Statement on

Real Country-Of-Origin-Labeling (COOL) Transparency in the U.S. Pharmaceutical Market: Foundation for a Secure & Resilient Drug Supply

at the Senate Hearing on

Truth in Labeling:
Americans Deserve to Know Where Their Drugs Come From

Statement before the

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Statement of

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Real COOL (Country-Of-Origin-Labeling) Transparency in the U.S. Pharmaceutical Market: Foundation for a Secure & Resilient Drug Supply

Thank you, Chairman Scott, Ranking Member Gillibrand, and other members of the Senate Special Committee on Aging, for the opportunity to provide information and insights at this hearing on "Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From." My remarks will address "Real Country-Of-Origin-Labeling (COOL) Transparency in the U.S. Pharmaceutical Market as a Foundation for a Secure & Resilient Drug Supply.

I am Stephen W. Schondelmeyer, Professor of Pharmaceutical Management & Economics at the University of Minnesota where I serve as Co-Principal Investigator for the Resilient Drug Supply Project in the Center for Infectious Disease Research and Policy (CIDRAP). In addition, I am Director of the *PRIME* Institute which focuses on research and policy issues related to the pharmaceutical market and its impact on society. These remarks are my own views based upon my research and experience in studying the pharmaceutical marketplace for over fifty (50) years. Thank you for the opportunity to testify at this hearing. During my career I have had the opportunity to interact with many of the federal entities that shape and influence our nation's healthcare system including the Department of Health and Human Services and many of its divisions such as FDA, CMS, ASPE, ASPR, BARDA and with other federal agencies such as the Department of Commerce, FTC, GAO, and OMB.

This hearing on the role of transparency and country-of-origin-labeling (COOL) in securing the U.S. drug supply comes at a critical time for the United States. The U.S. pharmaceutical market is facing ongoing challenges with economic and quality concerns and with new challenges from geopolitical risk that may precipitously interrupt pharmaceutical trade, distribution and the supply chain.

Challenges Impacting the U.S. Drug Supply

Prescription drugs are a cornerstone of American healthcare, with virtually all Americans needing and using prescription medications and related pharmacy services during their lifetime. Nearly one-half (45.8%) of all Americans and 85% of older adults (aged 60+) reported taking one or more prescription drugs in the last month.[1] Americans

[1] "Americans Take Prescriptions a Large Portion of Their Lives." U.S. Pharmacist, October 25, 2023. Accessed 01-24-2026 at: https://www.uspharmacist.com/article/americans-take-prescriptions-a-large-portion-of-their-lives#:~:text=University%20Park%2C%20PA%E2%80%94Over%20a,all%20Americans%20said%20the%20same; see, also, Jessica Ho. "Life Course Patterns of Prescription Drug Use in the United States." Demography (2023) 60(5):1549–1579, published September 20, 2023, DOI 10.1215/00703370-10965990

count on critical and essential medications for serious and life-threatening diseases such as diabetes, chronic heart disease, asthma, epilepsy, cancer, and almost every other condition or disease. Indeed, access to prescription drugs is a foundational component of a safe and effective healthcare system.

Historical Challenges to Drug Supply: Quality & Market Economic Issues. Americans expect essential medications to be available at a nearby community pharmacy, or at the local hospital, when they are needed. However, drug shortages have been, and still are, "a serious and recurring problem resulting from a web of factors rooted in an opaque drug production and drug supply chain, underfunded and underperforming government agencies, and a drug purchasing and distribution system with product allocation practices that are often secretive, unknown, and at times counterproductive."[2] Historically, drug shortages have been attributed to a variety of quality issues and market economic factors[3] including "manufacturing difficulties; quality problems and [drug] recalls; supply and logistic disruptions; unexpected demand surges; low prices for older, well-established generic drugs due to 'over-competition'; market [concentration and] manipulation by various stakeholders; and other factors."[4]

For more than three decades, there has been a substantial number of drug shortages in the U.S. market.[5,6] Both the FDA and the American Society of Health System Pharmacists (ASHP) routinely track and report on these drug shortages.[7,8] While the number of drug shortages has been growing over time, there are several relatively recent developments that have improved our understanding of, and response to, drug shortages. For example, organizations such as Angels for Change[9] and End Drug

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[2] Schondelmeyer S, Siefert J, Margraf D, et al, COVID-19: The CIDRAP Viewpoint, Part 6: Ensuring a Resilient US Prescription Drug Supply, October 21, 2020, available on the Resilient Drug Supply Project website at: https://www.cidrap.umn.edu/rds or directly at: https://www.cidrap.umn.edu/sites/default/files/public/downloads/cidrap-covid19-viewpoint-part6.pdf

[3] FDA. Drug Shortages: Root Causes and Potential Solutions. Report. Oct 2019.

[4] Stephen W Schondelmeyer. Statement on Strategic Assessment of the Resilience of the U.S. Drug Supply with Lessons from the Pandemic & Recommendations for Moving Beyond. Presented at Senate Hearing on COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps before the Committee on Homeland Security and Governmental Affairs, United States Senate, May 19, 2021. Accessed online on January 24, 2026 at: https://www.hsgac.senate.gov/wp-content/uploads/imo/media/doc/Testimony-Schondelmeyer-2021-05-19-13.pdf.

[5] FDA. Drug Shortages, Oct 2019.

[6] Fox ER, Birt A, James KB, et al. ASHP guidelines on managing drug product shortages in hospitals and health systems. Am J Health Syst Pharm 2009 Aug 1;66 (15):1399-406; and, ASHP website: https://www.ashp.org/Drug-Shortages/Current-Shortages.

[7] FDA reported drug shortages can be found at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

[8] ASHP reported drug shortages can be found at: https://www.ashp.org/Drug-Shortages/Current-Shortages

[9] Angels for Change. Our Mission. "Our focus is to advocate on behalf of any patient in a life-saving drug shortage, while building relationships with patients and members of the pharmaceutical supply chain ending all healthcare crises created by drug shortages." Angels for Change was founded in 2019. Accessed online on January 24, 2026 at: https://www.angelsforchange.org/ourmission.

Shortages Alliance (EDSA)[10] have emerged to work with patients, healthcare providers and health systems, the pharmaceutical industry, and supply chain stakeholders. In addition, the United States Pharmacopeia (USP) has developed and maintains the USP Medicine Supply Map which is an innovative digital platform "powered by AI technology and predictive analytics."[11] Using previous drug shortage data and other factors, the USP Medicine Supply Map employed predictive analytics to identify, characterize, and forecast shortage risks. In 2024, the USP model was able to predict a high risk of shortage for more than 98% of the sterile injectable drugs that later experienced an actual shortage in the U.S. market. Clearly, this historical, experience-based model works for predicting drug shortage risk driven by quality and market economic issues and it has improved our ability to anticipate and mitigate many drug shortages.[12]

New Challenges to a Secure Drug Supply: Trade Restrictions & Geopolitical Risk. With the advent of COVID-19, the global market for pharmaceuticals faced a new reality: trade restrictions and barriers for pharmaceuticals. There was a sudden global demand for a COVID-19 vaccine. Even when vaccines were developed and began to enter the market, the demand far outstripped the supply leading to intense global competition for the limited supplies of the vaccine. Vaccine-producing and high-income countries wanted to assure sufficient supply for their own populations before allowing export of the vaccine to other nations.[13] Countries such as those in the European Union, the United States, and India imposed export restrictions on the COVID-19 vaccine.[14] In addition, India was so concerned about having enough critical drugs to meet the needs of the Indian market that it restricted for a time the export of 26 APIs and finished drug

[10] End Drug Shortage Alliance (EDSA). About Us. Mission. EDSA was founded in December or 2021.

