As part of expanding access to medicine across geographies, in 2022, we:

- Received >470 global product approvals
- Completed 10 drug master filings
- Completed >134 submissions in >110 different countries, including >85 products in Emerging Markets
- Made >600 regulatory filings, which includes >250 individual market submissions for Emerging Markets

Ensuring Quality and Patient Safety in Processes and Products

Protecting patients and consumer health by ensuring the quality and safety of our products is at the heart of how we operate across our network. Every step of our development, manufacturing and monitoring processes – from developing products to sourcing of raw materials to producing and distributing finished dosage forms – is grounded in this commitment.

Quality Management

We maintain a robust quality infrastructure and strategy, encompassing all our operations and manufacturing sites globally. This infrastructure is comprised of the extensive experience and expertise of our personnel, our comprehensive Global Quality Policies that establish uniform requirements for fundamental processes and controls within our Global Quality Management System (QMS), as well as Global Quality IT systems, which are implemented and designed to establish industry best practices, consistency and global quality assurance throughout our network.

All our operations are supported by robust quality systems and standards and processes which are designed to ensure product quality and patient safety. These programs are designed and implemented across our global operations to ensure compliance with statutory and regulatory requirements, such as current Good Manufacturing Practices (cGMP), Good Pharmacovigilance Practices (GPvP), Good Distribution Practices (GDP) and Good Clinical Practices (GCP) for all markets that they serve. Each of our sites within our global network maintain the relevant licenses and GMP certifications required by their respective market and approved product authorizations.

We embed and incorporate relevant quality guidelines into our Global Quality Policies, including: Eudralex, Falsified Medicines Directive, ICH Quality Guidelines, WHO GMP, Food and Drug Administration Safety and Innovation Act and the EU Excipient Risk Assessment for ascertaining the GMPs for all the excipients of medicinal products for human use. We have developed and maintain a Regulatory Intelligence, Quality Action System and Knowledge Management Dissemination Program to inform, evaluate and implement regulatory updates, industry trends and internal knowledge across the Viatris network.

Our QMS and Product Safety and Risk Management System maintain standard operating procedures for quality-related core components, including the following:

- Managerial oversight and responsibility
- Ongoing and continuous training
- Frequent internal site and external supplier, contractor and service provider audits
- Testing practices and compendial compliance
- Product risk assessment
- Regular compliance monitoring and communication
- Incident investigation and corrective and preventive action
- Standardized document control and change management
- Compilation, trending and review of key quality metrics

In addition to the aforementioned quality standards for the development, manufacture and distribution of pharmaceutical products, several sites across our network have obtained external certification of their quality management systems including but not limited to ISO 9001 for general quality management, ISO 13485 for quality management for medical devices and related services and ISO 22716 for Good Manufacturing Practices for cosmetics.

Quality Governance and Organization

The Head of Global Quality reports to the President, and the following functions are within the overall Global Quality structure:

- Global Operations Audit
- Global Learning and Development
- Global Quality Compliance
- Global OSD and API Quality
- Global Injectables Quality
- Global Dermatologics Quality
- Global Complex Products Quality
- Global Clinical and Bioanalytical Quality
- Global Quality Systems/QA IT Technical Quality
- Global Quality Investigations, Surveillance and Regulatory Communication
- Global External Supply Quality and Supply Chain Quality
- Global Quality Integration

We continuously evolve our quality organization to ensure alignment with our business operations and to enhance compliance with applicable standards. Existing global quality resources are embedded within operational verticals to align closely with business units and drive consistency across sites. These enhancements promote closer connectivity among operational leaders and effectively safeguard product quality, supply continuity and patient access.

As a result of integration activities in 2022, Global Quality Policies were evaluated and enhanced to capture the best practices of both legacy Mylan and legacy Upjohn and to reflect current guidance, requirements and health authority expectations. Examples include Investigations, Data Integrity and Process Validation. Furthermore, legacy Upjohn sites were successfully integrated into Viatris' Quality management systems, including but not limited to Change Control, Investigations, Complaints, Document Control and Learning Management Systems. As part of this work, reviews of the requirements of applicable quality guidance documents such as the FDA, EMA and ICH were included to ensure that Viatris' quality systems have appropriate controls in place to prevent, identify and/or manage risk with respect to product quality.

