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BRANDNEWS

COVID–19
Vaccine Naming News

DSI
DrugSafetyInstitute
A Subsidiary of BRAND INSTITUTE, inc.
Where Safe Names Begin!

Brand Institute is proud to have partnered with Pfizer and BioNTech on the brand and nonproprietary (INN) name development for COMIRNATY® (tozinameran)!

The first vaccine approved for the prevention of coronavirus disease 2019 (COVID-19)

EU Brand Name	Nonproprietary Name (INN)
COMIRNATY®	tozinameran
Click to Listen	Click to Listen

Pfizer and BioNTech's COVID-19 vaccine has a brand name: COMIRNATY®. The name was first announced by the Swiss regulatory authority, Swissmedic, and was included in the conditional marketing authorisation published by the European Medicines Agency (EMA). The approval of the brand name by other global regulatory agencies will follow their respective guidelines, policies and procedures.

In a joint press release issued on December 21, 2020, the companies spoke about the vaccine's brand name, which was developed by Brand Institute, noting, "The vaccine will be marketed in the EU under the brand name COMIRNATY®, which represents a combination of the terms COVID-19, mRNA, community, and immunity, to highlight the first authorization of a messenger RNA (mRNA) vaccine, as well as the joint global efforts that made this achievement possible with unprecedented rigor and efficiency, and with safety at the forefront, during this global pandemic."

Brand Institute/Drug Safety Institute also partnered with Pfizer and BioNTech on the development of the nonproprietary name (INN), tozinameran.

Brand Institute's Chairman and CEO, James L. Dettore, commented on the news, "The entire staff at Brand Institute and Drug Safety Institute is honored to have partnered with two incredible companies, Pfizer and BioNTech, on the development of their COVID-19 vaccine's brand name, COMIRNATY®, and nonproprietary (p-INN) name, tozinameran. Naming a product that will have such a profound impact on humanity is humbling, and an opportunity for which we are truly grateful." Stay tuned for further COVID-19 vaccine branding and name development news.

Todd Darwin Bridges, R. Ph.

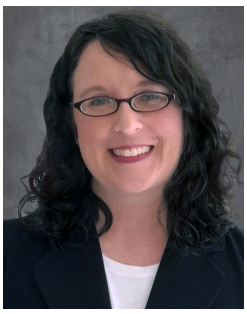
Global President
Drug Safety Institute

Mr. Bridges joined DSI – Rockville in May 2018 as Global President. Prior to joining DSI, Mr. Bridges was the Director of the Division of Medication Error Prevention and Analysis (DMEPA) in the Office of Surveillance and Epidemiology at the U.S. Food and Drug Administration (FDA). He has more than thirteen years of DMEPA experience with three of those years as the Director of DMEPA.

As Director of DMEPA, Mr. Bridges was responsible for supervising the premarket review and approval of proposed proprietary/brand drug names, labels/labeling, packaging, product design, United States Adopted Names, biological product proper name suffixes, and human factors studies in order to reduce the potential for medication errors with products regulated by the Center for Drug Evaluation and Research (CDER). DMEPA conducts review and analysis of post-marketing medication errors submitted to CDER to determine if regulatory action such as label/labeling revisions, names change, product redesign, or post-marketing communications to stakeholders is needed. DMEPA also works with external stakeholders, regulators, and researchers to better understand the causes of medication errors and the effectiveness of interventions at preventing them, and provides guidance to the pharmaceutical industry on drug development considerations from a medication errors perspective.

Mr. Bridges has contributed to FDA policy and guidances related to medication errors, represented FDA as a member of the National Coordinating Council for Medication Error Reporting and Prevention as well as the Joint Commission's Patient Safety Advisory Group, and was responsible for establishing FDA's ongoing membership with the International Medication Safety Network. In addition to his FDA experience, Mr. Bridges has thirteen years of pharmacy practice and supervisory experience prior to joining FDA. He has also received specialty training in medication error prevention and analysis from the Institute for Safe Medication Practices.

Mr. Bridges earned a B.S. in Pharmacy from Virginia Commonwealth University's Medical College.