[11] United States Pharmacopeia, USP Medicines Supply Map, USP. Accessed online on January 24, 2026 at: https://www.usp.org/supply-chain/medicine-supply-map; the USP Medicines Supply Map was initiated in 2018 and made public in 2022. Mary Van Beusekom. RDSP maps medicine supply to US to predict, prevent shortages (Part 1 of 2). CIDRAP News, University of Minnesota. March 31, 2022. Accessed on May 23, 2025 at: https://www.cidrap.umn.edu/supply-map-created-predict-drugshortages-find-solutions-part-1-2.

[12] United States Pharmacopeia. USP Annual Drug Shortages Report: Longstanding drug shortages persist in 2024. May 2025/ Accessed on January 24, 2026 at: https://go.usp.org/2025drugshortagesreport?_gl=1*zlzl4g*_gcl_aw*R0NMLjE3NjkzODA2MDAuQ2owS0NRaUFtOWZMQmhDUUFSSXNBSm9OT2N0NnlscUZPaDBpTnpWbWlXMFJGamxrVXlqMk1tX0d5TmVlaEpBZFFNNnhlUWxMNEZ1bDRPQWFBdTBuRUFMd193Y0I.*_gcl_au*NDQ3ODc4MTQxLjE3Njg5OTI3OTQuMTA2MzA4OTQ4Ny4xNzY5MDQxMjM5LjE3NjkwNDEyNzE.*_ga*NTgxOTMxNzIuMTc2ODk5Mjc5NA..*_ga_DTGQ04CR27*czE3Njk0MDEzODUkbzckZzAkdDE3Njk0MDEzODYkajU5JGwwJGgw/

[13] Victoria Pilkington Sarai Mirjam Keestra, Andrew Hill. "Global COVID-19 Vaccine Inequity: Failures in the First Year of Distribution and Potential Solutions for the Future." Frontiers in Public Health, PERSPECTIVE, March 1, 2022, Volume 10, doi: 10.3389/fpubh.2022.821117.

[14] Ibrahim, Imad Antoine. "Overview of Export Restrictions on COVID-19 Vaccines and their Components." American Society of International Law, Issue: 10, Volume: 25, June 01, 2021

products to prevent shortages in India.[15] More recently, the Trump administration has introduced tariffs on the trade of certain pharmaceutical products.[16]

Although geographic concentration of pharmaceutical production had been growing gradually for more than two decades, COVID-19 exposed the vulnerability of a highly concentrated supply chain. The dominant market share of India and China in certain pharmaceutical markets gives these countries significant leverage to raise price or, if hostilities exist, to withhold supply from the U.S. market.[17] With the current level of U.S. dependency upon drugs whose active pharmaceutical ingredients (APIs) were made in China or India, if either country decides for any reason to block export of pharmaceuticals to the U.S., the American healthcare system would face a major supply crisis.[18]

Geopolitical risk and trade restrictions are both factors that are largely independent from, and external to, the pharmaceutical market. However, these new types of risk can have a sudden and major impact on the U.S. drug supply chain. One analyst noted that "A major geopolitical conflict could compromise many supply chains, potentially ones quite different from those currently at high risk of shortage."[19] Such geopolitical risk and trade restrictions are new forces in the global pharmaceutical market that are likely to cause supply issues and shortages with a different set of drugs than are traditionally seen due to quality issues and market economic factors. Because of recent changes in the dynamics of global relationships, overall, both geopolitical risk and trade restrictions on pharmaceuticals have become real and are much more likely to impact the supply of drugs in the United States. The U.S. population, in general, does not have much visibility into the geographic source of the medications they take every day and the risk of disruptions to the supply chains for those medications.

What Is COOL (Country-of-Origin-Labeling)?

What is the Purpose of COOL? Country-Of-Origin-Labeling (COOL) is an established practice for important consumer goods including food, textiles, automobiles, and certain

[15] PTI, BloombergQuint. India restricts drug exports as threat of coronavirus rises. Mar 3, 2020.

[16] American Hospital Association, "President announces new tariffs, including for certain pharmaceuticals, set to begin Oct. 1." Sep 26, 2025. Accessed on January 24, 2025 at: https://www.aha.org/news/headline/2025-09-26-president-announces-new-tariffs-including-certain-pharmaceuticals-set-begin-oct-1.

[17] Stephen W Schondelmeyer, "Statement on Designing A Resilient U.S. Drug Supply: Efficient Strategies to Address Vulnerabilities" at the U.S.-China Economic and Security Review Commission Hearing on Dominance by Design: China Shock 2.0 and the Supply Chain Chokepoints Eroding U.S. Security Panel II: Preparing for China's Counterpunch: Vectors for Supply Chain Coercion, June 5, 2025. p. 19

[18] Schondelmeyer, "Statement on Designing A Resilient U.S. Drug Supply." P. 19.

[19] Marta E. Wosińska. "Drug shortages: A guide to policy solutions." Brookings, March 13, 2024. Accessed on January 24, 2026 at: https://www.brookings.edu/articles/drug-shortages-a-guide-to-policy-solutions/.

other consumer goods. When buying a T-bone steak, or a new t-shirt and blue jeans, the consumer is provided with a label on the end-product that clearly identifies the country where the product was “made.” In general, COOL in the consumer market serves as a mechanism to inform buyers about the product’s origin, thereby influencing perceptions of quality, safety, economics, or even the presumed patriotism of the purchaser. With respect to pharmaceuticals, the safety, efficacy, and quality assurance of the medication are paramount. Knowing the country of origin for the product can directly affect consumer trust and regulatory scrutiny. Furthermore, COOL reflects the regulatory frameworks, economic strategies, environmental conditions, and international trade policies that may have surrounded and influenced the making of the end-product. COOL is a tangible means to provide transparency, support consumer decision-making, and encourage a fair and competitive market.

Public policy regarding a variety of consumer goods requires the manufacturer to inform the purchaser about where the product being acquired and consumed was actually made. In a market where public policy requires that the consumer be informed about where their T-bone steak was raised or where their blue jeans were made, it seems unconscionable that society would consider it any less important to know where their life-saving cancer drug or diabetes medicine was made.

What Is COOL? COOL is the acronym for “Country-Of-Origin-Labeling” which means to provide the ultimate purchaser—the American patient—with pharmaceutical product labeling that clearly indicates where their medication was made. COOL has emerged as a critical element in the contemporary landscape of consumer goods, in general, and prescription pharmaceuticals, in particular. COOL involves marking the drug product received by the end-consumer with the name of the country in which the product was actually manufactured or made. For some industries, and in some trade agreements, the concept of COOL is the place where the product was “manufactured, processed, or substantially transformed.” The definition of where a pharmaceutical product is made is critical and should be clearly defined. For pharmaceutical products, the essence and value of the drug product is embodied in its active pharmaceutical ingredient(s) (API), and not necessarily in how it was processed or packaged.

For most pharmaceutical products, the API is typically made in a different location from where the final drug product is formed. Consequently, one can argue that “transformation” of the raw API material into the final form of the actual physical product such as a tablet, capsule, liquid, or other dosage form is relevant to the integrity and use of the end-product. In other words, the COOL for pharmaceutical products should account for both the country where the API is made and the country where the final pharmaceutical product is formed. In some cases, both the API and the finished product may have been made at the same plant and in the same country, although more often than not, the API and the finished drug product are made in different plants or even different countries.