Training for Continuous Improvement

Our Global Learning and Development program provides comprehensive and effective training to ensure the access to and delivery of knowledge to global operations personnel in coordination with vertical and site-based training programs. This program coordinates and standardizes training requirements, content, techniques and training delivery methods to continually strengthen our corporate learning culture.

We also have developed and maintain a regulatory intelligence program that provides personnel access to current global regulations, publications and industry trends.

Our Global Learning Development program ensures that role - specific and periodic cGMP training programs are compliant with regulatory requirements both regionally and globally. In addition, cGMP training is conducted on an annual basis and more frequently in accordance with regulatory requirements at the site and/or global level. Training programs are developed and maintained at a site/vertical level in adherence to local regulations and dosage form requirements but maintain alignment with Global Training requirements delineated as part of our Viatris Global Policies.

In addition to training on the theory and practice of cGMP, we utilize a curriculum-based approach to ensure all analysts, operators, and other personnel are fully trained based upon their defined job descriptions and assigned duties. The curricula are uniquely designed for specific job descriptions.

Procedural and cGMP training is required for all personnel whose duties are in any way associated with the manufacturing, packaging, processing, holding or testing of products or whose duties require them to enter manufacturing areas or laboratories, as well as any other personnel whose activities could affect the quality of the product. Personnel working in areas where contamination is a hazard, such as clean areas, sterile areas or areas where highly active, toxic, infectious or sensitizing materials are handled, are given additional specific training. Training in cGMP is conducted by qualified individuals to ensure that employees remain familiar with the specific cGMP requirements applicable to them.

Quality Monitoring and Assurance in Our Operations

Our Global Operations Audit program relies primarily on oversight by a specially trained team of internal global experts, augmented and supported by independent third parties. The global proactive internal audit program is a key component of our strategy, oversight and surveillance of the quality performance across our network. It serves to ensure compliance with the GQM/GQP and global cGMP regulations, and the internal audits are designed for that purpose.

The Quality Surveillance Program at Viatris is an independent assessment intended to analyze repeat product/process events with common causes and to identify potential trend signals.

- Dedicated audit leads are assigned to quality operations within each vertical to participate in all internal audits within that vertical. Site and vertical leadership collaborate to ensure continued, robust processes and to periodically evaluate existing processes and risk mitigation mechanisms. Internal audits are performed on a one- to three-year cycle based upon facility type, historical regulatory inspection performance, and potential risk for each production/API site, packaging site, distribution site and laboratory site.
- Internal sites are required to formally respond to all observations within 15 business days to the Global Operations Audit team and take appropriate corrective and preventative actions in response to any observations, with set timelines for implementation.
- Quality councils at each site oversee and monitor key performance indicators, track quality incidents, identify trends and have the authority to escalate incidents to senior quality leadership.
- At the global level, senior quality leadership routinely reviews and monitors key performance indicators from each vertical/site and their respective corrective/preventive actions for incidents and trends.

The global internal audit program includes expedited timelines for the issuance of observations and increased site leadership engagement to ensure the immediate remediation of the identified observations. We maintain a strong focus on global investigations oversight, third-party management and surveillance across our sites and further enhanced our investigatory and surveillance programs throughout 2022.

Following each internal audit, the inspected site is required to submit a corrective and preventive action (CAPA) plan to remediate any identified discrepancies. These CAPAs are submitted to our Global CAPA Management team for review and approval. Furthermore, any CAPAs from critical and/or major observations are reviewed and verified for completion by the Global Operations Audit Team prior to observation closure. In addition, CAPAs from critical and/or major observations are subject to additional review upon next scheduled internal audit to ensure compliance and the CAPA effectiveness.

Quality Risk Assessment

Proactive risk assessment is central to our approach to ensuring quality. We apply the principles outlined in the International Conference of Harmonization (ICH) Q9 Quality Risk Management as well as those in ICH Q10 Pharmaceutical Quality System.

Quality Culture

Colleagues are provided training on quality culture to ensure personnel have a clear understanding of our commitment to quality. Key components of our quality culture include:

- **Excellence** via Quality: We must all do what's right, not what's easy. We focus on getting our work done right the first time. We follow our robust processes and pay close attention to detail. And we understand the science.
- **Integrity** via Quality: If you see something that isn't right, speak up. Our reputation depends on it. We are all accountable for operating with integrity and empowered to take action to do what is right.
- **Accountability** via Quality: At Viatris, we are all accountable for operating with a quality-first mindset. Our commitment to quality gives patients the assurance they need to be empowered to live healthier at every stage of life.
- **Proactivity** via Quality: We are proactive and seek to address issues before they become problems. We collaborate with others to generate solutions and implement them quickly.
- **Reliability** via Quality: A focus on simplification — overly complex processes can lead to mistakes. We never settle for "good enough." Business continuity is enabled by a commitment to quality.

