White Paper

New Guidelines Strengthen Good Distribution Practice (GDP)

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Overview

The recently introduced EU Guidelines on the Good Distribution Practice of Medicinal Products for Human Use, (first published on March 8th 2013 as 2013/C 68/01 and updated on November 5th 2013 as 2013/C 343/01) places significant new demands on the manufacturers and distributors of pharmaceutical products.
Partly driven by the need to prevent counterfeit and falsified medicines from entering the legitimate supply chain, 2013/C 343/01 sets out the necessary requirements to ensure compliance with Directive 2011/62/EU, the 'Falsified Medicines Directive'. Moreover, the new guidelines also take account of the challenges (and opportunities) presented by new technologies and increasing globalisation, which have come about since the previous version was published in 1994.

Massive changes

It is no over-statement to say that the new EU Guidelines on GDP represent a massive step-change in expectations of the pharmaceutical industry. Even those with no appreciation of the detail of GDP will recognise that the obligations on manufacturers and distributors have increased dramatically, simply by realising that the 1994 Guidelines ran to 4 pages, whereas the new version runs to 14 pages, including a very useful glossary. Some of the new areas covered include topics such as outsourcing, quality risk Management, change control, falsified medicines, CAPA, changed requirements for the Responsible Person, management responsibilities, transportation and brokers.

This list alone illustrates the far-reaching implications of the new guidelines, and recognises that the distribution process is complex, often involving many parties, many procedures and potential vulnerabilities that might ultimately harm patients. These vulnerabilities include errors/failings during handling and transportation that can compromise the safety or efficacy of pharmaceutical products, such as breakage, contamination, and temperature excursions. They also include procedural oversights that might allow falsified/counterfeit medicines – including returns - to enter the legitimate supply chain, or indeed, that might assist criminals in stealing genuine supplies and distributing them through illegitimate, and fundamentally unsafe supply chains where quality is not a top priority.

Ever vigilant

We cannot be in any doubt that these vulnerabilities exist, and that there are criminals ready to exploit them.

In May 2014, the MHRA's enforcement team took part in Operation Pangea VII - a pan-European operation coordinated through Interpol – which seized £8.6 million of counterfeit and unlicensed medicines in the UK. This international crackdown on the illegal internet trade of medicines resulted in seizures totaling approximately £18.6 million globally, the arrest of 237 people, and suspension of more than 10,000 websites that were illegally selling counterfeit and unlicensed medicines.

Satisfying though it might be that some of the criminal activity has been closed down, it is evident that Operation Pangea VII has only scratched the surface of a much bigger problem.

The World Health Organisation has estimated that 1% of all pharmaceutical sales in developed countries, and 10% in less developed countries are counterfeits. The charity Health Poverty Action puts the counterfeit figure at more than 50% in some parts of Africa and Asia. Estimates of the global value of counterfeit sales are inevitably inaccurate, and not especially helpful, since the issue for individual patients is no more acute if the value is the oft-quoted U$200bn, or any other amount. In either case, the health of millions of people is at risk, and indeed, the financial stability/sustainability of the pharmaceutical industry as a whole is also threatened by the

availability and widespread penetration of falsified medicines.

Greater demands

Anything that improves the situation for patients, by improving the safety of pharmaceuticals and the integrity of the supply chain is clearly to be welcomed. So, whilst the new guidelines inevitably mean adhering to higher standards, and the increased effort that this might entail, the rewards of implementing the changes necessary to comply with them will be significant.

This observation does not apply only to the wholesale distributors and their agents. Under the new Guidelines for GDP, the onus is clearly on manufacturers to comply with the requirements, and as noted above, distribution should not be seen a stand-alone or external event that is somehow separate from the GMP environment.

Indeed, the distribution of pharmaceutical raw materials, as well as distribution of the finished products, should be seen as an integral part of the whole manufacturing and distribution process (GMDP). After all, the control needed to transport materials from supplier to the factory is no less important than the control needed to handle those raw materials when within the factory.

Similarly, the control of products en route to the distributors/wholesalers by land, sea or air, and thence to pharmacy/hospital should receive no less care than the control of the product from production line to warehouse.