Nora Roselle, Pharm.D.

President, U.S. Regulatory Affairs
Drug Safety Institute

Dr. Roselle joined DSI - Rockville as Managing Director of U.S. Regulatory Affairs in 2007, promoted in 2012 to Vice President, Global Regulatory Affairs and most recently promoted to President, U.S. Regulatory Affairs. Prior to DSI, she served as an officer (LCDR) in the U.S. Public Health Service. She joined the U.S. Food and Drug Administration (FDA) in 2001 as a Safety Evaluator in the Division of Medication Errors and Technical Support (DMETS), in the Office of Drug Safety (ODS), renamed the Office of Surveillance and Epidemiology (OSE), now known as the Division of Medication Error Prevention and Analysis (DMEPA). DMEPA is responsible for the approval of manufacturer's drug/biologic brand names and human factors/ medication error evaluation of drug and drug/device labeling, packaging, and product design to reduce medication errors.

As Team Leader, Dr. Roselle managed DMETS safety evaluators, proprietary (brand, line extension, and combination product) name reviews, labeling and risk management consults. Dr. Roselle has published several articles on medication errors. Two of her most widely known name safety articles include "Metadate ER or Metadate CD?; Drug Topics 2004,Oct 11:62,64" and "Confusion between Methylphenidate and Methadone, Patient Care 2003, Jan 15:76." Dr. Roselle earned a Doctor of Pharmacy from the University of Maryland (with Honors) and a B.S. in Biology with a Chemistry Minor from the University of Akron (Cum Laude).

Scott Sawler, B.Sc., LL.B., LL.M., M.B.A.

President, Canadian Regulatory Affairs
Drug Safety Institute

Mr. Sawler joined Brand Institute's regulatory subsidiary, Drug Safety Institute (DSI) - Ottawa as Managing Director, Canadian Regulatory Affairs in 2017 and in 2018 was promoted to President, Canadian Regulatory Affairs. Prior to joining DSI, he was Director General (DG) of Health Canada's Marketed Health Products Directorate (MHPD), which is responsible for reviewing and approving proposed proprietary (brand) names; conducting risk/benefit assessments of marketed health products; overseeing the advertising regulatory requirements of health products; providing policies to effectively regulate marketed health products etc.

Prior to this, Mr. Sawler was the DG of Health Canada's Natural and Non-prescription Health Product Directorate where he led the program through a transitional period. He re-established its strategic vision, overhauled its policies and streamlined management systems to put the program back on track. Mr. Sawler also has significant experience as an executive and counsel in clinical trial management, government, legal and regulatory affairs. His clients included pharmaceutical companies, health professional associations, and non-governmental organizations.

Mr. Sawler earned his LL.M. from Osgoode Hall at York University, an M.B.A. from the University of Laval, an LL.B. from the University of Ottawa, and a B.Sc. in Chemistry from the University of New Brunswick.

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.

Sophia Fuerst, M.S., M.B.A.

President, Nonproprietary Names Division
Drug Safety Institute

Ms. Fuerst joined Drug Safety Institute's Nonproprietary (USAN/INN) Names Division as Managing Director in 2005, and was promoted to President in 2007. Ms. Fuerst was formerly Director of the USAN Program at the American Medical Association (AMA) and served in various positions during her 18-year tenure with the Program, including AMA senior staff scientist in the area of Drug Nomenclature.

She was involved in negotiations between the USAN Council, pharmaceutical manufacturers and foreign nomenclature agencies. From 1986 to 2005, Ms. Fuerst was responsible for reviewing submissions, classifying compounds, creating new stems when appropriate and approving and adopting new USAN names.

Ms. Fuerst worked as a consultant, from 1999-2000, to the Secretariat of the INN Programme at the World Health Organization (WHO/INN) in Geneva, Switzerland. Ms. Fuerst holds a B.S. in Biology/Chemistry (pre-med) from St. Joseph's College, an M.S. in Medicinal Chemistry from the University of Chicago and an M.B.A. from Governor's State University in Illinois.

