BRANDNEWS

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DSI DrugSafetyInstitute
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Where Safe Names Begin!

Brand Institute is proud to have partnered with 900+ healthcare companies on over 3,300 pharmaceutical brand names, highlighted by these most recent name approvals from EMA

Important Update: The next deadline to submit names to EMA is January 7th, 2021. We are here to help with your next naming project. Please contact your local team for assistance or to schedule a meeting.

November 19, 2020	November 18, 2020	November 18, 2020
OXLUMO (lumasiran) for injection 94.5 mg/0.5 mL Alnylam Netherlands B.V.	INJECTION Nyvepria pegfilgrastim-apgf Pfizer	MenQuadfi™ Meningococcal (Groups A, C, Y, W) Conjugate Vaccine Sanofi Pasteur
July 27, 2020	**July 27, 2020**	**July 03, 2020**
PIQRAY® (alpelisib) tablets 50 mg · 150 mg · 200 mg Novartis Europharm Limited	Xenleta™ (lefamulin) Nabriva Therapeutics	Veklury® remdesivir 100 MG FOR INJECTION Gilead Sciences
July 03, 2020	**July 03, 2020**	**July 01, 2020**
ENERZAIR BREEZHALER indacaterol / glycopyrronium / mometasone furoate Novartis Europharm Limited	ZIMBUS BREEZHALER indacaterol / glycopyrronium / mometasone furoate Novartis Europharm Limited	MVABEA Ebola vaccine (MVA-BN-Filo [recombinant]) Janssen
July 01, 2020	**June 26, 2020**	**May 30, 2020**
ZABDENO Ebola vaccine (Ad26.ZEBOV-GP [recombinant]) Janssen	DAURISMO™ glasdegib tablets 100 mg | 25 mg Pfizer Europe	bemrist® breezhaler® indacaterol / mometasone Novartis Europharm Limited

DRUG SAFETY INSTITUTE (DSI) NAMING & LABELING EXPERT SPOTLIGHT

Ioannis (Nakos) Balamotis, Pharm.D.

President, EU Regulatory Affairs
Drug Safety Institute

Dr. Balamotis joined DSI - London as Managing Director, EU Regulatory Affairs in 2014 and in 2018 was promoted to President, EU Regulatory Affairs. Prior to joining DSI, he was a Scientific Administrator for the European Medicine Agency's (EMA) Name Review Group (NRG). NRG is responsible for evaluating and approving invented names submitted to the Agency via the centralized procedure. He played an integral role in the development of the EMA's 2014 NRG Guidelines, which were published in May 2014.

Dr. Balamotis reported directly to the EMA's NRG Secretariat during his tenure with the agency. He participated in all name review meetings and communicated meeting outcomes with NRG affiliates. And, while working on the 2014 guidance document, he liaised with Member States and representatives of the Pharmaceutical Industry, coordinating information and input from all relevant parties. He assisted the EMA in conducting technical reviews of the Product Information (Summary of Product Characteristics, Labeling and Package Leaflets) according to QRD (Quality Review of Documents) standards and in evaluating mock-ups and specimens (packaging artwork). He was also involved in the implementation of the new Pharmacovigilance Legislation, which involved the electronic submission of substance data according to ISO IDMP standards in the first EMA's electronic medicinal dictionary (XEVMPD). Dr. Balamotis is a current member of the BHBIA (British Healthcare Business Intelligence Association) Ethics & Compliance Committee.

Dr. Balamotis earned a Doctor of Pharmacy from Carlo Bo University of Urbino, Italy and a B.Sc. in Chemistry at Aristotle University of Thessaloniki, Greece.

José-ángel Ferrero, Pharm.D., M.Sc.

Vice President, EU Regulatory Affairs & Safety Research
Drug Safety Institute

Dr. Ferrero joined DSI - London in 2017 as Drug Safety Institute - Vice President, EU Regulatory Affairs & Safety Research. Prior to joining DSI, he was a Labeling Specialist and Scientific Administrator of the Name Review Group (NRG) – European Medicines Agency (EMA) for over 5 years, the group that is responsible for evaluating and approving invented names submitted to the Agency via the centralized procedure. In his role at EMA, he was responsible for the drafting and handling of revision 6 of the 2014 "Guideline on the acceptability of names for medicinal products processed through the centralized procedure."

Dr. Ferrero managed all aspects related to the activities and work of the NRG, including the preparation of NRG meetings, support to the NRG Chair before, during and following NRG meetings, preparation of agendas and minutes, preparation of all internal/external correspondence and preparation of reports/memos on NRG related Member States correspondence for invented name submissions, reviews and approvals. As labeling specialist, he was responsible for the management of the labeling review and Quality Review of Documents (QRD) standards' check of Summaries of Product Characteristics, Labeling and Package Leaflet for assigned product portfolio.

