EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Date of submission 23rd December 2011

Submission of comments on 'Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use'

(SANCO/C8/AMan D(2010) 380358)

Comments from:

Name of organisation or individual
DP DHL

Identification number in the EU Transparency Register: **48544465107-88**

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Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	DHL Life Sciences & Healthcare sector has reviewed the proposed new EU GDP guidelines that were submitted for public consultation by the European Commission Brussels SANCO/C8/AM/an D(2010) 380358 within its business units that handle, store and distribute medicinal products. DHL Life Sciences operates over 150 dedicated facilities around the globe operating to over 30 different types of GDP. DHL applauds the work that has been done to produce the proposed guidelines, as current EU GDP (94/C 63/03) is clearly not adequate. DHL has recognised the recent new GDPs being issued around the world, together with those recently by the World Health Organisation (WHO) TRS 957 Annex 5 and the Parenteral Drug Association (PDA) issue of Technical Report No 46 Last Mile GDP to end Users in 2009 and this year's Technical Report 52 on GDP for the Pharmaceutical Supply Chain. Hence DHL has seen trends that GDPs around the world are starting to become harmonised and that they are becoming more merged with GMPs; in fact the new proposed EU GDP Chapter Guidelines closely follow the Chapters of current EU GDP. DHL welcomes this trend and recognises the need to enhance current GDP and improve the quality	

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	requirements to ensure patient safety, product quality and regulatory compliance can be achieved. The cross referencing of the proposed guidelines with EU GMP and Directives 2001/83/EC and 2011/62/EU has been effective and is easy to follow. Whilst the word "Guideline" can be defined as a directing principle, they are not always viewed as a legal or mandatory requirement when operating in different languages. Whilst Article 80 (g) clearly states distributors must comply with GDP, the current GDP, if not read with the Directives and amending Directives, as it is not current can be misunderstood. Therefore the cross referencing of Chapters with principles with clauses is an improvement and should be easier to maintain going forward with changes in legislation. Moreover, DHL has experienced from its various facilities around Europe that DRAs (Drug Regulatory Authorities) and manufacturers have different standards and enforce these differently – having the guidelines more detailed and linked to the Directives will assist consistency. Following discussions with pharmaceutical manufacturers who have undertaken risk impact assessment as part of the European Medicines Agency Concept Paper on "Storage Conditions during Transport" dated 19 October 2010, some have identified that where non temperature controlled vehicles are used in temperate climatic zones during the winter there is an increased risk	

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	of some ambient products freezing e.g. in the Benelux countries. As some of those EU countries in question do not have to work strictly to temperature control as with other EU countries the potential risk should be addressed by the proposed guidelines. Therefore, it would be good if all country DRA inspectors attended the same auditor training to ensure greater consistency in GDP inspections across Europe, with the same standards and frequency and or risk based approach to audits and inspections. It is hoped the GMP/GDP Inspectors Working Group will be able to resolve these concerns. DHL has further been involved in discussions with its customers who are in the process of updating their requirements in workshops and individual meetings to meet the new Chapter 5 on Qualification of Suppliers. Our internal and external communication has been undertaken in a number of different European languages which in turn has lead to some further confusion and listed in Section 2 of this document under "Comments and rationale; proposed changes" by referring to the relevant text and page number. This process has highlighted that there is some confusion around terminology; what medicinal products are in scope, e.g. IMPs (Investigational Medicinal Products) and borderline products; who	

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	the guidelines actually apply to and are airlines and express parcel carriers also in scope? As mentioned under proposed changes, the Annex of Glossary of Terms can be expanded to cover these points around the definition of a medicinal product. DHL's comments are mainly around the impact on deliverables and workability of the proposed guidelines highlighting some clauses which will have an impact on the need for significant financial investment. Most of these will fall under Chapter 9 Transportation. DHL recommends GCCMP (Good Cold Chain Management Practices) are followed regarding the differences between "Storage" (highly controlled processes) and "Distribution" (variable processes). Hence the industry accepts "Manufacturing" and "Storage" processes can be validated, whereas "Distribution" i.e. "Transportation modes" (air, road, sea) can only be qualified as it is far more variable e.g. handling of product is more dynamic, supplier controls are more remote/off-site and the environment can be more extreme and variable. Therefore Chapter 3 on Qualification & Validation 3.26-3.29 and Chapter 9 Transportation 9.15 & 9.19 together with the Glossary in the Annex need to reflect these differences. The proposed EU GDP Guidelines are seen to focus primarily on activities within the sphere of wholesale distribution as defined in Article 1 Directive 2001/83/EC and does not directly address	