Additionally, the production of the API for a pharmaceutical product typically involves combining 2 to 5 or more key starting materials (KSMs) and may require up to a dozen or more supporting materials such as catalysts, solvents, enzymes and other agents.[20] Some have advocated that COOL should be required for the KSMs used in making the API for a pharmaceutical product. Other drug products require peripheral devices, or ancillary materials, to facilitate their safe and appropriate use. This would include devices such as an auto-injector pen for epinephrine or insulin, or an inhaler for an asthma medication, or glass vials and rubber stoppers for sterile injectable drugs. Some have advocated that COOL should be required for these peripheral devices and ancillary materials as well.

In summary, *Country-Of-Origin-Labeling* (COOL) for prescription pharmaceutical products is defined as "The mandatory disclosure of the specific country of the geographic location where a finished pharmaceutical product was made, and the country where its critical components (*i.e.*, the active pharmaceutical ingredient(s) (API)) were physically manufactured and made." At a minimum, the COOL for a prescription pharmaceutical product must include the country where the finished product was made and the country where the API was made. In some cases, where appropriate, the COOL may also require disclosure of the country where a peripheral device was made (*e.g.,* an auto-injector pen for epinephrine or insulin, or an inhaler device for an asthma medication) or the country where ancillary materials were made (*e.g*., a glass vial and rubber stopper for a sterile injectable drug).

As global pharmaceutical supply chains become increasingly complex and as intermediary goods and products move across multiple borders before reaching the end consumer, COOL has taken on greater importance and significance.

What Is Not COOL? With respect to prescription pharmaceutical products, it is not sufficient for the COOL-compliant label to name the country of: (1) the warehouse shipping the product; (2) the corporate headquarters of the firm marketing, selling, or distributing the product; (3) the U.S. address of a foreign-owned company operating in the United States; (4) the facility repackaging or relabeling the product; or (5) the pharmacy or healthcare entity dispensing the medication. The location and country of these additional facilities may be of interest or required for other reasons, but they are not COOL. If a finished pharmaceutical product is made using API from a factory in China and then the powder is shipped to New Jersey where it is pressed into a tablet, it is not sufficient to label this product as simply "Made in the USA." Such a label would be a material misrepresentation of where the functional component of the product was actually made. This product should be labeled as active ingredient "Made in China" and finished product "Made in the USA."

[20] Wosińska. "Drug shortages: A guide to policy solutions." Brookings, March 13, 2024.

What Are the Rules for COOL? U.S. law[21] currently requires that "all products of foreign origin imported into the United States must be marked with their country of origin."[22] The intent of this requirement is to protect the consumers' interests by informing the "ultimate purchaser" as to the "country of origin" of the goods that are being purchased, which includes prescription medications purchased at the retail level. The implementation of this provision was clarified on June 14, 2024 by the U.S. Customs and Border Protection (CBP) Headquarters in a letter (HQ H283420) to CVS Health.[23] This letter clarified that the 'consumer at retail,' rather than the pharmacy (or dispenser/repackager/seller) is the 'ultimate purchaser.' This change means that "the outermost container that ordinarily reaches the ultimate purchaser of a J-List article [includes prescription drugs] must be marked with the country of origin of the article."[24] This new interpretation means that "when a customer fills a prescription order for a medication, and purchases it at a retail pharmacy such as CVS, we [the CBP] find[s]that the customer, as the purchaser of the medication at retail, is the ultimate purchaser." Prior to this ruling the retail pharmacy had been considered the ultimate purchaser.

After this ruling, CBP made it clear that manufacturers (*i.e*., importers) were expected to provide the country of origin for their product to the downstream purchaser to enable that information to be placed on the prescription bottle at the time it is dispensed to the 'ultimate consumer.' In order to comply with this ruling, retail pharmacists must rely upon the importer (*i.e*., or proxy for the manufacturer) to disclose and report this information. The pharmacist must search for the 'country of origin' information, although there is no standardized format or place where it must be reported.

Where Can You Find COOL Information? The first place for the pharmacist to look is on the actual label attached to the bulk prescription bottle as purchased from the importer (manufacturer) or wholesaler. If the 'country of origin' is not on the label, then the pharmacist would need to look at the outer packaging surrounding the bulk container when it was shipped. If the 'country of origin' still is not found, the pharmacist

[21] 19 U.S.C. § 1304 and 19 C.F.R. § 134.11.

[22] U.S. Customs and Border Protection. "Fact Sheet: Marking of Prescription Medication for Retail Sale." CBP Publication No. 3812-0824. Accessed on January 24, 2026 at: https://www.cbp.gov/sites/default/files/2024-08/FACT%20SHEET%20Marking%20Prescription%20Medication%20for%20Retail%20Sale.pdf.

[23] U.S. Customs and Border Protection, Letter from Yuliya A. Gulis, Director, Commercial and Trade Facilitation Division to JoAnne Colonnello, Center Director, Pharmaceuticals, Health, and Chemicals, Center of Excellence and Expertise, U.S. Customs and Border Protection, 6747 Engle Road, Middleburg Heights, OH 44130, dated June 14, 2024; HQ H283420, OT:RR:CTF:CPMMA H283420 RRB, CATEGORY: Marking; RE: Internal Advice; Country of origin marking requirements for repackaged prescription medication sold by CVS Health; ultimate purchaser; 19 U.S.C. § 1304; 19 C.F.R. § 134.1(d)(1); 19 C.F.R. § 134.25. Accessed on January 24, 2026 at: https://rulings.cbp.gov/ruling/H283420.

[24] U.S. Customs and Border Protection, Letter to Yulia A. Gulis, June 14, 2024.

could log onto the National Library of Medicine's website, known as DailyMed,[25] that has a profile for each drug product at the national drug code level using the FDA's Structured Product Labeling database.[26] Once on the DailyMed website, one can search for a specific drug product using its brand or trade name, if it has one, or the generic name plus the manufacturer name. Then, one would need to search the extensive DailyMed profile of the drug product for the 'country of origin' in one or more of the following places: (1) a jpg image of the drug product label; (2) a jpg image of the outer carton surrounding the bulk package; (3) near the end of the section under the heading "Patient Counseling Information;" (4) near the end of the section under the heading "Patient Package Insert"; (5) on the jpg image titled "PACKAGE LABEL PRINCIPAL DISPLAY PANEL;" or, (6) near the end of the section under the heading "INGREDIENTS AND APPEARANCE" in the sub-heading titled "Establishment". If there is a firm named under the Business Establishment section, it may be indicated as the MANUFACTURER—the firm that made the finished dosage form (FDF) or finished drug product; or as the API MANUFACTURER—the firm that made the API. If found in this section, the firm name will be followed by an FEI (Federal Establishment Identifier) or a DUNS number[27] which would need to be looked up to find the firm address and its Country of Origin. As one can tell after reading this list of places to look for Country of Origin information, this process is labor-intensive and very time consuming. It may take a pharmacist 10 minutes to 30 minutes or more per prescription drug to search for this information, and they still may not find the Country of Origin as presented by the manufacturer.

While this process works theoretically, there are a number of practical problems. First, this process is dependent upon the importer (*i.e.*, manufacturer) reporting the Country of Origin as required and in a clearly understood manner. Second, if there is information on the Country of Origin one must interpret what it really means—for example, is it the finished product manufacturer, the API manufacturer, or something else. Third, there is not a uniform place to look for this information across products and manufacturers.

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[25] DailyMed is a database that contains labeling submitted to the Food and Drug Administration (FDA) by drug companies and as of January 25, 2026 included contains 154,512 products and their respective labels. Accessed on January 24, 2026 at: https://dailymed.nlm.nih.gov/dailymed/.

