Using GS1 Standards to combat counterfeiting and improve patient safety

ABSTRACT

AstraZeneca enhances patient safety, combats counterfeiting and meets global regulatory requirements by advocating GS1 Standards and working together with industry and GS1 to drive the development of harmonised standards and solutions globally.

By **Christoph Krähenbühl,** and **Ian Haynes,**
AstraZeneca   AstraZeneca

Background

Our global product security strategy focuses on safeguarding patients and protecting brand integrity by combating the counterfeiting and illegal trade of AstraZeneca products. The strategy focuses on these key areas: enforcement, product security systems and technical solutions, securing the supply chain, and collaboration with stakeholders. We work towards full GS1 compliance and are regularly involved in industry workgroups that promote the use of consistent and harmonised standards. We are also members of the global user group – GS1 Healthcare.

The company currently codes an increasing number of its packs using GS1 GTINs (Global Trade Item Numbers) and employs Axway Track & Trace, a GS1 EPCIS certified track and trace solution developed by Axway as a central component in its systems and technology approach.

About AstraZeneca

AstraZeneca is one of the world's leading pharmaceutical companies, with a major presence in the UK. We are focused on providing innovative, effective medicines that make a real difference in important areas of Healthcare. As a leader in gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease medicines, AstraZeneca generated global revenues of US$32.8 billion in 2009.

Complex global market requirements

The global growth of counterfeit medicines entering the legal supply chain and of reimbursement fraud has resulted in patient safety risks that both governments and pharmaceutical manufacturers are keen to address.

With the adoption of the EU Falsified Medicines Directive by the European Parliament on 16th February, which includes the requirements for safety features, tamper-evidence and coding to be applied to individual packs, industry is at a critical point in the development of coding and serialisation systems in Europe. Markets such as Turkey and France have already begun to impose regulations requiring pharmaceutical manufacturers to include GS1 2D DataMatrix codes, based on GS1 Standards identifiers such as GTINs, on all packs, for identification and traceability purposes. The US Food and Drug Administration (FDA) is also currently working on regulations to improve the identification and authentication of medicines in the supply chain, driven by the pending ePedigree solution in the State of California. Regulators, legislators and customers in other markets around the world, amongst them Brazil, China, and India, have mandated or are actively discussing coding requirements with similar declared aims.

The increasing number and rate of change, some not based on global standards, present a significant challenge for globally sourced pharmaceutical manufacturers. Keeping track of and understanding these requirements and implementing solutions to comply with them involves many people in different parts of our global organisation. Once implemented, manufacturing systems are required to switch between coding requirements on an order-by-order basis; this approach is costly, complex and can present a risk to supply.

Moving ahead of regulations and implementing GS1 Standards

In 2006, AstraZeneca decided to implement a product security solution to achieve our global product security strategy and ultimately improve patient safety. We chose Axway, a global Business Interaction Networks company, and Systech Tips, provider of at-line serialisation equipment, as the lead system providers; and as global GS1 Standards evolved, we also engaged with GS1 UK Solution Partner to develop the current solution.

AstraZeneca chose to pursue its product security item-level serialisation and verification project as an internal initiative at a time when there were no market requirements to do so. This forward-thinking strategy has put us in a position to respond quickly to emerging market requirements thanks to the choice of a flexible, scalable and GS1-compatible solution. The benefits of starting ahead of the curve meant that many of the technical challenges could be addressed early on, thus mitigating against the time pressure of complying with diverse requirements as they emerge.

Each product that AstraZeneca serialises at the production line has a unique EPC (Electronic Product Code) assigned to it, which includes a GS1 GTIN (Global Trade Item Number) and a serial number. The company's PSDM solution includes a repository of AstraZeneca's unique product identifiers (EPCs), which is compliant with the GS1 EPCIS (Electronic Product Code Information Services) standard.

AstraZeneca's Product Security Data Management (PSDM) system allows authorised staff to verify suspect packs by tracking any interactions that have been made with the EPC in the EPCIS repository, although until our internal system is linked to wider Product Verification infrastructures, such interactions are limited. At present, staff can check whether the product has been previously blocked, whether the EPC identifies the right product, batch and market variant ,and can trace all events that have been associated with a particular EPC. Packs can also be quickly and efficiently identified and tracked in the event of a product recall.