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	logistic service providers (e.g. express parcels, freight forwarders) and transport modes other than road (e.g. air and ocean freight). If the proposed Guidelines are applied directly to all these logistics service providers in the form, there will be significant investment requirements as outlined in this document.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
Introduction (page 4 – second para)		Comment: Wholesale distribution of medicinal products could imply finished commercial licensed pharmaceutical products. Logistics companies are licensed to handle, store and distribute unlicensed, special medicines and IMP (investigational medicinal products) in accordance with EU GMP Annex 13 as there is no reference in the current EU GDP (94/C 63/03). The fifth para of the introduction states, "Possession of a manufacturing authorisation shall include authorisation to be holder of a wholesale distribution authorisation". As GDP and GMPs merge it is important the standards and guidelines are linked. Proposed change (if any): Link EU GMP Annex 13 to new EU GDP	
Quality Risk Management (page 6 1.12-1.13)		Comment: Para 1.12 states, "It can be applied ….." this can be construed as optional Para 1.13' "Examples of the processes and applications of QRM can be found …" could be read as optional, i.e. read then decide. The wording of the QRM could be seen as optional unless	

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		formally aligned to EU GMP annexes. Also, as ISO 14971 for medical devices is seen by companies as a good standard and system, it should be referenced Proposed change (if any): Make the guideline more specific by referring to ICH Q9, Annex 20	
Responsible Person (Page 8) Clause 2.1		Comment: Clarification is needed in relation to the number of sites a RP (Responsible Person) can be responsible for? Expectation from GDP Inspectors currently is different. In some countries we currently have three types of roles: the Licence Holder, the RP and a deputy RP for where a licence covers multiple sites. Clarification of this type of structure will help clarify the point of "permanently available". As the Directives allow member states to have their own conditions, the application of the proposed GDP can be confusing when distribution takes place across various geographies. Proposed change (if any): Best practice should be adopted on types of roles	
Computerised Systems (pages 12-13)		Comment: What standard or level of validation? GAMP 5?	

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		Should only apply to systems that have GxP impact. Proposed change (if any): Stipulate GAMP 5 and link to EU GMP Annex 11	
Delivery (Page 18) Clause 5.32		Comment: Clarification is needed on how detailed the records of the journey need to be. (i.e. only locations of each cross docking site / hub or actual route? only start and end point? transport mode? Proposed change (if any):	
Returned Medicinal Products (Page 21) Clause 6.9 (ii)		Comment: Is the 5-day rule for both refrigerated (2°C to 8°C) and ambient product? Is this feasible from a logistics point of view at a national level? Current UK MHRA guideline for chill returns is 1 day as per instruction 13 April 2010. http://www.mhra.gov.uk/home/groups/is-insp/documents/websiteresources/con079200.pdf Further at an international level, based on the origin of the product and the associated customs clearance requirements, this may, in many cases not be possible.	

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		Proposed change (if any): Specify numbers of days for specific type of products to be returned (chill, ambient, and frozen).	
Returned Medicinal Products (Page 21) Clause 6.9 (v)		Comment: There are typos: "evidence that *"th" "the" product was "upplied"* Clarification is needed on what other options should be considered if the original delivery note is not available. This is a regular occurrence within the supply chain. Proposed change (if any):	
Returned Medicinal Products (Page 21) Clause 6.11		Comment: The number of returns can be significantly large for Distributors handling large volumes of products. RPs may not be present on site at all times, and processing returns on time is key not only from a stock level point of view but also from a commercial point of view to our clients. Delegation by the RP to trained and vetted personnel could be considered - or to confirm the process of approval does not have to be undertaken at the time of receipt.	

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		Proposed change (if any): Include that approval of returns can be delegated by the RP to qualified/trained personnel.	
Transportation (page 26) Principle		Comment: No clear guidelines on type of vehicle or requirements to avoid theft. Also clarification is needed on expectations for risk assessment to be done for route planning. Proposed change (if any): Specify if the use of curtain sided vehicles are allowed as long as a risk assessment is performed and level of risk for theft is at an acceptable level (i.e. security procedures and communication/escalation procedures are in place, direct deliveries/short routes from A to B).	
Transportation (page 26) Clause 9.1		Comment: DHL does welcome a clearer understanding around a move towards "ship to label", as we find not all European countries are consistent in approach and there are variances around shipping to stability data. Packaging information for ambient products is not harmonised and most product storage requirements are to keep below 25°C or 30°C. Would the use of non-temperature controlled vehicles (but	