[26] U.S. Food and Drug Administration, Structured Product Labeling (SPL). Accessed on January 24, 2026 at: https://open.fda.gov/data/spl/. "Drug manufacturers and distributors submit documentation about their products to FDA… There is considerable variation between drug products, since the information required for safe and effective use varies with the unique characteristics of each drug product."

[27] U.S. Food and Drug Administration, Business Entity Identifiers. Last updated on March 27, 2018. Guidance for Industry Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing. U.S. Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, May 2009, p. 10, FN 22; "D-U-N-S® Numbers are proprietary to and controlled by Dun & Bradstreet (D&B). Where practicable, the customer will refer to the number as a "D-U-N-S® Number" and state that D-U-N-S is a registered trademark of D&B." Source: Dun and Bradstreet D-U-N-S Number. Accessed on January 24, 2026 at: https://www.fda.gov/industry/structured-product-labeling-resources/business-entity-identifiers.

Fourth, after searching for the Country of Origin on hundreds of drug products in DailyMed profiles, one realizes that the terminology used is not well-defined, and it is not consistent or standardized.

The specific drug product labels use inconsistent and unclear language to precede the name of the firm and its country of operation. Labels use language such as: “Marketed by…”; “Distributed by…”; “Manufactured for…”; “Mfg. for…”; “Repackaged by…”; “Relabeled for…”; and a variety of other phrasing. Even when followed by a firm name or country of operation, none of these represents the country of origin for the importer (or manufacturer) of the finished drug product or the API. Such labeling of these drug products does not appear to comply with the COOL requirement if this is the only manufacturer information provided. Other drug products may have language such as: “Manufactured by…”; Manuf. by…”; “Product of…”; “Made in…” or numerous other somewhat similar phrases preceding the name of a firm, and sometimes the country or location of the firm. These labels may appear to comply with the COOL requirement, although even if a country is named, it is not clear whether this country is for the finished product manufacturer, the API manufacturer, a corporate headquarter, or some other site that is different from the actual manufacturing site.

What Can Be Done to Improve COOL Information? The requirement for COOL should specify the location for where the Country of Origin for the finished product manufacturer is to be reported and it should have a clearly-defined and consistent phrase to be used preceding the firm name and Country of Origin to eliminate the potential for confusion with free-form company-specific phrasing. Similarly, the COOL requirement for Country-of-Origin labeling of the API manufacturer should also have a clearly-defined and consistent phrase to be used preceding the drug product’s API manufacturer and its Country of Origin.

For some drug products the only information about the manufacturing firm is provided in a jpg image of the drug product label or the outer box container. However, for some jpg images on the DailyMed website, the quality is so poor that one cannot clearly read the fine print with the name or country of the product’s marketer, distributor, repackager, manufacturer, or other description. When the only place the information is found is in a jpg image on the DailyMed website, the jpg image must be of sufficient quality so that the words related to the drug company and its location can be clearly read. The FDA should establish a minimum readable level of pixilation for label jpgs that can be clearly read.

To the best of my knowledge, there is no compiled electronic-format list of NDCs for drug products with the associated Country of Origin for both the finished product manufacturer and the API manufacturer. Such a list should be compiled by FDA and/or a commercial database that would be readily available to pharmacies to facilitate compliance with the COOL provisions. While the pharmacist, and the pharmacy, are the

last point of contact where the ultimate purchaser receives the prescription drug, it does not make sense to hold the pharmacist accountable for reporting the Country of Origin for the drug product's manufacturer, if the manufacturer is not required to always and consistently report this information to the FDA and the FDA is not required to make this information readily available to pharmacists in an efficient manner. For most other types of consumer goods with COOL requirements, it is the manufacturer and not the retailer that attaches the COOL compliant label to the product.

Why Is COOL Information Hidden? Another major concern regarding the COOL provision as currently implemented is that the FDA allows drug sponsors who report the manufacturer name and location for a drug product to specify that this information is 'confidential' or 'proprietary' or a 'trade secret'. When the drug sponsor declares the information to be 'confidential', the FDA does not report the information in their public-facing records including the SPL database used to populate a drug product's profile on the NLM's DailyMed website.[28] FDA Regulations (21 CFR § 20.61) define Confidential Commercial Information (CCI) as valuable data that is "customarily held in strict confidence." For example, the FDA traditionally treats the specific factory location of an Active Pharmaceutical Ingredient (API) as CCI. In other words, the manufacturer can request that information not be made public, yet the pharmacist is still responsible for reporting the Country of Origin for the finished product manufacturer—even though the necessary information is not provided. Ironically, many times when a firm declares the name and location of the drug manufacturer to be confidential and does not report the information, it is not unusual to find that the same firm has issued a public press release announcing details of who the actual manufacturer is and where its production facility is located.

For example, the blockbuster drug products (*i.e.*, Mounjaro for diabetes and Zepbound for weight loss) are both made with the same active ingredient—tirzepatide. When one looks up these drug products on the DailyMed website[29], you find that the Sections of the drug profile which provide information on who makes each drug product are: (1) Patient Counseling Information; (2) Principal Display Panel; and (3) Ingredients and Appearance. In all three places for both Mounjaro and Zepbound, the labeling on the DailyMed website shows that these drugs are: "Marketed by: Lilly USA, LLC, Indianapolis, IN 46285. USA." Note that all sources report "Marketed by" and not "Manufactured by". Apparently, Lilly indicated that the information on the finished product manufacturer and on the API manufacturer is "Confidential". However, if one

[28] U.S. Food and Drug Administration. Step-by-Step Instructions for Creating SPL Files For Electronic Drug Establishment Registration and Drug Listing v2.0. Accessed on January 24, 2026 at: https://www.fda.gov/media/76331/download.

[29] National Library of Medicine, DailyMed website: tirzepatide. Accessed on January 24, 2026 at: https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=tirzepatide&pagesize=20&page=1.

does a Google search for “Who Makes Zepbound?”, you will find a Press Release[30] for Eli Lilly announcing investment in a new manufacturing facility “to manufacture active pharmaceutical ingredients (API) for Zepbound® (tirzepatide) injection and Mounjaro® (tirzepatide) injection.” The purpose of this example is to illustrate that information which may have been represented as “Confidential” to the FDA for labeling purposes often has actually been made public by the medicine company for another purpose.

The labeling (marking) statute (section 304 of the Tariff Act of 1930) as amended (19 U.S.C. § 1304), provides that unless excepted, every article of foreign origin (or its container) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or its container) will permit, in such a manner as to indicate to an ultimate purchaser in the United States the English name of the country of origin of the article. The Congressional intent of 19 U.S.C. § 1304 was “that the ultimate purchaser should be able to know by an inspection of the markings on the imported goods the country of which the good is the product. The evident purpose is to mark the goods so that at the time of purchase the ultimate purchaser may, by knowing where the goods were produced, be able to buy or refuse to buy them, if such marking should influence his will.”[31]

The statutes for FDA should be amended to allow, or require, that the Country of Origin for the manufacturer of the finished drug product and for the API should be made transparent for all prescription drug products. The manufacturers of drug products actually made in the United States should also be required to indicate that their drug product and/or API, if appropriate, was “Made in the USA.” If the products made in the USA are not labeled with the Country of Origin, the pharmacist will not know whether the Country of Origin for a given product is missing (not reported) or the United States. This could lead to making a (sometimes) false assumption that products without a Country of Origin on the label are Made in the USA.

