

Nederlandse Vereniging voor



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en Biofarmacie

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To whom this may concern,

With this letter the Dutch community in Clinical Pharmacology and Therapeutics would like to motivate the nomination of professor dr Adam Cohen, MD, PhD, FFPM, FBPhS, FACCp for the *EACPT Prize 2019 for Lifetime Achievement in Clinical Pharmacology*. Professor Adam Cohen has been selected for his life-long commitment and exceptional achievements in our field.

After successful doctorate degrees in pharmacy (1979) and medicine (1981) from Leiden State University, The Netherlands, dr Cohen joined the department of Clinical Pharmacology of the Wellcome Research Laboratories in Beckenham, UK. Here, he obtained experience in early drug development and was trained in clinical pharmacology under the guidance of among others Nobel Prize laureates professor James Black and professor John Vane. At Wellcome, Cohen's work led to a PhD thesis about the development of the antihistamine acrivastine and antiepileptic lamotrigine in 1986, under supervision of Prof. Dr. Douwe Breimer. His research with lamotrigine was renowned for its large educational and clinical impact. Eventually lamotrigine became the second bestselling drug of GSK. After further training in internal medicine and nephrology at King's College Hospital in London, he returned to Wellcome Biotech, one of the first biotech companies in the world. There he worked as European Clinical project leader for t-PA which furthered his knowledge and expertise in large scale clinical trials. Already in the early stage of his career, dr Cohen became a member of the steering committee of the prolific and ground-breaking International Study of Infarct Survival (ISIS) clinical trials in Oxford. Here, he worked with professor Richard Peto and professor Rory Collins who visionary and lasting changed the landscape of large scale clinical research...

His success made Cohen a renowned researcher in the field of clinical pharmacology. In 1987, he returned to Leiden, the Netherlands to set up a professional clinical pharmacology institute, the Centre for Human Drug Research (CHDR). CHDR was founded as a foundation practicing a globally unique mix of a scientific institute that provides services to the pharmaceutical industry and scientific community e.g. the university and the Leiden Medical University Center. Dr Cohen became CEO from 1987 to 2017, and during this period, CHDR grew to its current size (~200 FTEs). He has supervised more than 30 PhD theses in clinical pharmacology at CHDR and co-authored more than 320 publications in the last 3 decades. Publications in high impact journals, such as *The Lancet*, *Annual Revisions of Pharmacology Toxicology* and *Reviews Nature Drug Discovery*, emphasize his leading role in the field of Clinical Pharmacology & Therapeutics. Together with with some Leiden colleagues

from the Faculty of BioPharmaceutical sciences (including professor Prof. Dr. Douwe Breimer and Prof. Dr. Meindert Danhof), he became the leading figure founder of modern clinical pharmacology in the Dutch medical landscape. During his career he professionalized both research and education in clinical pharmacology without losing touch with the actual experimental work. He always worked (and still works) with undergraduate students and PhD fellows on a daily basis. As a result dr Cohen has been a mentor for many clinical pharmacologists also from outside the Netherlands that were trained at CHDR under his guidance. In addition, long lasting collaborations with clinical pharmacology departments in the Netherlands and internationally were established. To name just two of these: professor Cohen has established a collaboration with professor Eiji Uchida (president Japanese Society of Clinical Pharmacology) at Showa University, Tokyo, Japan and professor David Webb (President of the British Pharmacological Society and professors of clinical pharmacology) at Edinburgh, Scotland, UK.

Also, together with his colleagues at Leiden University Medical Center he has been teaching pharmacology and therapeutics at the Leiden University Medical Centre and developed an online teaching repository: the Teaching Resource System, a curriculum-wide E-learning program about pharmacological mechanisms of action, see <https://chdr.nl/education/trc>. This tool is currently used by more than 200.000 users in more than 100 countries including US, Australia, UK, and Germany. The website has more than 3.000.000 reads demonstrating its utility and wide spread acceptance of this unique resource. He is also the founding father of the Paul Janssen FutureLab, a Dutch initiative offering a professional post-graduate curriculum for life science entrepreneurs.

As a clinician, Cohen always remained actively involved in individual patient care at the department of nephrology of the Leiden University Medical Centre where he has an own out-patient clinic. To his opinion, the connection with individual patients is of utmost importance for a clinical pharmacologist. Cohen: "Research, otherwise would make me deal with groups only." To date, he still attends weekly renal pathology meetings, joins grand rounds and consults his patients with great enthusiasm.

