Figure 1: Patient safety is the motive behind the new guidelines

Images: Intelsius

Temperature Control

What will the European Union's new Good Distribution Practice guidelines mean to your supply chain? *PMPS* asked two experts from Intelsius to share their thoughts: Alex Roskoss, European Head of Technical Services, provides a scientific/technical point of view, while Stephen Healy, Global Director of Sales, looks at the business development side. Here they introduce this topic and debate a number of crucial questions

Let's face it: the new European Union (EU) guidelines for Good Distribution Practices (GDP) do not appear to be a very interesting subject on the surface. However, if you look a little deeper, it is a subject which affects all of us. Does someone in your home take over-the-counter or prescription drugs? Who doesn't? This is why the new rules are so very important to everyone.

Patient safety – that is the real motive behind the guidelines. Yet it is crucial to consider not only how the new guidelines put patient safety first, but also how they will affect drug manufacturers and wholesale distributors through their facilities, transportation, pharmacies and clinics.

The guidelines on GDP – first published in 1994 – are being amended, expanded and becoming more uniformly regulated in September 2013. Pharmaceuticals making it to their destinations undamaged and unadulterated is key in the sweeping changes to the new guidelines. Temperature-related damage to drugs is not readily visible and can occur at any point in the supply chain.

Pharmaceutical wholesale distributors will become responsible for the integrity of products when the new guidelines are implemented. From the manufacturer's gates to contract drivers delivering pharmaceuticals to medical offices, hospitals and pharmacies, the responsibility for product integrity is now clearly defined.

The European Commission intends to standardise the code relating to medicinal products for human use, in order to reduce the number of adulterated pharmaceuticals introduced

into the legal supply chain. While most pharmaceutical manufacturers have utilised GDP guidelines, many wholesale distributors and couriers are now scrambling to adhere to the GDP documentation requirements and training elements that all personnel involved in the pharmaceutical supply chain must receive.

While some areas being refined contain as few as four separate guidelines, chapters on operations and transportation each contain more than 20 separate guidelines. These cover areas as diverse as contracts, labelling and monitoring. The economic impact of implementing the new guidelines will be felt across all parties involved in distribution. The bottom line is that improving standards will bring significant changes to keep pharmaceuticals and other medications safe throughout the supply chain, and will ultimately reduce the risks for the people who use them.

The new guidelines will help every company to recognise and apply standards designed not to frustrate and confuse, but provide comfort, knowing that it has played a part in keeping patients safe by applying quality standards in every aspect of the chain of medicinal products for human use.

Accountability and integrity are the most important parts of the guidelines to drug manufacturers. What difference does a few degrees make to them? The difference between a product not simply making it to the doctor's office or pharmacy, but being maintained at the appropriate temperature throughout its journey to ensure its safety and efficacy when it reaches the patient.

Those in the temperature-controlled regulatory-compliant packaging industry have an expert understanding of thermodynamics, however wholesale distributors in Europe will need an education to understand how important temperature and integrity are to patient safety.

Turning now from an overview to more specific questions posed to us by *PMPS*, we consider the need-to-know aspects of the new guidelines from our different business perspectives.

PMPS: How will the guidelines affect drug manufacturers?

Alex Roskoss: These guidelines will pressure compliant manufacturers to only use GDP-compliant distributors. This could cause disruption with distributors who are currently offering GDP compliancy as a premium service.

What will be the economic impact?

AR: The economic impact will be an increase in monitoring, quality documentation and training, plus potential increases in drugs quarantined or destroyed.

Stephen Healy: The guidelines are going to impact on manufacturers' costs and will raise awareness of the quality standards to which they will now be held. The key to their success is an awareness of the possible consequences of non-compliance: if a company's products need to be destroyed, what will it do to its brand? It will have to be more selective of its suppliers and have tighter quality agreements with them. It will likely increase the distribution costs too.

And the consequences for personnel?

AR: They are going to have a positive impact on personnel – companies will have to have better-trained staff. The guidelines will encourage investment in staff training and will create value in trained staff, increasing specialised skills in GDP-compliant manufacturing and distribution.

SH: I agree: it is going to require more training and better quality standards. However, the costs of training will likely increase product prices.

How will the guidelines impact logistics?

AR: They may initially diminish the available logistics suppliers and drive up distribution costs. However, this would eventually stabilise as GDP offerings become more widespread.

SH: It may well mean that logistics suppliers will need to use different routing, which may add complexity or risk points.

What about the effect on wholesale distributors and their facilities?

AR: The impact on wholesale distributors will be increased quality

> "Many wholesale distributors and couriers are now scrambling to adhere to the GDP documentation requirements and training elements that all personnel involved in the pharmaceutical supply chain must receive"

Figure 2: Guidelines provide protection to patients and the treatments they receive

documentation and investment in quality and compliance. The initial reaction may be to split the market between those who buy into pharma GDP from day one and those who do not.