What Changes are Needed to COOL Policy? *Full transparency of the Country of Origin for the finished product manufacturer and the API manufacturer should be required for all prescription drugs*. The "Ultimate Purchaser" Rule[32] is a landmark change for transparency related to Country-of-Origin labeling for prescription drugs. The Country of Origin must be disclosed on the prescription container. CBP argues that trade secrets cannot override the statutory requirement (19 U.S.C. § 1304) to inform consumers of a product's origin. However, the FDA statutes, regulations, and guidance need to be changed to make sure that FDA makes public the information pharmacists

[30] Eli Lilly and Company, “Lilly Increases Manufacturing Investment to $9 Billion at Newest Indiana Site to Boost API Production for Tirzepatide and Pipeline Medicines”, Press Release, May 24, 2024. Accessed on January 24, 2026 at: https://investor.lilly.com/news-releases/news-release-details/lilly-increases-manufacturing-investment-9-billion-newest.

[31] United States v. Friedlaender & Co., 27 C.C.P.A. 297, 302 C.A.D. 104 (1940).

[32] Customs & Border Protection Ruling HQ H283420/H346255

will need to put the Country of Origin on the prescription container for every customer. Transparency facilitates public safety and allows patients to track recalls and adverse effects that may have come from their specific drug product such as the recalls for the ‘sartans’ (e.g., the 2018–2025) involving nitrosamine impurities from specific Chinese and Indian plants. Transparency also supports national security. Both the U.S. Pharmacopeia (USP) and the Department of Defense have argued that "confidentiality" hides the fact that the U.S. is dangerously over-reliant on foreign adversaries for critical medicines, which is a matter of public interest, not private profit.

Real Transparency for the Drug Supply Chain

The country of New Zealand serves as a real example of full transparency for the prescription drug supply chain. Medsafe is a unit in the Medicines and Medical Devices Safety Authority within the New Zealand Ministry of Health. MedSafe is the authority responsible for the regulation of therapeutic prescription products in New Zealand. All prescription drug products (at the equivalent of the NDC level) on the market in New Zealand have a transparent drug supply chain that is accessible through an online website.[33] This public database allows any person to search for a medication and see exactly which manufacturing sites are approved for that product. There is no "proprietary" or confidential shield for the factory's name or location.

Among the reported categories in the supply chain are: active ingredients; excipients; finished product testing sites; manufacturer(s) of active ingredients; manufacturer(s) of finished dosage forms; packing; secondary packing; and NZ site of product release. The database also reports all package sizes, indications, and the regulatory action history for each product. The profiles of two drugs are attached in Appendix B. Compare these MedSafe Product Detail profiles to the DailyMed Drug Product Ingredients profiles in Appendix A. There are strengths to each of the formats; however, the drug supply chain format in MedSafe appears easier to use, more consumer friendly, and does not require additional look up of codes in other databases to interpret. *The FDA and DailyMed should consider revising the format for their drug supply chain information to be similar to the format in MedSafe.*

New Zealand has demonstrated the feasibility and utility of a market-wide drug product database with detailed information on the upstream supply chain and they maintain the database on an ongoing basis. “The public transparency of this information does not appear to have commercially harmed the manufacturers or marketers of drug products

[33] MedSafe, Product Application Search, New Zealand. Accessed on January 23, 2026 at: https://www.medsafe.govt.nz/regulatory/DbSearch.asp

in New Zealand."[34] Many of the corporate entities marketing drugs in New Zealand are marketing the same, or very similar, drug products in the United States and they often use the same supply chain sources. The information for all drug products and their sites of manufacturer are transparent and accessible to all who can access New Zealand's MedSafe website. Clearly, New Zealand has been able to prioritize consumer and patient access, while still respecting truly proprietary information.

Building a COOL & Secure Drug Supply Foundation

Building a secure foundation for the U.S. drug supply requires re-framing our approach to understanding the U.S. drug supply and the challenges that it faces in the years ahead. The FDA is charged to review and approve drugs that are safe and effective for treating patients in the U.S. healthcare market. FDA has a tremendous amount of information about clinical and safety aspects of drug products in the market. In general, however, the FDA has not been empowered, authorized or appropriated resources to assess and manage the U.S. drug supply on a market-wide industrial and commercial basis. There is a need for an assessment of the data sources and analytics necessary to assure the security of the U.S. drug supply from a market-wide perspective that embraces, and goes beyond, the safety, effectiveness, and approval of individual drug products. This effort should be built using the cornerstone of the FDA drug data platforms while enabling integration with data from the business and consumer sectors as well as the global economy.

There is a need for an entity at the national level that can coordinate and stimulate the robustness of the entire pharmaceutical market at all levels and in all corners of the healthcare system. Drug data and systems are fragmented and a framework is needed for integration of data across federal and state agencies (including the FDA, CDC, DOD, VA, FTC, and others) as well with the private sector. Market-wide mapping is needed to integrate siloed drug approval data into a comprehensive, transparent system to ensure life-saving medicines remain available, affordable, secure, and of high quality. A core drug supply map needs to build new strengths and methods for understanding the national and global dynamics of the upstream drug supply chain and its vulnerabilities.

The recent changes to the COOL requirements have facilitated getting more complete information from drug companies about the origin of KSMs, APIs, and finished drug products. This information is now being provided to the FDA and has been used to enrich the drug product profiles on NLMs DailyMed platform. The U.S. government

[34] Stephen W Schondelmeyer, "Statement on Designing A Resilient U.S. Drug Supply: Efficient Strategies to Address Vulnerabilities" at the U.S.-China Economic and Security Review Commission Hearing on Dominance by Design: China Shock 2.0 and the Supply Chain Chokepoints Eroding U.S. Security Panel II: Preparing for China's Counterpunch: Vectors for Supply Chain Coercion, June 5, 2025. p. 6

needs to build upon the rich databases of the FDA, CMS, the Department of Commerce, the Department of Defense, Homeland Security, the Veterans Administration, and other entities as well as the quasi-governmental standard-setting body known as USP and its innovative USP Medicine Supply Map. Collaborations need to be encouraged across the whole of government and with the private sector.

Both the mapping and the transparency of this market-wide drug data system should be built with a three-tiered layering of access. The most complete and open access would be at the national level for specialized analysts and policy makers in government and key think tank participants who can think strategically about building and protecting a secure pharmaceutical market. The second level would provide access to integrated data and working projects at functional levels in federal agencies, academia, and with industry stakeholders. The third layer of this tiered access would be for the private sector, consumers, and the general public to have insights into data that facilitate their safe, effective and affordable use of prescription drugs.

At the top-tier level, the paradigm needs to shift from a reactive "fail and fix" drug supply framework to a proactive "predict and prevent" paradigm. Central to this top tier of the drug supply is a core medicine supply map that interfaces drugs with health, the economy, society, and other domains including the geopolitical realm. A mechanism to embrace and build upon the unique work of the USP Medicine Supply Map as the foundation of the whole of government strategic pharmaceutical industrial policy makes sense. USP is accustomed to working at the interface of government and the private sector and has a 200-year track-record of doing so.

Congress is encouraged to authorize and fund a national entity to maintain this master drug database for the whole of government market-wide approach to industrial pharmaceutical policy analysis. This work could be done by a new independent Congressional commission similar to MedPac or through a hybrid approach with USP and other selective contracting and collaborations across various government agencies and private entities. Funding for the core medicine supply map should have an initial annual appropriation and additional funds for a public-private research program to develop sentinel systems that use big data to detect signals for strategic change and to address security challenges in the pharmaceutical supply system of the United States.

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Appendix A
DailyMed Labeling & Packaging for Mounjaro & Zepbound

Mounjaro 15 mg NDC 00002-1657-80

17 PATIENT COUNSELING INFORMATION

What are the ingredients in MOUNJARO?

