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 product development to sourcing of raw materials to producing and distributing finished dosage forms - is grounded in this commitment. At Viatris, we take pride in doing what is right, not what's easy, every time.

Quality Management

We maintain a quality infrastructure at the global level that includes extensive experience and expertise, robust and comprehensive Global Quality Policies that establish uniform requirements for fundamental processes and controls within the Quality Management System (QMS), as well as Global Quality IT systems, which are implemented and designed to establish industry best practices and consistency throughout our global network.

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 also designed to ensure that our operations continue to remain in a state of sustained compliance with statutory and regulatory requirements, such as current Good Manufacturing Practices (cGMP), Good Pharmacovigilance Practices (GPvP) and Good Clinical Practices (GCP) for all markets that they serve.

We apply relevant quality guidelines to 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 GMP for excipients of medicinal products for human use. We use a Regulatory Intelligence and Knowledge Management Dissemination Program to better 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 but not limited to:

- Managerial oversight and responsibility
- Ongoing and continuous training
- Frequent internal/external audits
- Testing practice and compendial compliance
- Products risk assessment
- Regular compliance monitoring and communication
- Incident investigation, corrective and preventive action
- Standardized document control and change management
- Compilation, trending and review of key quality metrics

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 and Regulatory Quality
- Global Third Party/Affiliate Quality
- Global Quality Integration/ Surveillance

We continuously evolve our quality organization to ensure alignment with the business operations and to enhance compliance with applicable standards. Quality leadership was restructured to facilitate broader surveillance functions and to continue to strengthen compliance. Existing global quality resources are embedded within the operational verticals to align closely with the business units and drive consistency across the sites. These enhancements promote closer connectivity among operational leaders and lead to improved product quality, supply continuity and patient access.

As part of our integration of the two legacy companies, we also have further enhanced the Global Quality Manual, taking best practices from each legacy company. We also enhanced consistency across more than 20 global policies and procedures, including, but not limited to, the policies governing investigations, self-inspections, APR process, data integrity, Field Alert Reporting and Risk Management.

Training for Continuous Improvement

Our Global Learning and Development program provides comprehensive and effective training to assure 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 as part of Global Training policy requirement. We also provide 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. cGMP training is conducted on an annual basis and, as needed, more frequently in accordance with regulatory requirements at the site and/or global level.

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 specifically designed for each job description.

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 assure that employees remain familiar with the specific cGMP requirements applicable to them.

Quality Monitoring 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 internal audit program is a key component of our oversight and monitoring of the quality performance across our network. The internal audits are designed to proactively evaluate compliance against the GQM/ GQP and global cGMP regulations.

- 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 regular basis for each production/API site as well as our distribution, packaging and laboratory sites.
- Internal sites are required to 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.

In recent years we streamlined the global internal audit program to include expedited timelines for issuance of observations and increased site leadership engagement to ensure immediate remediation of identified observations. We further increased focus on global investigations oversight, third-party management, and surveillance across our sites.

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 CAPA from critical and/ or major observations are reviewed and verified for completion by the Global Operations Audit Team.

Quality Risk Assessment

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

Quality Culture

Employees are provided training on quality culture to ensure personnel have a clear understanding of our commitment to quality. In 2021 we kicked off a Quality Campaign with the following focus:

- **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 to operate 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:** 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 committee 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 right to conduct regular on-site audits to ensure compliance regulations, applicable regulatory reporting requirements, and allow access to all records related to the supplied products, among other requirements.

- 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.
- We conduct routine audits to assess the strength and performance of the QMS. Frequency is based upon cyclical audit requirements by facility type, historical regulatory inspection performance, and key product launches.
- In 2021, in response to the pandemic, we instituted a virtual audit program that enabled us to effectively conduct audits and remain in compliance with regulatory auditing requirements. In total, 612 GMP, 69 GCP and 23 pharmacovigilance (PV) audits were conducted by the company's global Operations Audit team at our facilities and suppliers.

External contractors and suppliers approved for business with us are recorded in an internal global database which 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, adverse-event reporting of other manufacturers' products, development of new scientific and testing criteria and evolving regulatory and manufacturing expectations everywhere we operate. We continuously learn from these interactions as scientific, technology and regulatory expectations continue to evolve.

- The health authority inspections provide extensive external certification of the company sites and our suppliers and provide authorization for further production and marketing.
- We are making progress to resolve the identified observations regarding Viatris' active FDA Warning Letters.
- In 2021, more than 90 health authority inspections were conducted across our facilities. The COVID pandemic has had an impact on this number compared to previous years.

Notable International Health Authority Inspections in 2021 include: FDA (USA), EMA, HPRA (Ireland), MHRA (United Kingdom), TGA (Australia) and WHO.

Patient and Product Safety

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 once placed on the market.

We are in the final stages of completing the integration of legacy Mylan and legacy Upjohn PV systems into one Viatris global pharmacovigilance system by ensuring appropriate policies, procedures, resources, IT infrastructure and agreements are in place to meet global pharmacovigilance requirements.

Global PV governance committees, such as the Corporate Product Safety Committee and the Pharmacovigilance System Oversight Committee, are responsible for periodic and ad-hoc evaluation of new safety-relevant information and facilitates full oversight of compliance and the performance of the Viatris PV system.