Ensuring a High-Quality Supply Chain

To help ensure the integrity of our supply chain, a highly experienced Viatris cross-departmental committee including Sourcing and Quality undertakes a rigorous review of suppliers and third parties prior to their selection for the supply of active pharmaceutical ingredients and drug products. After selection, those suppliers and third parties execute an agreement that specifically details our expectations and the right to conduct regular on-site audits

to ensure ongoing compliance with regulations, maintain applicable regulatory reporting requirements and allow access to all records related to the supplied products, among other requirements. As part of our external audit process with suppliers, contractors and service providers, auditees are required to provide formal responses to observations cited as part of the audit to the Global Operations Audit team within 30 days for review and acceptance by our Global Quality CAPA Management team.

To support external suppliers in meeting quality standards, we may place company Quality personnel at the site of a supplier to engage, monitor and mentor the site team and foster continued quality compliance.

- Our Global Operations Audit team conducts routine audits to assess the strength and performance of the QMS. The frequency of these audits, every two-five years, is based upon cyclical audit requirements by facility type, historical regulatory inspection performance, and key product launches. Cyclical audit requirements are supported by health authority audit requirements and/or recommendations.

For the latter part of 2022 and into 2023 as on-site visits became more accessible, Viatris has evolved the Global Operations Audit program for both internal and external audits to a hybrid model that incorporates both onsite and virtual audits.

- In total, 777 GMP, 69 GCP and 13 pharmacovigilance (PV) audits were conducted by Viatris' Global Operations Audit team at our internal facilities and external suppliers, contractors and service providers.

External contractors, suppliers and service providers approved for business with Viatris are recorded in an internal global database that encompasses a mixture of third-party manufacturers (sterile and non-sterile), third-party packagers, third-party laboratories, distribution centers, miscellaneous service providers, API suppliers (sterile and nonsterile), excipient suppliers and packaging component suppliers.

Working with Health Authorities

We constantly review our products, processes and facilities throughout our network and work closely with external health authorities to ensure transparency regarding emerging information, including shortages, the development of new scientific and testing criteria and evolving regulatory and manufacturing expectations everywhere we operate. We continuously learn from these interactions as scientific, technological and regulatory expectations continue to evolve.

- Health authority inspections provide extensive external certification of Viatris' internal sites and our external contractors/suppliers and provide authorization for further production and marketing.
- We work diligently to address all observations identified by Health Authorities and continue to make progress resolving Viatris' active FDA Warning Letters, including the closure of the FDA Warning Letter for our Unit 7 facility on February 16, 2023. FDA recently completed a follow up inspection at our Unit 8 API Facility with no 483 being issued.[1]
- In 2022, approximately 120 health authority inspections were conducted across our facilities. The number of health authority inspections has continued to increase globally to account for normal health authority inspection cycles and sites that were not inspected during the COVID pandemic due to health and safety concerns related to COVID-19.

In 2022, approximately 120 health authority inspections were conducted across our facilities.

Product Safety & Risk Management

Our Product Safety & Risk Management (PSRM) function has a Pharmacovigilance (PV) system with robust processes described in >120 global policies, standard operating procedures and work instructions, altogether ensuring patient care and safety in relation to the use of our products during both their development and their placement on the market.

As a major milestone in 2022, we created one Viatris global PV system to enable global oversight of patient safety and regulatory compliance. The integration work also involved building and expanding our organizational structure by hiring >350 additional highly qualified and experienced medical and scientific personnel to support our complex products.

As part of our PV system, the risk-benefit profile of all our products is continuously monitored and assessed through various core PV activities, such as Individual Case Safety Report (ICSR) management, aggregate data review and reporting, Signal Management and Risk Management Planning.

Global PV governance committees, such as the Corporate Product Safety Committee and the Pharmacovigilance System Oversight Committee, are responsible for the periodic and ad-hoc evaluation of new safety-relevant information so that the timely communication of the important new safety information to the regulatory authorities, healthcare professionals and patients is ensured, and they also facilitate full oversight of the compliance and performance of the Viatris PV system.