Active ingredient: tirzepatide

Inactive ingredients: sodium chloride, sodium phosphate dibasic heptahydrate, and water for injection. Hydrochloric acid solution and/or sodium hydroxide solution may have been added to adjust the pH.

MOUNJARO® is a registered trademark of Eli Lilly and Company.

Marketed by: Lilly USA, LLC Indianapolis, IN 46285, USA

For more information, go to www.MOUNJARO.com or call 1-800-545-5979.

This Medication Guide has been approved by the U.S. Food and Drug Administration

Revised: December 2025

Zepbound 15 mg NDC 00002-2457-80

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling *(Medication Guide and Instructions for Use)*.

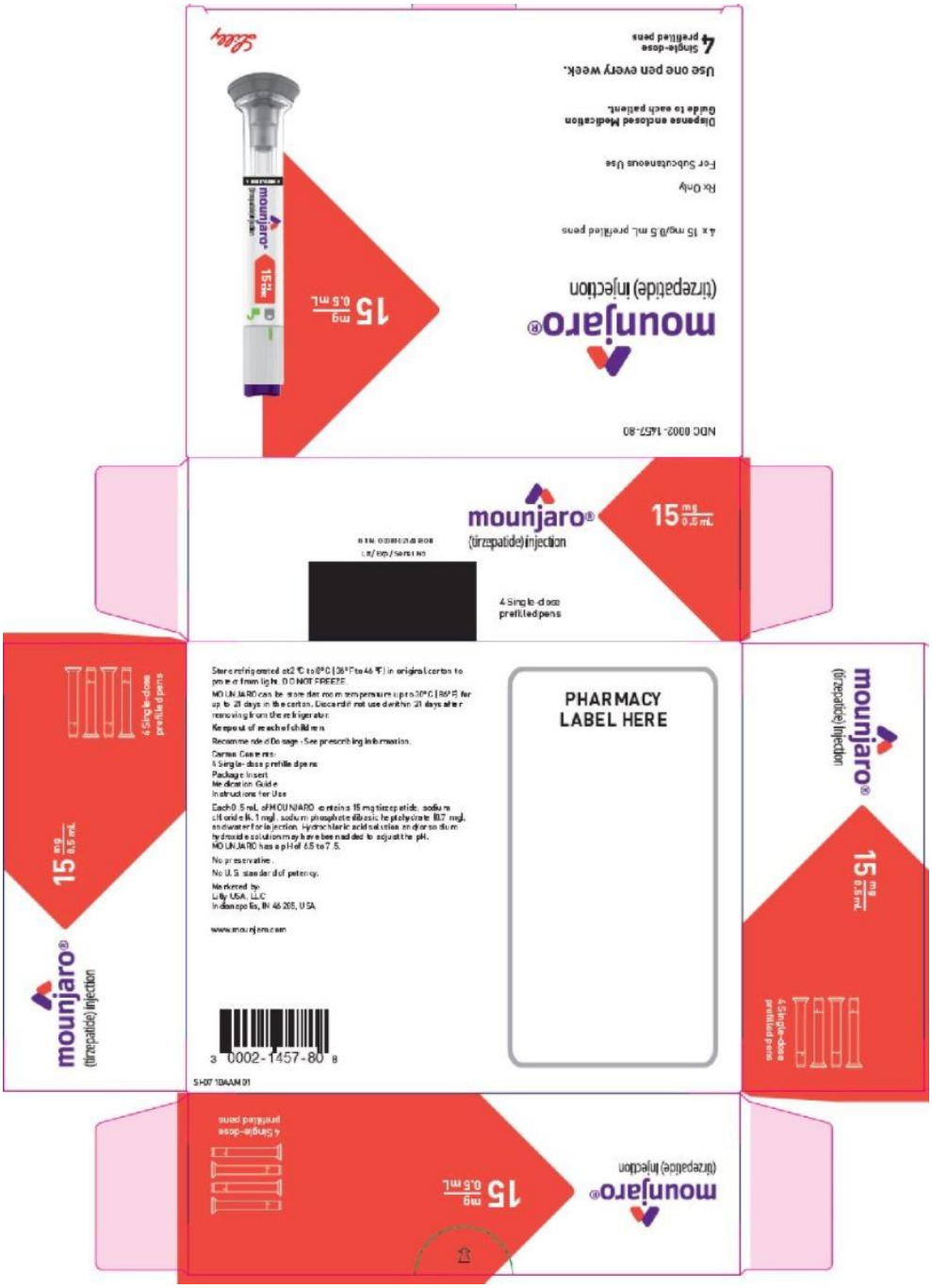
Marketed by: Lilly USA, LLC, Indianapolis, IN 46285, USA

Pat.: www.lilly.com/patents

ZEP-0011-USPI-20260107

Mounjaro 15 mg NDC 00002-1657-80

PRINCIPAL DISPLAY PANEL



Zepbound 15 mg NDC 00002-2457-80

PRINCIPAL DISPLAY PANEL

Mounjaro 15 mg NDC 00002-1657-80

INGREDIENTS AND APPEARANCE

ZEPBOUND
tirzepatide injection, solution

PRODUCT INFORMATION			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0002-2002
Route of Administration	SUBCUTANEOUS		

ACTIVE INGREDIENT/ACTIVE MOIETY		
Ingredient Name	**Basis of Strength**	**Strength**
tirzepatide (UNII: OYN3CCI6QE) (tirzepatide - UNII:OYN3CCI6QE)	tirzepatide	15 mg in 0.5 mL

INACTIVE INGREDIENTS	
Ingredient Name	**Strength**
Sodium Chloride (UNII: 451W47IQ8X)	4.1 mg in 0.5 mL
Sodium Phosphate, Dibasic, Heptahydrate (UNII: 70WT22SF4B)	0.7 mg in 0.5 mL
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	

PACKAGING				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0002-2002-01	1 in 1 CARTON	03/28/2024	
1		0.5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:0002-2002-04	4 in 1 CARTON	07/07/2025	
2		0.5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

MARKETING INFORMATION			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
NDA	NDA217806	11/08/2023	

Zepbound 15 mg NDC 00002-2457-80

INGREDIENTS AND APPEARANCE

ZEPBOUND
tirzepatide injection, solution

PRODUCT INFORMATION			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0002-2002
Route of Administration	SUBCUTANEOUS		

ACTIVE INGREDIENT/ACTIVE MOIETY		
Ingredient Name	**Basis of Strength**	**Strength**
tirzepatide (UNII: OYN3CCI6QE) (tirzepatide - UNII:OYN3CCI6QE)	tirzepatide	15 mg in 0.5 mL

INACTIVE INGREDIENTS	
Ingredient Name	**Strength**
Sodium Chloride (UNII: 451W47IQ8X)	4.1 mg in 0.5 mL
Sodium Phosphate, Dibasic, Heptahydrate (UNII: 70WT22SF4B)	0.7 mg in 0.5 mL
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	

PACKAGING				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0002-2002-01	1 in 1 CARTON	03/28/2024	
1		0.5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:0002-2002-04	4 in 1 CARTON	07/07/2025	
2		0.5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

MARKETING INFORMATION			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
NDA	NDA217806	11/08/2023	

Lilly Increases Manufacturing Investment to $9 Billion at Newest Indiana Site to Boost API Production for Tirzepatide and Pipeline Medicines

May 24, 2024

Largest investment in active pharmaceutical ingredient manufacturing of synthetic medicines in U.S. history

Since 2020, the company has committed more than $18 billion to build, upgrade and acquire facilities in the U.S. and Europe

INDIANAPOLIS, May 24, 2024 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that it has more than doubled its investment in its Lebanon, Indiana, manufacturing site with a new $5.3 billion commitment, increasing the company's total investment in this site from $3.7 billion to $9 billion. This expansion will enhance Lilly's capacity to manufacture active pharmaceutical ingredients (API) for Zepbound® (tirzepatide) injection and Mounjaro® (tirzepatide) injection so that more adults with chronic diseases like obesity and type 2 diabetes may benefit from these important treatments.

