



## Curriculum Vitae

Personal information **George Aislaitner**

Work experience

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1. Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Germany
  - Start date: January 2017
  - End date:
  - Position: Clinical Assessor and Lead Clinical Assessor
  - Activities: Clinical Assessor and Lead Clinical Assessor in the Department of Neurology, Psychiatry and Ophthalmology .
  - Country: Germany
2. National Organisation for Medicines (EOF), Greece
  - Start date: March 2014
  - End date: December 2016
  - Position: Acting Director of Division of Validation of Applications and Issue of Marketing Authorisations
  - Activities: Division that includes the following Departments: Validation of Applications, Issue of Marketing Authorisations, Updating of the Greek Drugs Database System and Pricing Department Performing assessments as CHMP alternate.
  - Country: Greece
3. National Organisation for Medicines (EOF), Greece
  - Start date: March 2014
  - End date: December 2016
  - Position: CHMP Alternate - EMA
  - Activities: (Co-)Rapporteur for various Centralised procedures including a referral and a re-examination.
  - Country: Greece
4. National Organisation for Medicines (EOF), Greece
  - Start date: July 2016
  - End date: December 2016
  - Position: Head of Electronic Data Management Section
  - Activities: Populating, Updating and maintenance of EOF 's medicines database.
  - Country: Greece
5. National Organisation for Medicines (EOF), Greece
  - Start date: December 2014
  - End date: July 2016
  - Position: Head of Validation and Registration of Applications Section
  - Activities: Validation of Applications, updating of CTS and issuing of minor variations
  - Country: Greece
6. National Organisation for Medicines (EOF), Greece
  - Start date: March 2014
  - End date: December 2014
  - Position: Head of Issuing Marketing Authorisations Section
  - Activities: Issuing of Marketing Authorisations and coding of decisions.
  - Country: Greece
7. National Organisation for Medicines (EOF), Greece
  - Start date: January 2012
  - End date: March 2014
  - Position: Head of Adverse Drug Reactions Department
  - Activities: RMP and DHPC assessment, Facilitate Implementation of new legislation and related activities, PRAC member
  - Country: Greece
8. National Organisation for Medicines (EOF), Greece
  - Start date: July 2012
  - End date: March 2014
  - Position: PRAC member
  - Activities: PRAC and RMP Rapporteur for two products
  - Country: Greece
9. National Organisation for Medicines (EOF), Greece
  - Start date: April 2011
  - End date: January 2012
  - Position: Head of Section for the Evaluation of Medicinal Products
  - Activities: Organising the evaluation and assessing applications for approval or variation or renewal of Marketing Authorisations via national, mutual recognition, decentralised and centralised procedures. Dealing with issues for uploading SPCs on EOF website and aspects of legal status as well as issues related to reimbursement and supervising work with lists of medicinal products. Performing assessments as CHMP member.
  - Country: Greece
10. National Organisation for Medicines (EOF), Greece
  - Start date: January 2011
  - End date: April 2011
  - Position: Acting Head of Section for the Evaluation of Medicinal Products
  - Activities: Organising the evaluation and evaluating applications for approval or variation or renewal of Marketing Authorisations via national, mutual recognition, decentralised and centralised procedures.
  - Country: Greece
11. National Organisation for Medicines (EOF), Greece

- Start date: May 2008
  - End date: March 2012
  - Position: CHMP member - EMA
  - Activities: (Co-)Rapporteur for various Centralised procedures including a referral and a re-examination.
  - Country: Greece
12. National Organisation for Medicines (EOF), Greece
    - Start date: February 2006
    - End date: April 2008
    - Position: CHMP alternate - EMA
    - Activities: Centralised procedures
    - Country: Greece
  13. National Organisation for Medicines (EOF), Greece
    - Start date: January 2004
    - End date: April 2004
    - Position: CPMP member - EMA
    - Activities: EMA centralised procedures.
    - Country: Greece
  14. National Organisation for Medicines (EOF), Greece
    - Start date: May 1999
    - End date: December 2011
    - Position: Efficacy\_Safety Assessor for medicinal products in the Evaluation Division
    - Activities: Evaluation of applications for approval or variation or renewal of Marketing Authorisations via national, mutual recognition, decentralised and centralised procedures.
    - Country: Greece
  15. Hoechst Marion Roussel
    - Start date: September 1996
    - End date: May 1999
    - Position: Sales representative and Product Manager
    - Activities: Antiinfectives, haemorrhology, cardiovascular and hormonal medicinal products
    - Country: Greece

## Education and training

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In chronological order:

