EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Maria Elisabeth Kalland

Work experience

1. Employer: Norwegian Medicines Agency
   - Start date: 022019
   - End date: present
   - Position: Norwegian delegate/member of the Committee for Orphan Medicinal Products (COMP) at the European Medicines Agency (EMA)
   - Activities: Membership duties and evaluation of applications assessed by the COMP, which is responsible for recommending orphan designations of medicinal products for rare diseases in accordance with the Orphan Regulation from the European Commission. Actively contributing to the discussions at the monthly COMP plenary meetings and the regular strategy meetings every half year, act as COMP Rapporteur/Co-Rapporteur for orphan designation applications and review of the orphan designation criteria at the time of marketing authorisation (MA) and MA extension. The following represent the priority tasks of the Committee: orphan designation, protocol assistance, review of criteria for maintenance of orphan status at time of MA and MA extension (i.e., condition and therapeutic indication, prevalence, seriousness, and significant benefit when applicable), and giving advice to the Commission on the establishment and development of policies concerning orphan medicinal products for the EU/EEA.
   - Country: Netherlands/Norway
2. Employer: Norwegian Medicines Agency
   - Start date: 022015
   - End date: present
   - Position: Senior scientific adviser/Clinical assessor
   - Activities: Assessment of clinical data on the efficacy and safety of new medicinal products for which marketing authorisation is applied for or for the extension of indications, within the following therapeutic fields: Oncology, immunology, infectious diseases, and diabetes. Health technology assessments (HTA) and reimbursement decisions for hospital medicines.
   - Country: Norway
3. Employer: Apotek 1 Gruppen AS
   - Start date: 092014
   - End date: 022015
   - Position: Nationwide Ambulatory Pharmacist
   - Activities: Provide pharmacies belonging to the pharmacy chain called "Apotek 1" at national level with knowledgeable and flexible pharmaceutical manpower.
   - Country: Norway
4. Employer: AbbVie AS
   - Start date: 092013
   - End date: 082014
   - Position: Medical Advisor, Immunology/ Rheumatology
   - Activities: Scientific/medical expert with primary responsibility for the tumour necrosis factor (TNF)-alpha inhibitor adalimumab (Humira) for the treatment of patients with spondylarthritis (PsA, AS and nr-axSpA).
   - Country: Norway
5. Employer: Apotek 1 Gruppen AS
   - Start date: 042011
   - End date: 092013
   - Position: Nationwide Ambulatory Pharmacist
   - Activities: Provide pharmacies belonging to the pharmacy chain called "Apotek 1" at national level with knowledgeable and flexible pharmaceutical manpower.
   - Country: Norway
6. Employer: Centre for Molecular Medicine Norway (NCMM) and Biotechnology Centre of Oslo, University of Oslo
   - Start date: 082007
   - End date: 092012
   - Position: Research Fellow, Molecular Medicine/ Immunology
   - Activities: Scientific research in the field of immunology and oncology (immunotherapy). Development and systematization of protocols for carrying out basic research in the laboratory. Project management, national and international collaboration and networking. Publication of research results in international scientific journals and mentoring of colleagues. Organization and facilitation of courses and lectures at scientific seminars and conferences.
   - Country: Norway
7. Employer: Biotechnology Centre of Oslo, University of Oslo
   - Start date: 012006
   - End date: 082007
   - Position: Research assistant, Molecular Medicine/ Immunology
   - Activities: Carrying out basic research in the field of immunology and oncology (immunotherapy). Establishment of new research techniques and development of protocols for these in the laboratory of my research group.
   - Country: Norway
8. Employer: Apotek 1 Sfinxen
   - Start date: 112004
   - End date: 072008
   - Position: Pharmacist, part-time
   - Activities: Responsible pharmacist at work. Performance of prescription dispensing that require basic knowledge of pharmacology, pharmacokinetics, and medicine interactions, as well as an overview of the guidelines issued by the Authority and the Norwegian Labor and Welfare
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Administration (NAV). The main focus is to provide good information to customers to ensure that medicines and pharmaceutical equipment are used optimally.
- Country: Norway

Education and training

1. Subject: Doctoral program and Doctor of Philosophy (Ph.D.) degree
   - Start date: 082007
   - End date: 092012
   - Qualification: Ph.D. in Immunology/oncology
   - Organisation: The Norwegian Cancer Society and Institute of Clinical Medicine, Medical Faculty, University of Oslo. Doctoral thesis, title: "*Phosphorylation-Based Signaling in Human Immune Cells – A Systems View*": https://www.duo.uio.no/bitstream/handle/123456789/34491/dravhandling_kalland.pdf?sequence=2
   - Country: Norway
2. Subject: 5-and-a-half-year professional study program in pharmacy
   - Start date: 082000
   - End date: 122005
   - Qualification: Candidata pharmaciæ (Cand.pharm./ MSc.Pharm)
   - Organisation: School of Pharmacy, University of Oslo. Master thesis in Pharmacology, title: "*Drug candidates for treatment of HIV-1 infection; characterization of new chemical entities acting as antagonists of PKA type I in human peripheral T lymphocytes*"
   - Country: Norway