Since 2020, Lilly has committed more than $16 billion to develop new manufacturing sites in the U.S. and Europe. New locations outside Indiana include Research Triangle Park and Concord, North Carolina; Limerick, Ireland; and Alzey, Germany. Separately, the company has invested an additional $1.2 billion to update existing manufacturing facilities in Indianapolis and recently acquired an injectable manufacturing facility in Pleasant Prairie, Wisconsin, from Nexus Pharmaceuticals. Together, these manufacturing investments total more than $18 billion.

"Today's announcement tops the largest manufacturing investment in our company's history and, we believe, represents the single largest investment in synthetic medicine API manufacturing in U.S. history," said David A. Ricks, Lilly's chair and CEO. "This multi-site campus will make our latest medicines, including Zepbound and Mounjaro, support pipeline growth and leverage the latest technology and automation for maximum efficiency, safety and quality control. Importantly, we are investing in our home state of Indiana, creating high-wage, advanced manufacturing, engineering and science jobs for hundreds of current and future Hoosier families."

Lilly embarked on a significant manufacturing expansion in 2020, driven by the research results for tirzepatide. The company made this strategic investment decision at risk so that upon the approval of Mounjaro (2022) and Zepbound (2023), it could make these medicines available to adults living with type 2 diabetes and obesity, respectively. Since then, the strong demand for these medicines – the only approved treatments activating two incretin hormone receptors, GIP and GLP-1 – underscores the urgent unmet need for treatments in both type 2 diabetes and obesity.

As part of this additional investment in the Lebanon site, located within Indiana's LEAP Research and Innovation District, Lilly expects to add 200 full-time jobs for highly skilled workers such as engineers, scientists, operating personnel and lab technicians, resulting in an estimated 900 full-time employees when the facility is fully operational. Additionally, there will be more than 5,000 construction jobs during the site's development.

"Lilly continues to play a transformational role in shaping Indiana's opportunity economy, and I couldn't be more proud about their pole position leadership in developing the LEAP Research and Innovation District in Lebanon, Indiana. Lilly has long been driving global innovation and economic growth that will be felt for decades here at home," said Indiana Governor Eric J. Holcomb. "As an international company, headquartered in Indiana, Lilly had a world of options to consider before making this investment, and choosing Indiana once again reinforces the incredible environment we've cultivated and the talented workforce we have to carry Lilly's success forward. I can't wait to see the incredible benefits this investment leads to for patients around the world, knowing they were made in Indiana."

To support Lilly's expansion project, the state will partner on infrastructure solutions – road improvements, water, electric and other utilities – as well as workforce development commitments and certain economic incentives tied to the company's achievement of investment and employment goals. The state's workforce development support includes the contribution of land, pending approval, for the construction of a learning and training center that will be part of the larger LEAP industrial development, along with a commitment to work with Lilly to raise capital for its completion. The new training center aligns with Lilly's previously announced financial support for scholarship and training programs with Purdue University and Ivy Tech Community College, and the BioCrossroads-led training center at 16 Tech – part of Indiana's recent Tech Hub designation.

"Lilly's commitment to meeting the demand for our life-changing medicines goes beyond buildings and extends to improving education opportunities and upskilling a global workforce of the future," said Edgardo Hernandez, executive vice president and president, Lilly Manufacturing Operations. "Academia is a critical partner to both industry and government as we work together to advance innovation in our state and communities around the globe."

Since breaking ground at its Lebanon manufacturing site in 2023, Lilly has transformed a significant portion of the nearly 600 acres within the complex into an active construction site. The company expects to begin making medicines in Lebanon toward the end of 2026 – with operations scaling up through 2028.

Appendix B
MedSafe Product Detail
Profile for Mounjaro & Paxlovid

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Medicines

Revised: 31 May 2019

Medsafe Product Detail

File ref: TT50-11479/1e

Trade Name	*Dose Form*	*Strength*	*Identifier*
Mounjaro	Solution for injection	15 mg/0.5mL	Pre-filled Pen
Sponsor	*Application date*	*Registration situation*	*Classification*
Eli Lilly and Company (NZ) Limited P O Box 109 197 Newmarket AUCKLAND 1149	8/1/2025	Consent given Approval date: 22/12/2025 Labelling exemption expires 11/12/2027	Prescription

Composition

Component	*Ingredient*	*Manufacturer*
solution for injection	Active	
	Tirzepatide 30 mg/mL	Corden Pharma Colorado Inc 2075 North 55th Street Boulder Colorado 80301 UNITED STATES OF AMERICA Eli Lilly and Company Inc Lilly Corporate Center Indianapolis Indiana 46285 UNITED STATES OF AMERICA
	Excipient	
	Dibasic sodium phosphate heptahydrate	
	Hydrochloric acid	
	Sodium chloride	
	Sodium hydroxide	

Water for injection

Production

Manufacturing step	*Manufacturer*
Finished Product Testing	Eli Lilly and Company Inc Lilly Corporate Center Indianapolis Indiana 46285 UNITED STATES OF AMERICA
	Eli Lilly Italia SpA Via Gramsci 731-733 Sesto Fiorentino Florence 50019 ITALY
	Eurofins Lancaster Laboratories Inc 2425 New Holland Pike Lancaster Pennsylvania 17601 UNITED STATES OF AMERICA
	Vetter Pharma-Fertigung GmbH & Co KG Eisenbahnstrasse 2-4 Langenargen D-88085 GERMANY
	Vetter Pharma-Fertigung GmbH & Co KG Helmut-Vetter-Str. 10 Ravensburg Baden Wurttemberg 88213 GERMANY
	Vetter Pharma-Fertigung GmbH & Co KG Mooswiesen 2 Ravensburg D-88214 GERMANY
	Vetter Pharma-Fertigung GmbH & Co KG Schuetzenstrasse 87, 99-101 Ravensburg D-88212 GERMANY
Manufacture of Active Ingredient	Corden Pharma Colorado Inc 2075 North 55th Street Boulder Colorado 80301 UNITED STATES OF AMERICA

	Eli Lilly and Company Inc Lilly Corporate Center Indianapolis Indiana 46285 UNITED STATES OF AMERICA
Manufacture of Final Dose Form	Eli Lilly and Company Inc Lilly Corporate Center Indianapolis Indiana 46285 UNITED STATES OF AMERICA
	Vetter Pharma-Fertigung GmbH & Co KG Mooswiesen 2 Ravensburg D-88214 GERMANY
Packing	Eli Lilly and Company Inc Lilly Corporate Center Indianapolis Indiana 46285 UNITED STATES OF AMERICA
	Vetter Pharma-Fertigung GmbH & Co KG Mooswiesen 2 Ravensburg D-88214 GERMANY
Secondary Packaging	Eli Lilly and Company Inc Lilly Corporate Center Indianapolis Indiana 46285 UNITED STATES OF AMERICA
	Eli Lilly Italia SpA Via Gramsci 731-733 Sesto Fiorentino Florence 50019 ITALY
NZ Site of Product Release	Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics 6 Te Kapua Drive Mangere Auckland 2022

Packaging

Package	*Contents*	*Shelf Life*

Syringe, glass, type I glass, elastomeric plunger, single-use pen with 29G needle	2 dose units	24 months from date of manufacture stored at 2° to 8°C (Refrigerate, do not freeze) protect from light 21 days not refrigerated stored at or below 30°C protect from light
Syringe, glass, type I glass, elastomeric plunger, single-use pen with 29G needle	4 dose units	24 months from date of manufacture stored at 2° to 8°C (Refrigerate, do not freeze) protect from light 21 days not refrigerated stored at or below 30°C protect from light

Indications

Type 2 Diabetes Mellitus: MOUNJARO is indicated for the treatment of adults with insufficiently controlled type 2
diabetes mellitus as an adjunct to diet and exercise
" as monotherapy when metformin is not tolerated or contraindicated.
" in addition to other medicinal products for the treatment of type 2 diabetes.