1. MSc: University of Peloponese, Faculty of Social and Education Policy
  - Start date: September 2011
  - End date: July 2014
  - Qualification: Master of Science
  - Organisation: Health Institutions and Policies (topics include research methods, economic and health units' management, anthropology of health, health education policy, health law and in the broader issue of social protection)
  - Country: Greece
2. Training at the National Centre for Public Administration and Local Government
  - Start date: November 2013
  - End date: November 2013
  - Qualification: Certificate for the preparation of support groups for the Greek Presidency of EU
  - Organisation: Preparation of support groups for permanent representatives during the Greek Presidency of EU and training for negotiations of the proposed legislations
  - Country: Greece
3. Training at European Medicines Agency (in co-operation with EFPIA)
  - Start date: May 2013
  - End date: May 2013
  - Qualification: Eudravigilance – Extended Eudravigilance Medicinal Products Database
  - Organisation: Training in Eudravigilance XEVMPD
  - Country: Greece
4. Training at European Medicines Agency (in co-operation with EFPIA)
  - Start date: April 2012
  - End date: April 2012
  - Qualification: Certificate: Eudravigilance \_ Individual Case Safety Reports
  - Organisation: Training in Eudravigilance ICSRs
  - Country: United Kingdom
5. Professional License: Central Council of Health in Greece
  - Start date: 1995
  - End date: 1995
  - Qualification: Pharmacist License
  - Organisation: Examinations to obtain Pharmacist License
  - Country: Greece
6. Post-doc: King's College London, Chelsea Department of Pharmacy
  - Start date: August 1993
  - End date: April 1995
  - Qualification: Postdoctoral Research
  - Organisation: Research associate in two projects detection of the ratio of major nicotine metabolites in smokers' urine and formation of cyano derivatives of nicotine imminium metabolites in animals.
  - Country: United Kingdom
7. PhD: King's College London, Chelsea Department of Pharmacy
  - Start date: September 1989
  - End date: June 1993
  - Qualification: PhD
  - Organisation: Thesis title "Comparative in vitro metabolism of some minor tobacco alkaloids"
  - Country: United Kingdom
8. First degree: Aristotle University of Thessaloniki
  - Start date: September 1984
  - End date: November 1988
  - Qualification: Degree in Pharmacy
  - Organisation: Pharmacy
  - Country: Greece