Additional information

Publications

Selection of published full papers in peer reviewed indexed journals:

1. Palomo GM, Pose-Boirazian T, Naumann-Winter F, Costa E, Duarte DM, Kalland ME, Malikova E, Matusevicius D, Vitezic D, Larsson K, Magrelli A, Stoyanova-Beninska V, Mariz S. *Navigating the orphan medicinal product designation: Evidence requirements for gene therapies in Europe*. Mol Ther. 2024; S1525-0016(24)00675-0. doi: 10.1016/j.ymthe.2024.10.015.
2. Kalland ME, Pose-Boirazian T, Palomo GM, Naumann-Winter F, Costa E, Matusevicius D, Duarte DM, Malikova E, Vitezic D, Larsson K, Magrelli A, Stoyanova-Beninska V, Mariz S. *Advancing rare disease treatment: EMA's decade-long insights into engineered adoptive cell therapy for rare cancers and orphan designation*. Gene Ther. 2024; 31(7-8):366-377. doi: 10.1038/s41434-024-00446-0.
3. Palomo GM, Pose-Boirazian T, Naumann-Winter F, Costa E, Duarte DM, Kalland ME, Malikova E, Matusevicius D, Vitezic D, Larsson K, Magrelli A, Stoyanova-Beninska V, Mariz S. *The European landscape for gene therapies in orphan diseases: 6-year experience with the EMA Committee for Orphan Medicinal Products*. Mol Ther. 2023; 31(12):3414-3423. doi: 10.1016/j.ymthe.2023.09.020.
4. Naumann-Winter F, Wolter F, Hermes U, Malikova E, Lilienthal N, Meier T, Kalland ME, Magrelli A. *Licensing of Orphan Medicinal Products-Use of Real-World Data and Other External Data on Efficacy Aspects in Marketing Authorization Applications Concluded at the European Medicines Agency Between 2019 and 2021*. Front Pharmacol. 2022; 13:920336. doi: 10.3389/fphar.2022.920336.
5. Sheean ME, Naumann-Winter F, Capovilla G, Kalland ME, Malikova E, Mariz S, Matusevicius D, Nistico R, Schwarzer-Daum B, Tsigkos S, Tzogani K, Larsson K, Magrelli A, Stoyanova-Beninska V. *Defining Satisfactory Methods of Treatment in Rare Diseases When Evaluating Significant Benefit-The EU Regulator's Perspective*. Front Med (Lausanne). 2021; 8:744625. doi: 10.3389/fmed.2021.744625.
6. Ali S, Kjeken R, Niederlaender C, Markey G, Saunders TS, Opsata M, Moltu K, Bremnes B, Grønevik E, Muusse M, Håkonsen GD, Skibeli V, Kalland ME, Wang I, Buajordet I, Urbaniak A, Johnston J, Rantell K, Kerwash E, Schuessler-Lenz M, Salmonson T, Bergh J, Gisselbrecht C, Tzogani K, Papadouli I, Pignatti F. *The European Medicines Agency Review of Kymriah (Tisagenlecleucel) for the Treatment of Acute Lymphoblastic Leukemia and Diffuse Large B-Cell Lymphoma*. Oncologist. 2020; 25(2):e321-e327. doi: 10.1634/theoncologist.2019-0233.
7. Størvold GL, Landskron J, Strozynski M, Arntzen MØ, Koehler CJ, Kalland ME, Taskén K, Thiede B. *Quantitative profiling of tyrosine phosphorylation revealed changes in the activity of the T cell receptor signaling pathway upon cisplatin-induced apoptosis*. J Proteomics. 2013; 91:344-57. doi: 10.1016/j.jprot.2013.07.019.
8. Kalland ME, Solheim SA, Skånland SS, Taskén K, Berge T. *Modulation of proximal signaling in normal and transformed B cells by transmembrane adapter Cbp/PAG*. Exp Cell Res. 2012; 318(14):1611-9. doi: 10.1016/j.yexcr.2012.05.014.
9. Kalland ME, Oberprieler NG, Vang T, Taskén K, Torgersen KM. T *cell-signaling network analysis reveals distinct differences between CD28 and CD2 costimulation responses in various subsets and in the MAPK pathway between resting and activated regulatory T cells*. J Immunol. 2011; 187(10):5233-45. doi: 10.4049/jimmunol.1101804.
10. Oberprieler NG, Lemeer S, Kalland ME, Torgersen KM, Heck AJ, Taskén K. *High-resolution mapping of prostaglandin E2-dependent signaling networks identifies a constitutively active PKA signaling node in CD8+CD45RO+ T cells*. Blood. 2010; 116(13):2253-65. doi: 10.1182/blood-2010-01-266650.
11. Mahic M, Kalland ME, Aandahl EM, Torgersen KM, Taskén K. *Human naturally occurring and adaptive regulatory T cells secrete high levels of leukaemia inhibitory factor upon activation*. Scand J Immunol. 2008; 68(4):391-6. doi: 10.1111/j.1365-3083.2008.02148.x.

Projects

Memberships

Other Relevant Information