Where we stand today, AstraZeneca's track and trace solution is flexible and robust enough to meet the current and emerging legal requirements of the markets in which we do business. We also have the capability to create and share lists of GS1 GTINs (product codes) and serial number from our EPCIS track and trace repository; and an increasing number of our packing lines have the capability of coding packs in-line with GS1 DataMatrix 2D bar codes that contain batch variable and even serial numbers in addition to the GTIN.

Currently, AstraZeneca has 10 manufacturing sites and 30 product lines connected to our PSDM system. Axway Track & Trace – the GS1 certified EPCIS repository provided by Axway – holds over 100 million serialised packs and we are currently planning to roll this out further with more sites and brands. Capability extension projects include the exploration of multilevel aggregation and linking third-party Contract Packers to the AZ repository.

Ensuring a global and interoperable solution with GS1 Standards

Many manufacturers and suppliers such as AstraZeneca are already incorporating GS1 Standards into their products and processes due to the global reach of the standard. The European Federation of Pharmaceutical Industries and Associations (EFPIA) supports the approach of applying a combination of tamper-evident packaging and a unique code for each medicine pack, based on one harmonised coding solution across Europe, and recommends the use of GS1 Standards.

In the UK, the pharmaceutical industry has set up a GS1 2D bar code pharma working group facilitated by GS1 UK and driven by the Department of Health to ensure a consistent approach is adopted by the industry including the NHS.

As part of our commitment to the global adoption of GS1 Standards, we continue to work closely with GS1 and have benefited from the support of GS1 UK on a number of projects, such as the move to standardised coding of cases/shippers as part of a larger European ERP consolidation project, and the global process for assigning GTINs throughout the company to ensure full compliance. A cross-functional team is currently working globally to close the gaps in existing processes, better understand these numbers, their use and function, and to assign new GTINs and streamline fragmented legacy ways of working.

AstraZeneca believes that the adoption of global and interoperable GS1 Standards is vital to enable the pharmaceutical sector to cope with new legislation and customer demands.

Conclusion

AstraZeneca has built a strong foundation to combat counterfeiting, respond to different market requirements and improve the visibility of its supply chain. We are currently rolling out the serialisation of our packs at key manufacturing sites around the world. The next phase will be to securely link up our EPCIS repository to external systems as they are established, to allow point-of-dispensing verification and enable our staff to have much greater visibility of our products, thus ensuring greater patient safety and product security.

The adaptability and scalability of our GS1 compliant track and trace solution is vital to AstraZeneca, and will continue to be essential as we ramp up operations moving forward. We will continue to work with GS1 and the industry to ensure that a consistent approach is taken to improve patient safety and combat counterfeiting.

ABOUT THE AUTHORS

Christoph Krähenbühl, Technology Lead, Pack Coding and Product Security at AstraZeneca.

Christoph is one of the experts in AstraZeneca's Pack Coding and Security Features Programme and has been project manager of the Product Security Data Management serialisation system project since 2006. He is currently also involved in improving the global process of handling GTINs in AstraZeneca. Previous roles included leading the work on a global master data management system after the merger between Astra and Zeneca and managing the cross-functional Enterprise Performance Visibility data warehouse. Christoph is a member of the EFPIA Coding and Identification Project team and represents AstraZeneca in GS1 Healthcare. Prior to his move to AstraZeneca in 1998, Christoph worked for Ciba Specialty Chemicals and Ciba-Geigy in Basel, Switzerland in supply chain management and ERP systems projects.

Ian Haynes, Associate Engineering Director, AstraZeneca.

Ian works in the AstraZeneca Global Engineering Technology Group and has a particular interest in packaging and logistics. Ian works closely with the marketing, packaging, purchasing and supply chain functions anticipating and collaborating in the development of AstraZeneca's future requirements for packaging and manufacturing systems. Ian has played a key role in product security being closely involved in the development of the companies approach and technical solutions. Ian joined ICI Pharmaceuticals Division after graduating in 1980 with a first class honours degree in mechanical engineering from Liverpool University. Following a period as design development manager in Zeneca Engineering, he joined the Technology and Development Group of Zeneca Pharmaceuticals which later became AstraZeneca Global Engineering Technology.