## Additional information

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### Publications

1. Gorrod, J.W., & Aislaitner, G., (1992). "The metabolism of 1'-N\_methylanabasine; a potential marker for

- environmental tobacco smoke exposure." In: *Quality of the Indoor Environment*, Ed. Lester, J.N., Perry, R., & Reynolds, G.L., pp. 331\_340.
2. Pattichis, K., Jarman, J., Glover, V., Sandler, M., Aislaitner, G., & Gorrod, J.W. (1992). "Red wine as a migraine trigger: examination of its effects on [<sup>14</sup>C]5-hydroxytryptamine release from platelets". In: *5-Hydroxytryptamine Mechanisms in primary headaches*, Ed. Olesen, J., Saxena, P.R., pp. 242\_246.
  3. Aislaitner, G., & Gorrod, J.W. (1992). "The in vitro metabolism of anabasine and methylanabasine." *Br. J. Clin. Pharmacol. Proceedings Suppl.*, 33: 230.
  4. Aislaitner, G., Li, Y., & Gorrod, J.W. (1992). "In vitro metabolic studies on (–)(S)-nornicotine" *Med. Sci. Res.*, 20: 897\_899.
  5. Aislaitner, G., Jahanshahi, M., & Gorrod, J.W. (1992). "Comparative studies on the microsomal metabolism of 1-N-methylanabasine and nicotine." *Med. Sci. Res.*, 20: 891\_896.
  6. Aislaitner, G., Damani, L.A., & Gorrod, J.W. (1992). "Porcine hepatic flavin containing monooxygenase (FMO) mediated N-oxidation of (S)-1-N-methylanabasine." *Med. Sci. Res.*, 20: 885\_889.
  7. Li, Y., Li, N.Y., Aislaitner, G., & Gorrod, J.W. (1992). "In vitro metabolism of cotinine". *Med. Sci. Res.*, 20: 903\_904.
  8. Aislaitner G., Yang, S., & Gorrod, J.W., (1992). "Preliminary evidence for the formation of reactive intermediates during the in vitro metabolism of minor tobacco alkaloids" *Med. Sci. Res.*, 21, 819\_821.
  9. Gorrod, J.W., & Aislaitner G., (1993). "The in vitro metabolism of anabasine, a volatile constituent of tobacco smoke" In: *"Volatile Organic Compounds in the Environment"*, Eds G. Leslie and R. Perry, Lonsdale Press Ltd., London pp. 539\_556.
  10. Aislaitner, G., Hutt, A.J., & Gorrod, J.W., (1993). "The synthesis of 1'-N-methyl-2'-oxoanabasine, an analogue of cotinine" *Bioorganic and Medicinal Chemistry Letters*, 4, 515\_520.
  11. Rose, S., Hindmarsh, J.G., Silva, M.T., Pitcher, A., Aislaitner, G., Moore, P.K., Gorrod, J.W., Jenner, P. & Marsden, C.D., (1994). "The novel monosodium salt of 7-nitroindazole inhibits brain nitric oxide synthase and elevates striatal dopamine efflux in vivo" *British Journal of Pharmacology*, 112, S P.41
  12. Gorrod, J.W. & Aislaitner G., (1994) "The metabolism of alicyclic amines to reactive iminium ion intermediates" *European Journal of Drug Metabolism and Pharmacokinetics*, 19, 209\_217.
  13. Aislaitner, G. & Gorrod, J.W., (1994) "Factors affecting the in vitro metabolism of anabasine" *European Journal of Drug Metabolism and Pharmacokinetics*, 19, Suppl. 69, P87.
  14. Aislaitner, G., Ulgen, M. & Gorrod, J.W., (1994) "In vitro microsomal metabolic studies on secondary aromatic amides: Comparative rates of hydrolysis" *European Journal of Drug Metabolism and Pharmacokinetics*, 19, Suppl. 73, P93.
  15. Silva, M.T., Rose, S., Hindmarsh, J.G., G. Aislaitner, G., Gorrod, J.W., Moore, P.K., Jenner, P. & Marsden, C.D., (1995). "Increased striatal dopamine efflux in vivo following inhibition of cerebral nitric oxide synthase by the novel monosodium salt of 7-nitro indazole" *British Journal of Pharmacology*, 114, 257\_258.
  16. G. Aislaitner, A. Bello, S.C. Tan, A.J. Hutt, C. Marriott and J. W. Gorrod (1997) "Metabolism of (–)(S)-nicotine in the isolated perfused rabbit lung" *European Journal of Drug Metabolism and Pharmacokinetics*, 22, 395\_402.
  17. Tsai, M.C., Yang S., Y., Li, Y., Aislaitner, G. and Gorrod, J.W. (1999) "The biosynthesis of [<sup>5</sup>-<sup>14</sup>C]-cotinine and other radiolabelled nicotine metabolites" *Journal of Labelled Compounds and Radiopharmaceuticals*, 42, 387\_407
  18. Borg, J.J.; Robert, J.L.; Wade, G.; Aislaitner, G.; Pirozynski, M.; Abadie, E.; Salmonson, T.; Vella Bonanno, V. (2009) "Where is Industry Getting it Wrong? A Review of Quality Concerns Raised at Day 120 by the Committee for Medicinal Products for Human Use during European Centralised Marketing Authorisation Submissions for Chemical Entity Medicinal Products" *J Pharm Pharmaceut Sci* ([www.cspCanada.org](http://www.cspCanada.org)) 12(2):181\_198, 2009
  19. Borg, J. J.; Aislaitner, G.; Pirozynski, M. ; Mifsud, S. (2011) "Strengthening and rationalising pharmacovigilance in the European Union. Where is Europe heading to? A review of the new EU legislation on pharmacovigilance" *Drug Safety*, 34 (3):187\_97, March 2011
  20. Borg, J. J.; Aislaitner, G.; Pirozynski, M.; Mifsud, S. (2011) "The Authors' Reply" *Drug Safety*, 34 (6): 530\_531, June 2011
  21. Borg, J. J.; Tomasi, P.; Pani, L.; Aislaitner, G.; Pirozynski, M.; Leufkens, H.; Melchiorri, D.; (2014) "Licensing of Generic Medicines: Are There Any Challenges Left? A Pharmaceutical Regulatory Perspective" *Sci Pharm.* 2014; 82: 847–856, doi:10.3797/scipharm.1312\_10
  22. Borg, J. J.; Tanti, A.; Kouvelas, D.; Lungu, C.; Pirozynski, M.; Serracino-Inglott, A and Aislaitner, G.; (2015) "EU pharmacovigilance capabilities: potential for the new legislation" *Ther Adv Drug Saf.* 2015 Aug; 6(4):120\_40. doi: 10.1177/2042098615591802
  23. Apostolidou, E.; Aislaitner, G.; Klironomos, L.; Kapou, A.; Kouvelas, D. «The Impact of the New Pharmacovigilance Legislation on the Applications and Files Submitted to the Department of Adverse Drug Reactions of the National Organisation for Medicines in Greece (EOF)», *Pharmacoepidemiology and Drug Safety* 24(S1):446 - September 2015
  24. Accreditation report of the Undergraduate programme: Pharmacy, Institution: University of Patras Date: 29 February 2020 [https://www.ethaae.gr/en/quality\\_assurance/undergraduate\\_programme\\_accreditation\\_reports](https://www.ethaae.gr/en/quality_assurance/undergraduate_programme_accreditation_reports)
  25. Sforzini et al. 2022 «A Delphi\_method\_based consensus guideline for definition of treatment\_resistant depression for clinical trials», *Molecular Psychiatry* 27, 1286–1299 (2022). [https://doi.org/10.1038/s41380\\_021\\_01381\\_x](https://doi.org/10.1038/s41380_021_01381_x)
  26. Florence Butlen\_Ducuing, Drummond E\_Wen McCulloch, Marion Haberkamp, Taina Mattila, Ewa Bałkowiec-Iskra, Georgios Aislaitner, Pavel Balabanov, Johan Lundberg, Dea Siggaard Stenbæk, Andre Elferink, Gitte M Knudsen, Steffen Thirstrup, The therapeutic potential of psychedelics: the European regulatory perspective, *The Lancet*, Volume 401, Issue 10378, 2023, Pages 714\_716, ISSN 0140\_6736, [https://doi.org/10.1016/S0140\\_6736\(23\)00264\\_7](https://doi.org/10.1016/S0140_6736(23)00264_7). (<https://www.sciencedirect.com/science/article/pii/S0140673623002647>)
  27. Butlen-Ducuing F, Haberkamp M, Aislaitner G, Bałkowiec-Iskra E, Mattila T, Doucet M, Kollb-Sielecka M, Balabanov P, Leuchs A-K and Elferink A. "The new European Medicines Agency guideline on antidepressants: a guide for researchers and drug developers" *European Psychiatry*. 2024; 67(1):e2. doi:10.1192/j.eurpsy.2023.2479
- RECENT ORAL PRESENTATIONS
1. P. Koufaki, E. Zintzaras, J. Stefanidis, G. Aislaitner (2015) «Medical prescription and medicines for off\_label use: the two faces of Ianos» Presentation at the 11th Panhellenic Conference for Health Management Economics and