As policy maker, dr Cohen has been extremely influential both nationally and internationally. He served as vice chairman of the Central Ethics Committee and Competent Authority for Clinical trials in the Netherlands and this work gave him a wide ranging experience in governmental/political affairs. He was chair of the implementation committee for the EU Clinical Trial Directive in the Netherlands. This led to the smooth implementation of the directive in the EU, being widely acknowledged as the Dutch Model with some envy. In addition, he chaired several committees dealing with irregularities in research, in industry and the Ministry. He was also representing the Netherlands in the EU negotiations on the implementation of the new EU directive in Brussels and London, supported by a working party at the Ministry of Health. As clinical pharmacologist, he was involved in the assessment of the incidents that occurred in the TGN1412 and BIA 10-2474 trial. His critical reflections led to the implementation of structured risk analysis in protocols, the EMA First-in-Human guideline and to practical tools such as the Investigator's Brochure Derisk Analyzer tool (<https://www.ib-derisk.org/login/>), reflecting both his strategic vision and practical, hands-on mentality. His diligent view on drug development also led to the concept of rational drug development, considering drugs as prototypes instead of routine programs in a sequential "phase system". This approach was defined as "question-based drug development" (QbD) and has led to international awareness and the successful conduct of more than 300 clinical trials at CHDR only in the last decade.

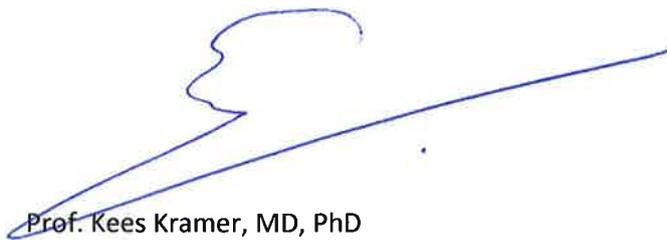
Regarding his publishing activities, dr Cohen has been (and still is) a role model for many students, researchers and clinicians. He edited the Dutch Medical Journal (Nederlands Tijdschrift voor Geneeskunde) and was involved in the successful repositioning of the Journal and joined the executive editorial board of the British Journal of Clinical Pharmacology (BJCP). Since 2014, he is the editor-in-chief of BJCP, being one of the highest ranked journals in the field.

Dr Cohen has performed several extracurricular activities in volunteer organisations. During a period of several weeks, he volunteered as a relief physician for refugees on the Greek island of Lesbos during the peak of the crisis in January 2016. He is an active clarinet and bass clarinet player and is an experienced yacht skipper on the North Sea.

As of January 1st 2018, Cohen stepped down as CEO to continue as Director Innovation Services at CHDR. On November 9th 2018, professor Cohen will become an emeritus professor of Clinical Pharmacology at Leiden University after 24 inspiring years with a well-acknowledged legacy. This legacy is indelible, ranging from the inception of a world-leading clinical pharmacology research institute with 200 FTEs to the set-up of a modernized E-learning curriculum about pharmacological mechanisms of action at the Leiden Medical school.

Altogether, we believe that Prof. Dr. Adam Cohen is a broadly trained professional with many faces. From the perspective of a clinician, researcher, entrepreneur and policy advisor, he was able to make a change on the (inter) national playground of clinical pharmacology research and education, patient care, industry and EU legislations. From the perspective of an innovator, he was responsible for the introduction of several commonly used and paradigm shifting tools, such as question-based drug development and rational risk analysis in study protocols. From a human perspective, his innovative and visionary way of thinking has never stopped him from keeping in touch with his patients. We are confident that Cohen's dedication, drive and enthusiasm will continuously inspire students, fellow researchers and clinicians, at the present time and in the future.

In conclusion, we wholeheartedly nominate professor dr Adam Cohen to be awarded the EACPT Lifetime Achievement in Clinical Pharmacology because of his exceptional track record of achievements in the international development of Clinical Pharmacology and Therapeutics.

A handwritten signature in blue ink, appearing to read 'Prof. Kees Kramer, MD, PhD'. The signature is written in a cursive style with a long, sweeping underline that extends to the right.

Prof. Kees Kramer, MD, PhD

Chairman of the Dutch Society for Clinical Pharmacology and Biopharmaceutics