DRUG SAFETY INSTITUTE (DSI) NAMING & LABELING EXPERT SPOTLIGHT

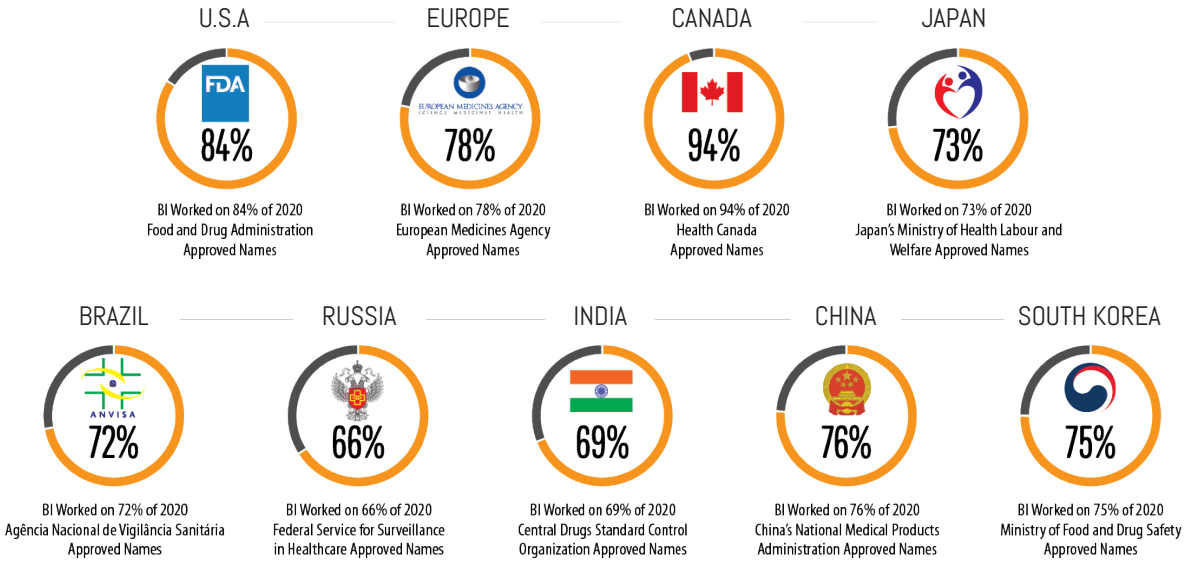
Sandra Van Laan, B.S.

Vice President, Regulatory Affairs, Nonproprietary Names Division
Drug Safety Institute

Ms. Van Laan joined Drug Safety Institute's Nonproprietary (USAN/INN) Names Division as Vice President, Regulatory Affairs, Nonproprietary Division in 2006. Prior to joining DSI, she worked for 26 years at the American Medical Association (AMA). Ms. Van Laan was the Associate Secretary to the United States Adopted Names (USAN) Council and a Senior Research Associate at the AMA within the Division of Science and Technology where she provided pharmaceutical expertise to AMA staff for several publications including Current Medical Information and Technology (CMIT), Current Procedural Technology (CPT) and the Journal of the American Medical Association (JAMA). In her role with the USAN Program she provided structural and mechanistic compound analysis to accurately categorize newly submitted names into the appropriate stem classification and shared the responsibility for devising new stems within the taxonomy of nomenclature, when appropriate. The AMA USAN Program is responsible for evaluating and approving nonproprietary names.

She supplied guidance to pharmaceutical companies on the preparation of submissions to the USAN Council and negotiated name candidates with the members of the USAN Council and INN Expert Committee to obtain scientifically appropriate nonproprietary names for worldwide use. Ms. Van Laan has worked closely with the Food and Drug Administration (FDA), Center for Biologics, Evaluation and Research (CBER), and the United States Pharmacopeial (USP) Convention for the standardization of nonproprietary nomenclature and has participated in regulatory strategic planning sessions and intellectual property protection discussions pertaining to nonproprietary names. Ms. Van Laan co-chaired the Pronunciation Committee that developed the USAN Pronunciation Guidelines that are in use today.

BRAND INSTITUTE'S 2020 GLOBAL SHARE OF MARKET NAME APPROVALS



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