Investment will also be required in terms of training, procedures, reporting and accountability, and also liability changes. This will place a premium on GDP-compliant services and will have to be charged out accordingly. This will provide larger players with a distinct advantage, as they can absorb the cost of quality more easily, and it will remove low-rent operations from the pharmaceutical market.

Wholesale distributors will initially see increased logistics costs, as only GDP-compliant logistics parties will be available.

SH: The spotlight is now clearly on the wholesale distributors where it wasn't before.

What will this mean for pharmacies/clinics?

AR: Clinics will have to ensure that suppliers are GDP-compliant and must take some responsibility for the monitoring and rejection of suspect shipments. They will be part of the supply chain and subject to GDP regulations for training, as well as monitoring and reporting. Again, staff will receive additional training and increased awareness of GDP, especially in taking positions on rejections or quarantining drugs.

SH: While the patient is of course the final recipient of a product, in a values-based way, pharmacies are the real end of the distribution chain. The guidelines will ensure that they will be receiving products that are correct and of a higher quality.

How will the guidelines affect patients?

AR: With distribution being far more trackable and accountable, the guidelines should increase the quality of drugs received by patients. We may initially see product shortfalls and bottlenecks in supply on implementation as distributors adjust their processes, and patients are likely to experience increased costs associated with distribution.

SH: But hopefully they will go under the radar for the patient. It should not even be a consideration that they might receive anything less than the product they need.

What will be the impact on the transportation of medicinal products for human use?

AR: Both large and small providers will need to approach compliance through procedures, training and documentation. All medicinal products should come under GDP, although these will be addressed on

a risk-based approach with lower risk drugs requiring reduced standards.

SH: The temperature and stability of the product are the most important issues during physical movement, but security is also a factor. Companies have to ensure that the drug makes it from point A to point B without having been tampered with, stolen or altered. It is an opportunity for leaders to differentiate themselves from the competition. It may also work against providers who have previously dominated this space but who now need to follow these guidelines. It may prevent new businesses from starting up in this area because of the many restrictions created.

How will government agencies be affected?

AR: There will certainly be increased audit responsibilities. Agencies will be adding to Good Manufacturing Practice (GMP) audits and investigations with GDP activities above those previously experienced in registering pharma distributors.

SH: Government agencies will drive the standards but they will not want to see an increase in price for having a better service or product. Health systems will need to ensure that products they are bringing into the national health system are compliant. They will be asking, "How can we shorten the supply chain?"

What consequences will the guidelines have for temperature-controlled customers?

AR: There will be limited front end impact, apart from possible supply restrictions. In the long term I think this will increase the cost of drugs as more attention has to be paid to the process and less uncontrolled or poorly controlled activities will take place.

SH: Customers moving samples or pharmaceuticals will be required to consider their distribution earlier and view it as a critical component. They will have to form more strategic relationships with their suppliers.

What impact will the guidelines have on packaging and the global supply chain?

AR: EU GDP and US Food and Drug Administration codes will mean that all supply into the EU will have to be compliant, so expect quality agreements, monitoring and reporting requirements to become more global as suppliers and distributors outside the current scope of regulation will work to comply in order to keep more markets open to them.

SH: Temperature control and tamper-proofing are becoming more intertwined. We have to keep asking: "How do we make this tamper-proof or more secure?" The current supply system is very poorly designed. In the short term it should provide an opportunity, but the long-term question remains: will companies move their manufacturing to other parts of the world or employ a turnkey manufacturer to distribute regionally?

What questions still remain to be asked?

AR: Will the guidelines push people to active solutions? Will packaging system failures lead to significant disruption of supply and headlines? Will there be widespread compliance from day one or only as inspection regimes are established?

What will non-compliant distributors, wholesalers, third party and pharmacies/clinics do? Will they reduce their offerings, step back from sensitive products in the market-place, or invest in the people and processes necessary to comply?

Implementing these guidelines will increase the quality of the product at the patient end. This is the part of the chain that matters most. As we have seen with GMP and good clinical practice, improving standards brings more effective treatments to more patients. Too many drugs are damaged, doctored or tampered with, and GDP will tighten the controls and enhance the chances that a patient, a relative, or a friend, receives a treatment that works as expected.

About the authors

Alex Roskoss worked as an instrument developer with a large defence contractor before moving into product development and, ultimately, joining Intelsius as European Head of Technical Services. In addition to overseeing new product development, Alex assesses new marketplace technologies, assists with technical sales inquiries, and manages the ISTA-certified testing laboratory. He holds a doctorate degree in Experimental Physics. Alex has helped patent a number of new technologies at Intelsius and has authored numerous articles and papers. **Email: publicrelations@intelsius.com**

Stephen Healy joined Intelsius as Global Director of Sales in February 2013. He is focused on sales-related activities to drive the company's efforts to grow within the pharmaceutical clinical trials and drug distribution arenas. Prior to joining Intelsius, Stephen held high-level sales and marketing management positions at another company in the temperature-controlled packaging industry. He has represented the industry at dozens of trade shows and has given presentations at conferences around the world.
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