As such, the new guidelines should be viewed in the context of wider industry moves for adopting higher standards. The new Gold Standard for Responsible Persons (RP), and the 'Falsified Medicines Directive' for example, are raising the bar in other areas of pharmaceutical production. The Gold Standard for Responsible Persons is especially pertinent to a discussion of the new Guidelines for GDP, since the RP is the person with specific duties for ensuring that GDP is observed and practised.

More specifically, under the new Gold Standard defined by Cogent with support from the MHRA, it is stated that the RP is required to:

- Understand their own responsibilities
- Carry out all duties in such a way as to ensure that the wholesale distributor can demonstrate GDP compliance
- Define personal and staff roles, responsibilities and accountabilities and record all delegated duties
- Ensure that initial and continuous training programmes are implemented and maintained
- Ensure all personnel are trained in GDP, their own duties, product identification, the risks of falsified medicines and specific training for products requiring more stringent handling
- Maintain training records for self and others and ensure training is periodically assessed.

Education and training

The need for education and training comes through very strongly in all of the above, both for the RP directly (in order that they can understand GDP and carry out their own duties), but also of all those included in the manufacturing and distribution process. This extends from senior managers down to the most junior member of staff.

The implications for senior managers, CEOs and managing directors etc should not be overlooked. The EU GDP Guidelines make specific reference to senior managers "actively participating in and managing GDP". There is an over-arching responsibility on senior management to ensure that all parties, including sub-contractors and external suppliers, are complying with the regulations, and there is no delegation of responsibility in this respect.

Senior managers requiring more insight into what might feel like new obligations should perhaps consider attending a one-day training course designed specifically to give them an overview of GDP from a management perspective.

Clearly, from the day to day operational perspective much relies on the Responsible Person, and it is only fairly recently that specific training of any kind has been available for RPs.

RSSL launched the first such training course as recently as 2009, and as the leading provider of RP training is now playing an important role on the Expert Panel set up to further develop the Gold Standard, by defining the RP Training Standard.

The RSSL RP course is accurately aligned with this Training Standard, and they are set to introduce new courses covering the 'soft skills', should the market demand this. Like all of their training courses, these can be offered in-house by arrangement, or at their training centre on frequent dates throughout the year.

Moreover, a welcome addition to the range has been introduced for other key personnel affected by the new Guidelines for GDP, with an online GDP course for drivers.

Drivers clearly have a crucial role to play in ensuring the safety of their cargoes, and the new guidelines require, for the first time, specific training for drivers, as for other key participants. The MHRA have elaborated on the training requirement for drivers, stating in December 2013 at the GDP Symposium "… all drivers including agency, temporary and holiday relief drivers should be trained on GDP so they fully understand their personal responsibilities when handling medicinal products."

Conclusion

The new Guidelines for GDP represent a major change for the pharmaceutical industry and place new demands on manufacturers and distributors of pharmaceutical raw materials and finished products. Much more explicit and far reaching than the guidelines first issued in 1994, the 2013 version pays greater attention to the challenges presented by falsified medicines, and the issues presented by new technologies and greater globalisation.

The guidelines recognise that compliance will largely depend on appropriate training of staff, and make specific requirements for staff to receive training, and for training to be continuous and for training records to be kept. This implies a demand for a higher level of training for the RP in particular, and training for more personnel in general, including senior managers and (for the first time) drivers.

Challenging though it will be for some, adhering to the new guidelines should bring better protection to patients, and do much to ensure that the legitimate supply chain is not compromised, nor inadvertently feeds product in to the illegitimate channels.

Ciarán M Brady

Ciarán has over 25 years' experience in Supply Chain and Materials Management in the Pharmaceutical and Healthcare industry, working with major multi-national as well as start-up companies. In particular, his extensive current working knowledge of FDA and MHRA & IMB/HPRA requirements, has enabled him to assist Pharmaceutical Wholesalers, Manufacturers/Logistics and Transportation companies in all aspects of Good Distribution Practice, Responsible Person and Supply Chain Management, including preparation for license applications. He is also able to support inspections and any subsequent remedial work required. Currently he lecturers for the National Institute for Logistics & Transportation/DIT on their Supply Chain for the Pharmaceutical Industry Masters course, and has worked with Institutes of Technology and Life Science Ireland. Ciarán has built a strong reputation in GDP and RP training, demonstrated consistently by participant's exceptional feedback.

For further information, please contact Customer Services on enquiries@rssl.com