Chronic Weight Management: MOUNJARO is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management, including weight loss and weight maintenance, in adults with an initial body mass index (BMI) of:
" NLT 30 kg/m2 (obesity) or
" NLT 27 kg/m2 to <30 kg/m2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes or type 2 diabetes mellitus).

Latest Regulatory Activity

Application Date	*Application Type*	*Change(s)*	*Status*	*Payment Date*	*Priority*
8/1/2025	New Higher-risk Medicine Application	Abridged new higher-risk medicine containing one or more new active substance; Additional strength - Grade 1; Additional strength - Grade 3	Withdrawn 10/2/2025		
17/3/2025	New Higher-risk Medicine Application	New higher-risk medicine containing one or more new active substances; Additional strength - Grade 1; Additional strength - Grade 3; Additional strength - Grade 5	Granted 22/12/2025	22/4/2025	Y

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Medicines

Revised: 31 May 2019

Medsafe Product Detail

File ref: TT50-10969

Trade Name	*Dose Form*	*Strength*	*Identifier*
Paxlovid	Film coated tablet		150 mg/100 mg
Sponsor	*Application date*	*Registration situation*	*Classification*
Pfizer New Zealand Limited P O Box 3998 AUCKLAND 1140	10/11/2021	Consent given Approval date: 12/11/2024	Prescription

Composition

Component	*Ingredient*	*Manufacturer*
film coated tablet, Nirmatrelvir 150 mg film-coated tablets	Active	
	Nirmatrelvir 150mg	Esteve Quimica SA C/ Ter 94, Poligon Industrial Celra Girona 17460 SPAIN
		Pfizer Ireland Pharmaceuticals Unlimited Company Ringaskiddy Active Pharmaceutical Ingredient Plant Ringaskiddy County Cork P43 X336 IRELAND
		Changzhou SynTheAll Pharmaceutical Co. Ltd 589 North Yulong Road Xinbei District Changzhou 213127 CHINA
		Jilin Asymchem Laboratories Co. Ltd. No. 99, Hongda Road, Economic Development Zone Dunhua Jilin 133700 CHINA
	Excipient	
	Colloidal silicon dioxide	
	Croscarmellose sodium	
	Lactose monohydrate	
	Microcrystalline cellulose	
	Opadry pink 05B140011	
	Purified water	
	Sodium stearyl fumarate	
film coated tablet, Ritonavir 100 mg film-coated tablets	Active	

Ritonavir 100mg	AbbVie S.r.l S.R. 148 Pontina Km 52 Snc Campoverde di Aprilia Latina 04011 ITALY

Production

Manufacturing step	*Manufacturer*
Finished Product Testing	AbbVie Deutschland GmbH & Co KG Knollstrasse Ludwigshafen 67061 GERMANY
	Pfizer Ireland Pharmaceuticals Unlimited Company Little Connell Newbridge County Kildare W12 HX57 IRELAND
	Pfizer Ireland Pharmaceuticals Unlimited Company Little Connell Newbridge County Kildare W12 HX57 IRELAND
	Pfizer Italia SrL Localita Marino del Tronto Ascoli Piceno (AP) I-63100 ITALY
	Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 Freiburg Im Breisgau 79108 GERMANY
	Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 Freiburg Im Breisgau 79108 GERMANY
	Quinta-Analytica sro Prazska 1486/18c Prague 10 CZ-102 00 CZECH REPUBLIC
	Quinta-Analytica sro Provozovna Brno Karasek 2296/1n Brno-Reckovice 621 00 CZECH REPUBLIC
Manufacture of Active Ingredient	AbbVie S.r.l S.R. 148 Pontina Km 52 Snc Campoverde di Aprilia Latina 04011 ITALY
	Changzhou SynTheAll Pharmaceutical Co. Ltd 589 North Yulong Road Xinbei District Changzhou 213127 CHINA
	Esteve Quimica SA C/ Ter 94, Poligon Industrial Celra Girona 17460 SPAIN

	Jilin Asymchem Laboratories Co. Ltd. No. 99, Hongda Road, Economic Development Zone Dunhua Jilin 133700 CHINA
	Pfizer Ireland Pharmaceuticals Unlimited Company Ringaskiddy Active Pharmaceutical Ingredient Plant Ringaskiddy County Cork P43 X336 IRELAND
Manufacture of Final Dose Form	AbbVie Deutschland GmbH & Co KG Knollstrasse Ludwigshafen 67061 GERMANY
	Pfizer Ireland Pharmaceuticals Unlimited Company Little Connell Newbridge County Kildare W12 HX57 IRELAND
	Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 Freiburg Im Breisgau 79108 GERMANY
Packing	Pfizer Ireland Pharmaceuticals Unlimited Company Little Connell Newbridge County Kildare W12 HX57 IRELAND
	Pfizer Italia SrL Localita Marino del Tronto Ascoli Piceno (AP) I-63100 ITALY
	Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 Freiburg Im Breisgau 79108 GERMANY
Secondary Packaging	DHL Supply Chain (New Zealand) Ltd 6 Manu Tapu Drive Mangere Auckland 2022
NZ Site of Product Release	Pfizer New Zealand Limited Level 10, 11 Britomart Place Auckland CBD Auckland 1010

Packaging

Package	*Contents*	*Shelf Life*
Blister pack, Nirmatrelvir 150mg in OPA/Al/PVC blisters	10 tablets	24 months from date of manufacture stored at or below 25°C
Blister pack, Ritonavir 100 mg in OPA/Al/PVC blisters	10 tablets	24 months from date of manufacture stored at or below 25°C
Blister pack, Nirmatrelvir 150mg in OPA/Al/PVC blisters	20 tablets	24 months from date of manufacture stored at or below 25°C
Combination pack, OPA/Al/PVC combination	20 tablets	24 months from date of manufacture stored at or below 25°C
Combination pack, OPA/Al/PVC combination	30 tablets	24 months from date of manufacture stored at or below 25°C

Indications

Paxlovid is indicated for the treatment of coronavirus disease 2019 (COVID- 19) in adults 18 years of age and older, who do not require initiation of supplemental oxygen due to COVID-19 and are at increased risk of progression to hospitalisation or death.

Latest Regulatory Activity

Application Date	*Application Type*	*Change(s)*	*Status*	*Payment Date*	*Priority*
10/11/2021	Provisional Consent (Section 23)	New higher-risk medicine containing one or more new active substances	Granted 2/3/2022	1/12/2021	Y
30/8/2023	New Higher-risk Medicine Application	Provisional to full approval (clinical need) higher-risk NCE	Granted 12/11/2024	20/9/2023	
29/11/2024	CMN 24(5)	Formulation - G4; Active ingredient manufacture - G3; Finished product manufacture - G3	Additional evaluation started 06/11/2025	11/12/2024	
30/6/2025	Changed Medicine Notification	Indications/dosage - G2; Contraindications, warnings and precautions - G1; Data sheet - G2	Granted 1/10/2025	9/7/2025	