To manage the safety of a diversified and complex product portfolio – consisting of prescription medicines, over-the-counter medicines, combination products, medical devices, food supplements and cosmetics – we have highly skilled and trained cross-functional teams of more than 1,000

Sources

[1]As per May 5, 2023

medical and scientific professionals who review and report our risk and benefit assessments to regulatory authorities worldwide.

- In 2022, the company submitted more than 350,000 Individual Case Safety Reports and more than 1,450 aggregate reports to regulatory authorities and business partners with a high compliance rate.
- The company currently has more than 340 risk management plans and associated interventional measures designed, where required, to help ensure our products are used safely and effectively.

As part of our PV system, the benefit-risk profile of all our products is continuously monitored and assessed, ensuring safety information about our products is provided to regulatory authorities, healthcare professionals and patients in a timely manner. Also, PSRM is engaged in a number of Post-Authorization Safety Studies (PASS) to ensure the safety of approved products is monitored continuously with effective risk minimization measures.

Our PV system operates in accordance with global policies, standard operating procedures and work instructions. to ensure managerial responsibility and standardized processing for all activities. The procedures are continuously monitored for appropriateness and updated, as necessary, to enhance the overall system or to adopt regulatory changes.

Key activities are monitored for performance and compliance against standards, targets and thresholds. The PV system is subject to Viatris-internal audits, business partner audits and inspections by regulatory authorities from around the world. The company's compliance and deviation monitoring mechanisms are in place for any observations resulting from audits and inspections to ensure they are thoroughly analyzed for root causes and that their impact is addressed.

As appropriate, the required corrective and preventive actions are implemented and their effectiveness is tracked to ensure compliance with worldwide pharmacovigilance regulations. All processes are designed to be compliant with the EU Good Pharmacovigilance Practices (GVP) and General Data Protection Regulation (GDPR) or, if applicable, stricter regulations anywhere in the world.

The internal audit schedule relating to pharmacovigilance activities is based on a robust risk assessment with all PV system processes in scope. The frequency of the audits is normally annually for global processes, every three years maximum for global service providers and approximately once every four years or less for affiliates based on a risk assessment.

Our Product Safety & Risk Management (PSRM) function is a key component of our PV system and participates in all internal and external audits.

In 2022, 10 internal and three external audits were performed by Viatris' Global Operations Auditing function. In addition to this, Viatris PSRM hosted seven external PV audits and 29 audit questionnaires by business partners and five PV inspections by regulatory authorities. No critical findings were identified in these audits and inspections in 2022.

We conduct training that complies with the company's policy on PV Training Standards, which defines training curriculum, its frequency, effectiveness measurements, documentation and other requirements. Employees who are part of our PV system are assigned professional development training courses based on individual experience. In 2022, more than 44,000 individuals participated in our mandatory annual Basic PV-training, which included Viatris' workforce and staff of applicable service providers.

We have robust processes to ensure that pharmacovigilance obligations are consistently and adequately considered for all new/updated/terminated business relationships with third parties. PSRM liaises with such third party stakeholders to ensure pharmacovigilance requirements are identified and assessed. Following this assessment, a Pharmacovigilance Agreement (PVA), if required, is established and implemented. The company currently manages more than 1,000 active PVAs for various business relationships.

In our ongoing effort to innovate and enhance our system, we continued our work in 2022 to further explore the use of emerging technologies, such as cloud-based solutions, automation, artificial intelligence (AI), data analytics and digital communication interfaces in our areas of safety-case report management, upgrading our global safety database (ARGUS) and safety surveillance to potentially enhance our product safety evaluation, communication and risk mitigation capabilities. The implementation of these solutions was conducted in accordance with all Viatris company security and privacy procedures.

During the COVID-19 pandemic, the PSRM function implemented the Pharmacovigilance Business Continuity Plan, which outlines a comprehensive approach to risk management, staffing and safety systems, among other items, to ensure continued operations during unplanned disruptions. This helped minimize the potential impact to patients and HCPS.

Product Testing

All ingredients used in our products undergo rigorous testing to ensure they meet registered specifications. For all products, as regulated by cGMP, we conduct extensive testing, including raw materials as well as intermediate and finished products. As required by applicable regulations, we also conduct post-distribution stability testing.

