



United Kingdom

Complying with New Legislation at Mölnlycke Health Care



by **Jenny Gough**

ABSTRACT

Mölnlycke, one of the world's leading providers of wound care and single-used surgical products and services to the healthcare sector, has gone through several mergers and acquisitions over the years, adding to its business various companies with different processes and product ranges. Standardising internal processes was essential, and urged in 2009 when the Andalusian Health Service in Spain mandated GS1 Standards for the coding and symbol requirements for products they were manufacturing and purchasing.



Introduction

Mölnlycke was founded in 1849 as a textile company, going through several mergers and acquisitions over the years. During the last decade in particular various companies with different processes and differing product ranges have been incorporated by Mölnlycke.

Today, its products are manufactured in nine countries covering three continents, with marketing and sales offices in thirty countries.

In 2009, whilst trying to standardise internal processes, Mölnlycke was impacted by the Andalusian Health Service in Spain mandating GS1 Standards for the coding and symbol requirements for products they were purchasing.

This demand aimed to maximise the reliability of the identification of a product and its characteristics, and to promote the effective use of automatic product identification systems within the supply chain.

Initial assessment

The company met the tight deadlines set by the Andalusian Health Service in late 2009 by incorporating the relevant bar



codes into the product labelling for this region.

In 2010 the company decided to complete a full assessment of its products against the specifications set by GS1. This research was initially conducted on products distributed within Europe but was then expanded to look at products worldwide.

The results of the assessment showed that, while the products within Mölnlycke were labelled with GS1 bar codes, there were a number of cases where the bar codes did not meet the detailed specifications set out by GS1. This was explained by acquisitions that had not yet been fully integrated, different processes being used within the manufacturing sites and the varying product ranges.

Mölnlycke has about 7,000 employees and manufacturing plants in Belgium, Czech Republic, Finland, France, Malaysia, Thailand, Poland, UK and US.

Applying GS1 Standards

Initially it was thought that to solve the problem the company could use a single label design and update the packaging artworks where required.

After looking into the results in more detail, it was apparent that a single label was not a viable solution due to the different product information required on the labellings (e.g. CE marking, sterilisation methods). Therefore, Mölnlycke decided to design a range of product labels that would satisfy the requirements both internally and externally.

Case Study: Mölnlycke Health Care

Mölnlycke worked closely with GS1 UK on a joint project to ensure that they were working towards a solution that was both compliant with the GS1 Standards and the up-and-coming new regulations covering Unique Device Identification (UDI).

The data within the GS1 bar codes now enables automatic identification of the products at any point in the supply chain. There was also investment in new verification equipment to ensure that all bar codes met not only the GS1 standards but also the print quality standards set out in ISO 15416 for the printing of bar codes.

The labels also needed to be adaptable so that they could be changed to fit local requirements where possible. This meant that new acquisitions could be easily merged into the company in the future.

The benefits of using the GS1 system in the healthcare sector

The benefits of using a single, globally accepted system for positive identification of medical devices included:

- Increased patient safety through identification and traceability
- Continued marketing of products in different countries. In the UK in particular it has helped to meet the new NHS regulations for universal codes on medical products
- Long-term financial benefits through increased efficiency and meeting of requirements
- Much easier product recalls



Figure 1: Product package with GS1 bar code label

Conclusion

Since the initial analysis of the product range in 2010, a significant amount of time and effort has been spent to ensure full compliance with GS1 Standards. Mölnlycke is now in the final stages of completing this initiative.

The global nature of GS1 Standards makes it easier to market the products throughout the world and expand into new markets. As technology is always evolving, it ensured that new developments are addressed by a dedicated specialist resource, and that the GS1 Standards are being met for any new acquisitions, in order to safeguard patient safety through the identification and tracking of products.

About the Author

Jenny Gough has been working with GS1 Standards since 1996. This was mainly in the retail sector working for FMCG

companies but for the last 7 years she has been working in the Healthcare sector for Mölnlycke Health Care. Jenny is also actively involved with GS1 UK and Irish HUGs and Eucomed UDISC Task Force.

About Mölnlycke

Mölnlycke, founded in 1849, is one of the world's leading providers of wound care and single-use surgical products and services to the health care sector. The company has about 7000 employees and manufacturing plants in Belgium, Czech Republic, Finland, France, Malaysia, Thailand, Poland, the UK and the US.



Figure 2: Labelling specification