence? Is it initiation, implementation, persistence? Only after this analysis, a proper “cure” can be offered to the patient. In every single instance, this offered solution will be tailored to the individual situation, no “one pill cures all illnesses”.

Pharmacists can contribute to analyzing the different steps of non-adherence. For instance, more than 3000 community pharmacies are sharing pharmaceutical dossiers (subject to patients’ consent), and this number is steadily growing Thanks to this shared pharmaceutical dossier, pharmacists can use repeat prescription frequency to measure persistence.

Tailored solutions for individual patients are being offered in the pharmacy, and it seems that they always combine technology with counselling. Never one without the other. Some of these counselling services are being reimbursed within the compulsory health insurance, others are at present under study. They all focus on health literacy, patient empowerment, resolving possible risks for non-adherence and adjusting advice towards solutions based on the individual patient’s feedback.
Each day, about 500.000 Belgians step into their community pharmacy. This makes the setting extremely powerful in running public health campaigns, as Belgian pharmacies have been done for a number of years now.

Jan Saevels

LIST OF PARTICIPANTS

Name	First	Affiliation
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RYDANT	Silas	KAVA
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Thank you for taking part in the first ACTO symposium!