Product Recall Management

Effective quality and product safety management systems are designed to detect and manage potential risks. These programs may result in Health Authority Notifications (such as Field Alert Reports) and/or product recalls as part of their design. Health Authority Notifications can be used to quickly identify potential quality defects in distributed drug products that may present possible risk. Recalls are largely initiated by a pharmaceutical company voluntarily as a precautionary measure in cases of possible risk to the quality and safety of the product and/or the patient. However, a recall decision is

not always driven by quality concerns in the medicine itself and may be conducted for other reasons such as changes to artwork, labeling or product shelf life.

There is currently no globally harmonized international standard on what constitutes a recall. Viatris has established standard best practices through the implementation of a global standard operating procedure detailing the notification and assessment of critical quality events to determine whether notification to the national health authorities, and/or a recall will be conducted. Such decisions are made in alignment across Quality, Legal Regulatory, and Communication teams including the oversight of the Global Head of Quality. Each site must develop and maintain a written procedure to govern the recall of products based upon local health authority regulatory requirements in the territories in which their respective products are provided. A product recall serves to safeguard the health of patients — demonstrating our responsibility and the efficacy of the Quality Management System (QMS).

It is relevant to point out that as the vast majority of recalls are voluntary and not mandated by health authorities, the level of conservatism demonstrated by a company can influence its total number of recalls. This number is also heavily impacted by the type and number of products within a company's portfolio, along with other factors.

Conducting Responsible Clinical Development

Clinical operations, including clinical trials, are key to advancing access to medicine for patients across the world. We are committed to conducting clinical trials in an ethical way and to promoting patient safety and the protection of patient rights throughout the study's lifecycle. Our global program for clinical research and applicable standard operating procedures are designed to adhere to international best practice and good clinical practice (GCP) as defined in the Declaration of Helsinki and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) framework.

In 2022, we continued research activities across diverse regions in which patients may experience various health care and/or economic challenges. Our research encompassed varied therapeutic areas, including mental health disorders, dermatologic conditions, ocular maladies and reproductive health, among others. Viatris has increased its focus on ophthalmology therapies, and several associated studies are planned for 2023 as this therapeutic area expands at Viatris.

We conduct clinical trials in many regions of the world as part of the process to eventually make treatments available to patients. To support the geographic expansion of products and bring more products to more patients with diverse needs, the number of trials in new settings has increased. Moving forward, Viatris will continue to work to include patient representatives of the regions where approval is sought, focusing on improving patient access to needed therapies globally.

Diversity in Clinical Trials

Viatris supports efforts focused on diversity in clinical trials and works to include diverse patient populations for global studies that will be submitted for approval to health authorities around the world. Considerations for diversity include both demographic criteria (e.g., gender, race and ethnicity) as well as non-demographic criteria (e.g., co-morbidities, organ dysfunction, the extremes of weight ranges). Viatris is committed to working with health authorities to enhance safety, scientific rigor and diversity in our clinical trials.

Health authorities across the globe have called for increased pediatric research to support accurate labelling for pediatric populations. Viatris committed to comply with with applicable GCP requirements to ensure that pediatric clinical trial requirements are implemented with a focus on patient safety and integrity.

Management and Oversight

The Head of Global Clinical Operations reports to the Chief Medical Officer, who reports to the company's President. Our Global Quality Management System (QMS) is at the core of our clinical investigations. It includes procedures on internal processes associated with drug development as well as processes for overseeing and auditing outsourced activities completed by our vendor partners. Dedicated independent members of our Quality team conduct periodic assessments and audits across our operations and at our vendors. Any potential or actual incidents are managed through clear processes and escalated to senior management as appropriate. Our QMS requires the ongoing review of procedures to ensure continued alignment with GCP regulations and guidance documents.

Our range of clinical experience and scale includes:

- 27,000 study participants across nine therapeutic areas;
- 800 pharmacokinetic/pharmacodynamic modeling/adhesion and human factor studies with over 30,000 healthy volunteers; and
- more than 80 clinical development and post marketing programs inclusive of Phase I, Phase II/III and Phase IV.

Global Standards

Regardless of where the trials are conducted and whether they are performed in-house or by a qualified third party, adherence to Good Clinical Practice (GCP) applies, promoting adherence to applicable policies, procedures and regulatory requirements. We develop clinical study protocols for every clinical trial that contains criteria and procedures for the conduct of each trial. The procedures for clinical site assessment are developed prior to the selection of investigators. The company maintains procedures that require ongoing evaluation of a clinical site's conduct of clinical studies from study initiation through the study's completion. We work with our partners to ensure that clinical investigators are carefully screened prior to being selected to participate in a clinical study and require that clinical investigators conduct careful screening and selection of patients consistent with written study protocols.