Dr. Ferrero earned a post-graduate Pharm.D. degree in Clinical Pharmacy (secondary care) from the University of Bradford, UK and a B.Sc. in Pharmacy from the University of Salamanca, Spain. Prior to joining EMA, he accomplished senior clinical pharmacist roles at Sheffield Teaching Hospitals, UK.

Baptiste Lacoustille, Pharm.D., M.S.

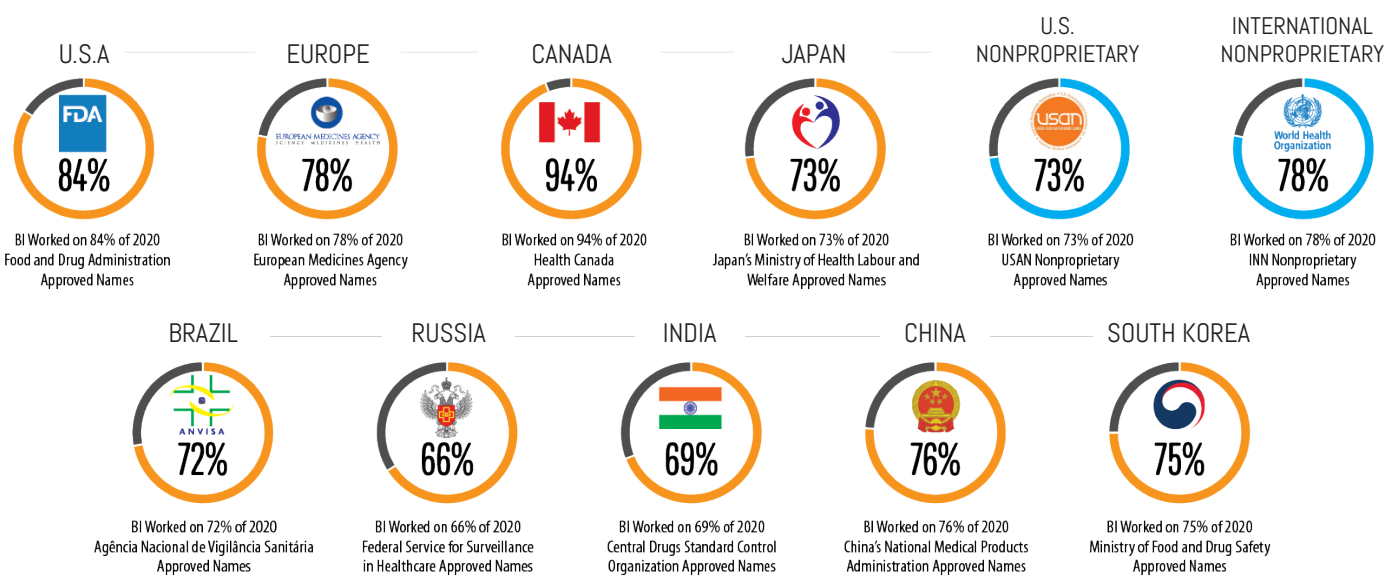
Drug Safety Evaluator
Drug Safety Institute

Dr. Lacoustille joined BI - Basel in 2017 as Vice President, Brand Development and was promoted to Drug Safety Evaluator in 2019. Prior to joining BI, he worked in the Labeling Review and Standards Office at the European Medicines Agency (EMA) in London, UK. In this role Baptiste participated in Name Review Group (NRG) meetings, and was responsible for researching, analyzing and preparing for the review and acceptability of invented names for medicinal products according to the EMA 2014 NRG Guidelines. Baptiste reported directly to the NRG Chairperson, the head of the division responsible for evaluating and approving invented names submitted to the agency via the centralized procedure.

Dr. Lacoustille's additional responsibilities at the EMA included reviewing the quality of product information (SmPC, package leaflet, labeling) according to QRD (Quality Review of Documents) standards for centrally authorized medicines in different therapeutic areas. He was appointed "Labeling Specialist" for the Immunosuppressants Product Portfolio where he served as an integral member of an "EMA Product Team" made up of various experts, providing labeling advice to pharmaceutical companies at pre-submission, assessment and post-authorization stages.

Prior to his time at the EMA, he served in Regulatory Affairs at GlaxoSmithKline and in Regulatory Compliance at LFB Biomédicaments. He earned his Pharm.D. and Master's degree in "International Regulatory Environment of Healthcare Industries and Health Products" from Montpellier University (UM).

BRAND INSTITUTE'S 2020 GLOBAL SHARE OF MARKET NAME APPROVALS



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