Health Policies by the National School of Public Health, Friday 11 December 2015, Athens, Hilton Hotel.

2. G. Aislaitner (2016) «Approval procedures for medicinal products and Patients' safety» Presentation at the Second Educational Seminar of the Greek Alliance of Rare Diseases, 29th February 2016, Eugenides Foundation

3. G. Aislaitner (2016) «Medicinal products: From Development to approval to administration to patients» 9th Panhellenic Conference of the Greek Society of Basic and Clinical Pharmacology, Thessaloniki, 21st May 2016, Electra Palace Hotel.

4. G. Aislaitner (2017) «Diagnosis and impact of TRD: Health Regulatory perspective \_ EMA» International College of Neuropsychopharmacology (CINP) 2017 Prague Thematic Meeting on Treatment Resistant Depression (TRD), 20th July 2017, Prague, Grandior Hotel

5. Aislaitner G. (2022) «Psychedelic Drugs for the Treatment of Neuropsychiatric Diseases \_ A European Regulatory View», 2022 American Society of Clinical Psychopharmacology (ASCP) Annual Meeting, Scottsdale, Arizona, 01.06.2022 (digital)

6. Aislaitner G and Haberkamp M: The Global Health Protection Programme (GHPP), Major Depressive Disorder - presentation, 18th October 2023 and discussion 9th November 2023, BfArM, both virtual

## Projects

### Memberships

Member of the Greek Society of Pharmacology (since 2015)

Affiliate Member of the Royal Society of Chemistry (since 2003)

Member of Royal Society of Chemistry, Toxicology Group (since 1990).

Member of Convocation\_University of London (since 1993)

Member of the Panhellenic Association of Pharmacists (since 1996).

External expert for Accreditation Review Panels for the Hellenic Authority for Higher Education in Greece

### Other Relevant Information

PEER REVIEWER in:

- Transplant International ([http://www.wiley.com/bw/journal.asp?ref=0934\\_0874&site=1](http://www.wiley.com/bw/journal.asp?ref=0934_0874&site=1))
- Journal of Cardiothoracic Surgery (<http://www.cardiothoracicsurgery.org/>)
- Diagnostic Pathology (<http://www.diagnosticpathology.org/>)
- Eastern Mediterranean Health Journal (<http://emhj.edmgr.com/>)