



Curriculum Vitae

Personal information **André Elferink**

Work experience

1. Employer: College ter Beoordeling Geneesmiddelen
 - Start date: 01-01-2007
 - End date: 23-11-2024
 - Position: Principal Assessor
 - Activities: As principal clinical assessor I was responsible for the assessment team of clinical assessors of Pharmacotherapeutic group I. This group is responsible for CNS products in the broadest sense (e.g including pain, senses), dermatological products and rheumatology products, among some other medicinal disciplines.
 - Expert for the MEB/EMA concerning scientific advices, Member of Scientific Advice Working Party. Chair of CNSWP, Member Guideline Consistency Group.
 - Country: Netherlands
2. Employer: Diaconesses ziekenhuis Voorburg
 - Start date: 01-01-1985
 - End date: 31-12-1985
 - Position: Resident Neurology
 - Activities: Physician neurology, patient care
 - Country: Netherlands
3. Employer: Erasmus University
 - Start date: 01-01-1986
 - End date: 31-12-1989
 - Position: Doctoral/Ph D student Neurophysiology
 - Activities: Resident Department Neurophysiology Ph.D Thesis Tilt discrimination and spatial orientation in men Lecturer medical students
 - Country: Netherlands
4. Employer: College ter Beoordeling Geneesmiddelen CBG_MEB
 - Start date: 01-01-1992
 - End date: 31-12-2006
 - Position: Clinical assessor Dutch Medicines Evaluation Board
 - Activities: As a clinical assessor I advise the Dutch Medicines Evaluation Board and the European Committee for Proprietary Medicinal Products whether a medicinal agent can be approved for a claimed indication and if so, under which conditions. This advice is based upon the critical evaluation of the data and results of clinical trials submitted by the company. This evaluation is written down in a so-called clinical assessment rapport by the clinical assessor. The official language is English. As clinical assessor I started as a generalist with a neurological background. Later I specialised in CNS_products including neurology, psychiatry, pain and senses. In addition, dermatological product, eye products and rheumatology is within the responsibilities.
 - I was also consultant for methodological and statistical questions with respect applications outside the CNS field.
 - Intensive taught / coaching of clinical assessors for the future
 - Country: Netherlands
5. Employer: Academic Hospital Dijkzicht , Rotterdam
 - Start date: 01-01-1990
 - End date: 31-12-1991
 - Position: Resident department Neurology
 - Activities: Physician neurology, patient care
 - Country: Netherlands

Education and training

1. Subject: Medical University Nijmegen
 - Start date: end 08-1977
 - End date: begin 05-1984
 - Qualification: Doctor of Medicine, MD
 - Organisation: General medical training, MD
 - Country: Netherlands
2. Subject: Erasmus University Rotterdam
 - Start date: 1986
 - End date: 1998
 - Qualification: Ph.D
 - Organisation: Education as scientist _ 1986 Biostatistics Erasmus University Rotterdam. _ 1987 First Certificate in English, Grade A. _ 1989 Epistemology Erasmus University Rotterdam. _ 1986_1989 Ph.D. thesis: Tilt discrimination and spatial orientation in men
 - Country: Netherlands
3. Subject: Medical University Nijmegen
 - Start date: 05-1984
 - End date: 31-12-1984
 - Qualification: Na
 - Organisation: Student assistant Neuroanatomy
 - Country: Netherlands
4. Subject: Free University Amsterdam

- Start date: 1988
 - End date: 1989
 - Qualification: Clinical epidemiologist A
 - Organisation: Methodologist/Biostatistics
 - Country: Netherlands
5. Subject: University Leicester
- Start date: 2001
 - End date: 2003
 - Qualification: na
 - Organisation: Course MSc medical statistics Further education methodology / biostatistics
 - Country: United Kingdom

Additional information

Publications

Alzheimer's disease: EU regulatory horizons, Oriane Blanquie, Lorenzo Guizzaro, Ralf Herold, Marion Haberkamp, André Elferink, Pavel Balabanov, Falk Ehmann, Lancet neurology. In Press.

Do efficacy results obtained from randomized controlled trials translate to effectiveness data from observational studies for relapsing-remitting multiple sclerosis? Verweij S, Ahmed W, Zhou G, Mavridis D, Nikolakopoulos S, **Elferink AJ**, Rengerink KO, Bijlsma MJ, Mol PGM, Hak E. *Pharmacoepidemiol Drug Saf.* 2024 May;33(5):e5810. doi: 10.1002/pds.5810. PMID: 38720409 Review.