We also require that all clinical studies receive review and approval from institutional review boards/independent ethics committees (IRB/EC). These committees evaluate and provide approval and ongoing review of clinical trials with a primary goal of ensuring patient rights and safety. The review of each clinical study must be properly documented for every clinical site participating in a clinical study for the company. IIRB/EC documentation of review/approval must be available for all clinical sites that participate in a clinical study. Additionally, health authorities may place clinical study activities on hold should there be concerns that arise that warrant such action.

The company's governance councils, quality committees and clinical development teams oversee the conduct of clinical trials, including regular monitoring of ongoing trials, and partner with internal and external experts and investigational sites to promote patient safety and data integrity across our clinical development programs. In addition, we use quality councils, governance boards and independent data monitoring committees when appropriate to support quality, safety, and protection of participants in our clinical development programs.

Our standard operating procedures specifically address the requirements associated with the development of Investigator Brochures, Clinical Protocols and Informed Consent Forms to adhere to applicable regulations. A cross-functional development and review process is incorporated into the procedures to ensure that experts in various functions have input into the design and approval of these documents. These documents provide clinical investigators with sufficient background on the investigational product to protect the safety of research participants, that the clinical study is scientifically rigorous and that participants are well informed of the potential risks and benefits, study goals, procedures, and their critical role in clinical research. All employees involved in this aspect of a clinical trial are subject to training for this purpose.

Informed Consent

The company's standard operating procedure governing the informed consent process is part of the QMS. It includes detailed procedures regarding the development, review, approval, implementation and confirmation of the informed consent process for adult and pediatric trials.

- Informed consent documents are written in a manner that allows potential trial participants, regardless of reading skills and local language, the ability to make an informed decision that considers the potential risks and benefits of trial participation.
- Local independent ethics committees review and approve informed consent forms prior to patient participation in a clinical study.
- The clinical investigator ensures that patients understand the informed consent document prior to participation in the clinical study.
- As part of adhering to GCP, trial participants are provided instructions for contacting clinical site staff to address questions and concerns during the course of the clinical trial.

Site staff are likewise provided company clinical development team contacts who are available to provide support as needed.

Risk Management in Clinical Development

The QMS provides procedures on assessing potential risks associated with the various aspects of clinical development, such as study design, vendor selection, site selection and patient populations. The application of data analytics supports efficient trial management and oversight.

Trial Data Transparency

The company's QMS addresses the publication of clinical trial data in publicly accessible registries, as required by global regulations to promote transparency. We publish results of applicable clinical trials in publicly accessible registries including www.clinicaltrials.gov and others. As part of complying with the GCP, we follow the Food and Drug Administration Amendments Act (FDAA) 801 and the Final Rule requirements for disclosure and results posting in the U.S. and adhere to EU and other regional requirements for clinical trial transparency.

The company also maintains procedures that describe a scientifically rigorous process for the preparation and dissemination of scientific articles addressing the results of clinical trials to ensure that HCPs and patients have access to information on the results of clinical trials.

Moving forward, Viatris' Global Clinical Operations will continue to work to transform the clinical trials process through new ways of working and process optimization with the implementation of innovative clinical trial solutions from end to end, as well as globally aligned systems and processes. Our priorities will always be patient safety, regulatory and protocol compliance and data integrity.

Animal Studies

We do not conduct animal testing unless it is required by national regulations. We are committed to the "3R" approach (Replacement, Reduction and Refinement) with respect to ethical animal testing. Facilities performing animal testing on our behalf are required to comply with regional scientific procedures for laboratory animal science. These facilities use and/or are approved by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). Our Global Operations Audit (GOA) team performs regular audits on entities and facilities involved in animal testing to ensure compliance. In 2022, GOA audited 12 AAALAC-certified facilities.

Promoting Product Security and Fighting Falsified Medicines

To mitigate the risks from counterfeit products and protect the security of products and safety of patients, we have a formal infrastructure to support oversight of product security and guide the applicable efforts. Our Product Integrity Coordination Committee consists of leaders from Compliance, Quality, Regulatory, Medical Affairs and Security.