Potential new safety-relevant information is assessed and evaluated through our corporate safety governance structure and important new information is communicated in a timely manner to regulatory authorities, healthcare professionals and patients.

To manage safety of a diversified and complex product portfolio — made up of prescription medicines, over-the-counter medicines, combination products, medical devices, food supplements, cosmetics - we have highly skilled and trained cross functional teams of medical and scientific professionals who review and report our risk and benefit assessments to regulatory authorities worldwide.

- In 2021, the company submitted more than 350,000 individual safety reports and more than 1,500 aggregate reports to health authorities and business partners with a compliance rate of over 99%.
- The company currently has more than 310 risk management plans and associated interventional measures designed, where required, to help ensure our products are used safely and effectively.

Mechanisms like periodic meetings of the Joint Pharmacovigilance Governance Committee for oversight of new safety and compliance matters and service delivery teams for the operational matters have played a vital role for the Viatris Product Safety & Risk Management department to maintain oversight of the safety profile and regulatory compliance for legacy Upjohn products, managed in Pfizer's system, during the transition period.

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 to allow oversight and PV governance. In late 2021, relevant procedural documents have been updated to meet the requirement of new EU Clinical Trial Regulations implemented in January 2022.

Key activities are monitored for performance and compliance against standards, targets and thresholds. The PV system is subject to both internal and external 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 impact is addressed.

As appropriate, corrective and preventive actions required are tracked until effective implementation of compliance with worldwide pharmacovigilance regulations. All processes are designed to be compliant with the EU Good Pharmacovigilance Practices (GVP) 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 and global service providers and approximately once every three years or less for affiliates based on risk assessment.

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

In 2021, in addition to the 23 internal PV audits commissioned by our Global Operations Auditing team, there were eight external PV audits by business partners and six PV inspections by national health authorities. No critical findings were identified in these audits or inspections in 2021.

We conduct training that complies with the company's policy on PV Training Standards, which defines training curriculum, 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 2021, we conducted the mandatory annual Basic PV-training for our approximately 37,000 colleagues.

In our continuous effort to innovate and enhance our system, we continued our efforts in 2020 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 of our global safety database (ARGUS) and safety surveillance with objective to potentially enhance our product safety evaluation, communication and risk mitigation capabilities.

During the COVID-19 pandemic, the PSRM function developed and implemented our 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 assure they meet registered specifications. For all products, as regulated by cGMP, we conduct extensive testing, including raw material, intermediate and finished product. 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 product recalls as part of their design. Recalls are largely initiated by a pharmaceutical company as a precautionary measure in cases of possible or actual risk to the quality and safety of the product, and/or risk to the patient. Although there is no harmonized international standard between countries on what constitutes a recall, Viatris has internal global requirements that each company site must maintain a written procedure to govern the recall of products based upon health authority regulatory requirements in the territories in which our 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 the type and size of a product portfolio, along with other factors, may impact the number of recalls across companies.

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 protection of patient rights throughout the study 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 2021, 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, allergies, and pulmonary diseases, among others.

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 FDA's guidance on Diversity in Clinical Trials and works to include diverse patient populations for global studies that will be submitted for approval to FDA and other health authorities. Considerations for diversity include both demographic criteria (e.g., gender, race, ethnicity) as well as non-demographic criteria (e.g. co-morbidities, organ dysfunction, the extremes of weight range). 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 complies with applicable GCP requirements to ensure that pediatric clinical trial requirements are completed with a focus on patient safety and integrity of clinical trials data.

Our range of clinical experience and scale includes: 27,000 study participants across 9 therapeutic areas; 800 PKPD / adhesion & 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.

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 ongoing review of procedures to ensure continued alignment with GCP regulations and guidance documents.

Global Standards

Regardless of where the trials are conducted and whether they are performed in-house or by a qualified third party, the company's global standard operating procedures apply with the aim to ensure the robust adherence to applicable policies, procedures and regulatory requirements. We develop clinical study protocols for every clinical trial, which contain 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 study closeout. 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 the 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 in order 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 undergo 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 such as www.clinicaltrials.gov, https://eudract.ema.europa.eu, 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 are following the EU Clinical Trial Directive (EC) No. 001/20/EC in the EU. When the Clinical Trial Regulation EU No. 536/2014 goes into effect, we will comply with that regulation.

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 through 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 regulation. We are committed to the "3 R" 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 team performs regular audits on entities and facilities involved in animal testing to ensure compliance.

Promoting Product Security and Fighting Falsified Medicine

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 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 which 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, platforms 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:

- Experienced compliance team
- Dedicated suspicious order monitoring team
- Data and analytical programs
- Customer due diligence
- Education and training
- On-going engagement with state and federal regulators

In addition, we also have a dedicated product diversion program, which 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. New and updated procedures have also been implemented across all manufacturing sites 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. Eventually, the serialization process will leverage aggregation, which places a unique code on shipping packages of our products. This code will associate data for 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 emphasis on data and product integrity.

For global manufacturers the challenges with serialization are requirements that vary by markets. 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.

Integration of legacy Upjohn products into Viatris' serialization architecture progressed in 2021 and will continue in 2022.