The new European Medicines Agency guideline on antidepressants: a guide for researchers and drug developers. Butlen-Ducuing F, Haberkamp M, Aislaitner G, Bałkowiec-Iskra E, Mattila T, Doucet M, Kollb-Sielecka M, Balabanov P, Leuchs AK, **Elferink A.**, *Eur Psychiatry.* 2023 Dec 15;67(1):e2. doi: 10.1192/j.eurpsy.2023.2479. PMID: 3809836

[The therapeutic potential of psychedelics: the European regulatory perspective.](#) Butlen-Ducuing F, McCulloch DE, Haberkamp M, Mattila T, Bałkowiec-Iskra E, Aislaitner G, Balabanov P, Lundberg J, Stenbæk DS, **Elferink A**, Knudsen GM, Thirstrup S. *Lancet.* 2023 Mar 4;401(10378):714-716. doi: 10.1016/S0140-6736(23)00264-7. Epub 2023 Feb 1

Comment on: "The Assessment of Patient-Reported Outcomes for the Authorisation of Medicines in Europe: A Review of European Public Assessment Reports from 2017 to 2022". de Vries ST, Al-Mugotter NHS, Petkoska I, Verweij S, Elferink AJA, Mol PGM. *Appl Health Econ Health Policy.* 2024 Jan;22(1):123-124. doi: 10.1007/s40258-023-00850-4. Epub 2023 Nov 16. PMID: 37971664.

Alzheimer's disease: EU regulatory horizons, Oriane Blanquie, Lorenzo Guizzaro, Ralf Herold, Marion Haberkamp, André Elferink, Pavel Balabanov, Falk Ehmann, Lancet neurology. In Press.

European regulators' views on a wearable_derived performance measurement of ambulation for Duchenne muscular dystrophy regulatory trials. Haberkamp M, Moseley J, Athanasiou D, de Andres_Trelles F, Elferink A, Rosa MM, Magrelli A. *Neuromuscul Disord.* 2019 Jul;29(7):514_516. doi: 10.1016/j.nmd.2019.06.003. Epub 2019 Jun 7.

European regulatory use and impact of subgroup evaluation in marketing authorisation applications. Tanniou J, Teerenstra S, Hassan S, Elferink A, van der Tweel I, Gispén_de Wied C, Roes KCB. *Drug Discov Today.* 2017 Dec;22(12):1760_1764. doi: 10.1016/j.drudis.2017.09.012. Epub 2017 Sep 21.

Identification and validation of biomarkers for autism spectrum disorders. Loth E, Spooren W, Ham LM, Isaac MB, Auriche_Benichou C, Banaschewski T, Baron_Cohen S, Broich K, Bölte S, Bourgeron T, Charman T, Collier D, de Andres_Trelles F, Durston S, Ecker C, Elferink A, Haberkamp M, Hemmings R, Johnson MH, Jones EJ, Khwaja OS, Lenton S, Mason L, Mantua V, Meyer_Lindenberg A, Lombardo MV, O'Dwyer L, Okamoto K, Pandina GJ, Pani L, Persico AM, Simonoff E, Tauscher_Wisniewski S, Linares_Garcia J, Vamvakas S, Williams S, Buitelaar JK, Murphy DG. *Nat Rev Drug Discov.* 2016 Jan;15(1):70_3. doi: 10.1038/nrd.2015.7

Balabanov P, Haas M, Elferink A, Bakchine S, Broich, Addressing the regulatory and scientific challenges in multiple sclerosis: a statement from the EU regulators. *Mult Scler.* 2014 Sep;20(10):1282_7. doi: 10.1177/1352458514546876.

Maliepaard M, Banishki N, Gispén_de Wied CC, Teerenstra S, Elferink AJ. Interchangeability of generic anti_epileptic drugs: a quantitative analysis of topiramate and gabapentin. *Eur J Clin Pharmacol.* 2011 Oct;67(10):1007_16. doi: 10.1007/s00228_011_1041_4. Epub 2011 Apr 15. PubMed PMID: 21494766

Mattila T, Stoyanova V, Elferink A, Gispén_de Wied C, de Boer A, Wohlfarth T. Insomnia medication: do published studies reflect the complete picture of efficacy and safety? *Eur Neuropsychopharmacol.* 2011 Jul;21(7):500_7. doi: 10.1016/j.euroneuro.2010.10.005. Epub 2010 Nov 16. PubMed PMID: 21084176.