The company's Product Security team conducts an annual risk assessment of the portfolio to determine those products that may be at a higher risk for counterfeiting or diversion activity. This assessment takes into consideration several aspects including therapeutic category, dosage type, regulatory concerns medical affairs concerns, and previous incident history. Products with higher levels of risk are given priority attention when it comes to analysis and market monitoring. We also use intelligence gathered from open market analysis to prioritize risk.

We conduct investigations when there is suspicion of counterfeit or at-risk products and to support health authorities and law enforcement investigations. In addition to internal resources, we collaborate with external stakeholders such as online sales platforms and others as needed to further identify and prevent the distribution of counterfeit products.

We have controls to guard against theft and diversion of controlled substances and operate a system to identify suspicious orders of controlled substances.

We have a cross-functional team including members from Compliance, Customer Relations, Controlled Substance Monitoring, Global Security, Distribution Center, Regulatory Legal and Regulatory Affairs that works to operate our strong programs designed to detect and prevent diversion within the supply chain. This cross-functional team has established strong partnerships with custom agents, local and federal law enforcement, and state and local licensing. At the same time, we take steps to assure that patient care is not interrupted by disruptions in the flow of medication to our customers and patients across the globe.

Our suspicious order monitoring program includes, for example:

- An experienced compliance team
- A dedicated suspicious order monitoring team
- Data and analytical programs
- Customer due diligence
- Education and training
- Ongoing engagement with state and federal regulators

In addition, we have a dedicated product diversion program that encompasses anonymous reporting mechanisms, which together with our suspicious order monitoring systems supports risk mitigation. Falsified medicine – medicine that is sold as authorized, authentic medicine but in fact contains ingredients of poor or toxic quality or dosage – continues to be an issue for the pharmaceutical industry. We have made significant investments in packaging and information technology to further enhance our ability to detect and prevent the distribution of counterfeit products.

By lowering the likelihood that falsified products will enter the supply chain, we are helping to ensure the integrity of distributed products and continued access to high-quality medicine. The company has global policies to govern validation, operations, serialization and product security. All manufacturing sites have procedures to drive consistency in packaging, management, master data and distribution of serialized product. Among these are processes to track and trace serialized products. An internal product safety group assists in monitoring the supply chain to help ensure it is not breached.

Serialization

Serialization is a process that helps companies obtain valuable information about the products they sell and where they are made and shipped. It is required by a myriad of government regulations that require pharmaceutical companies to track their products along the supply chain and verify their authenticity. The goal of serialization is to ensure that medicines reaching consumers are not counterfeit, stolen or contaminated. Our quality, regulatory and serialization teams work to ensure that serialization requirements for all countries are met. In doing so, the company works closely with industry groups such as the RxGPS Alliance, a group of multinational pharmaceutical supply chain stakeholders who have a common interest in advancing global alignment of drug serialization and tracing requirements to harmonize various standards among countries.

Serialization efforts include technology that uniquely numbers each pack and places a serialization mark, known as a 2D data matrix, on products. We work internally and externally (with contract manufacturers) to ensure that products made for patients include these identifying marks. Depending on the region, the serialization process will leverage aggregation, which places a unique code on shipping packages of our products. This code will associate the data of each packaged product.

Once products are serialized, our work continues. Large amounts of data created by serialization must be managed, maintained and reported to authorities or trading partners. Shipments to customers will also include serialization data. This new way of conducting business is driving the digital supply chain with an emphasis on data and product integrity.

For global manufacturers, the challenges with serialization are requirements that vary by market. Various versions of track and trace and endpoint authentication have emerged around the world, and we are working hard to meet these requirements to ensure access to high-quality, affordable, and authentic medications to ensure patient safety and compliance with global serialization regulations.

In 2022, Viatris implemented a Center of Excellence for Global Serialization. We improved the quality of serialization services and processes and widened the reach of capabilities as we follow the trend of an increased number of countries implementing serialization. We also integrated legacy Upjohn products into Viatris' serialization architecture.

To prepare for the U.S. FDA's Drug Quality and Security Act requirement for aggregation that will take effect in November 2023, our teams are creating solutions, systems and processes at our packaging sites and distribution center to ensure compliance.

In addition, a new Rest of World Verification and Traceability Initiative (VTI), which is a multi-stakeholder partnership, has been created. The goal of this collaboration is to support countries to reduce the urgent risk of falsified medicines in national supply chains. While we are beginning to see many new countries deploy serialization in the upcoming year, the first two markets under the VTI program will be Malawi and Nepal.