Maliepaard M, Hekster YA, Kappelle A, van Puijenbroek EP, Elferink AJ, Welink J, Gispén_de Wied CC, Lekkerkerker FJ. Requirements for generic anti_epileptic medicines: a regulatory perspective. *J Neurol.* 2009 Dec;256(12):1966_71. doi: 10.1007/s00415_009_5231_2. Epub 2009 Jul 15. Review. PubMed PMID: 19603244

Gispén_de Wied CC, Kritsidima M, Elferink AJ. The validity of biomarkers as surrogate endpoints in Alzheimer's disease by means of the Quantitative Surrogate Validation Level of Evidence Scheme (QSVLES). *J Nutr Health Aging.* 2009 Apr;13(4):376_87. Review. PubMed PMID: 19300886.

Storosum JG, Wohlfarth T, Schene A, Elferink A, van Zwieten BJ, van den Brink W. Magnitude of effect of lithium in short_term efficacy studies of moderate to severe manic episode. *Bipolar Disord.* 2007 Dec;9(8):793_8. Review. PubMed PMID: 18076528.

Wohlfarth TD, van Zwieten BJ, Lekkerkerker FJ, Gispén_de Wied CC, Ruis JR, Elferink AJ, Storosum JG. Antidepressants use in children and adolescents and the risk of suicide. *Eur Neuropsychopharmacol.* 2006 Feb;16(2):79_83. Epub 2005 Nov. 18. PubMed PMID: 16298514.

Wohlfarth T, Storosum JG, Elferink AJ, van Zwieten BJ, Fouwels A, van den Brink W. Response to tricyclic antidepressants: independent of gender? *Am J Psychiatry.* 2004 Feb;161(2):370_2. PubMed PMID: 14754791.

van Krimpen C, Elferink A, Broodman CA, Hop WC, Pronk A, Menke M. The prognostic influence of neuroendocrine differentiation in breast cancer: results of a long_term follow_up study. *Breast.* 2004 Aug;13(4):329_33. PubMed PMID: 15325669

Storosum JG, Elferink AJ, van Zwieten BJ, van den Brink W, Huyser J. Natural course and placebo response in short_term, placebo_controlled studies in major depression: a meta_analysis of published and non_published studies. *Pharmacopsychiatry.* 2004 Jan;37(1):32_6. PubMed PMID: 14750046.

Storosum JG, Elferink AJ, van Zwieten BJ, van Strik R, Hoogendijk WJ, Broekmans AW. Amisulpride: is there a treatment for negative symptoms in schizophrenia patients? *Schizophr Bull.* 2002;28(2):193_201. PubMed PMID: 12693427.

Storosum JG, Elferink AJ, van Zwieten BJ, van den Brink W, Gersons BP, van Strik R, Broekmans AW. Short_term efficacy of tricyclic antidepressants revisited: a meta_analytic study. *Eur Neuropsychopharmacol.* 2001 Apr;11(2):173_80. Erratum in: *Eur Neuropsychopharmacol* 2001 Aug;11(4):325. PubMed PMID: 11313164.

Elferink AJ, Toivonen M, van Bronswijk H. Safety and efficacy of vigabatrin and carbamazepine. CPMP. The Committee for Proprietary Medicinal Products. *Lancet.* 1999 Oct 16;354(9187):1387_8. PubMed PMID: 10533890.

Storosum JG, van Zwieten_Boot BJ, Elferink AJ. Effectiveness of rivastigmine in Alzheimer's disease. Guidelines do

not ignore clinically relevant end points. BMJ. 1999 Sep 4;319(7210):642. PubMed PMID: 10523096. de Graeff PA, Elferink AJ, Lekkerkerker JF. [Risk factors for dying among ibopamine users]. Ned Tijdschr Geneesk. 1999 May 22;143(21):1114_5. Dutch. PubMed PMID: 10368748. Storosum JG, Elferink AJ, van Zwieten BJ. Schizophrenia: do we really need placebo_controlled studies? Eur Neuropsychopharmacol. 1998 Dec;8(4):279_86. Elferink AJ, Van Hof MW. Binocular and monocular tildiscrimination in the rabbit: evidence for hemispheric dominance? Acta Neurobiol Exp (Wars). 1988;48(6):371_6. PMID:3251408. Elferink AJ, van Hof MW. Behav Brain Res. 1990 Dec 21;41(3):261_2. doi: 10.1016/0166_4328(90)90113_s. PMID: 2288677

Projects

Memberships

2012 Membership SAWP 2017

2021 Vice_Chair CNS_WP

2021 Chair CNS_WP

2021 Member of EMA Guideline Consistency Group

Other Relevant Information