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		monitored) be allowed? Furthermore, during ground transport, there are many cases within the parcel and heavy (air) fright supply chains when the product will be in "active" or "passive" temperature controlled packaging. With monitoring in place, will the use of temperature controlled vehicles be required? Discussions with some manufacturers who have undertaken risk impact assessment as part of the EMA's Concept Paper on "Storage Conditions during Transport" dated 19 October 2010, noted there is a risk that some ambient products that fall below 2°C in Northern and Central European countries where temperatures are frequently below O°C in winter; thus if goods are not protected, they risk freezing. Current requirements are inadequate, thus DHL would welcome greater clarity that helps the industry ensure we are focused towards patient safety where by the product quality is not compromised. We see a difference in approach geographically and within some manufacturers' divisions between OTC (Over the Counter) medicines versus Rx (Prescription Medicines) This will result in a cost impact where this is not currently enforced. Proposed change (if any): Stipulate requirements of vehicles to be used and under which conditions.	

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Transportation (page 26) Clause 9.4		Comment: As mentioned at 9.1 above, stipulation on the types of vehicles is required to ensure definitions around suitability are clear e.g. whether all vehicles must be temperature controlled and with solid sides. In some countries in Europe where non temperature controlled or curtain sides vehicles are used, there will be capacity issues of equipment being available from competent authorised licensed distributors. This will result in higher costs to invest in and qualify and validate new equipment and train drivers in the use of new equipment. Another concern would be individual countries in Europe operating to different standards as under current enforcement of existing regulations, which could allow distributors in some countries to operate under different standards, which would not be conducive to patient safety or fair trading practices. Proposed change (if any): Stipulate vehicle requirements	
Transportation (page 26) Clause 9.5		Comment: Is the expectation that drivers of mail and parcel companies will need GDP training as well? Express Parcel companies such as Yodel and Parcel Force are regularly used in the industry for small deliveries to hospitals, pharmacies and even direct to patients, however the number of Drivers in these	

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		companies can be in the thousands and the turn over of staff can also be big making the training difficult to manage and also costly. Is the term "delivery" understood to also include transfers within the heavy freight environment; e.g., from a terminal to an airport? As described above for the parcel environment, the numbers of companies and staff involved will make such training costly and difficult to manage. Do these requirements also remain in place when the product is loaded in "active" or "passive" temperature controlled packaging? DHL supports this clause but feels that clarification on the extent of training is needed. Clause 2.10 other Personnel states all personnel involved in wholesale distribution activities should be qualified and at Clause 9.5 which states delivery drivers (including contract drivers) should be trained in relevant areas of GDP. Where mail and express drivers are used they may not know they are transporting medicinal products as the goods are packed and secured differently to products that go through dedicated routes. Therefore compliance could be difficult to undertake and maintain. Clause 9.5 may not be required if 2.10 is used to incorporate expectation of delivery drivers.	

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		Proposed change (if any): Clause 2.10 other Personnel states all personnel involved in wholesale distribution activities should be qualified and Clause 9.5 which states should be trained in relevant areas of GDP	
Transportation (page 26) Clause 9.6		Comment: Clear guidance on the type of agents which can be used (i.e. as those used in manufacturing sites) is needed. Proposed change (if any): A list of approved cleaning agents (either specific or generic types such as ionic, non-ionic) would be extremely beneficial as part of this clause.	
Transportation (page 26) Clause 9.8		Comment: The phrase "where possible" leaves options open. Clarification is needed on what the expectation is around justification for using non-dedicated vehicles (i.e. risk assessment in conjunction with our clients for specific product range) especially when using Parcel companies. Furthermore, does this clause also apply when product is loaded in active or passive temperature controlled packaging in a parcel or heavy air freight environment? If so, this will have significant cost impact.	

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		Proposed change (if any):	
Transportation (page 27) Clause 9.12		Comment: This current interpretation of this clause would see many transport operators requiring having Wholesale Authorisation, i.e. Licenses in place if they handle any cold chain or they normally store medicinal products for more than 24 hours – even on an in-transit basis. DHL Life Sciences & Healthcare operations has experience of obtaining wholesale licences for cross dock operations that operate in this way and would like to highlight it would take time for DRA (Drug Regulatory Authorities) to approve new license submissions within the time limits of the new EU GDP coming into operation 6 months after its publication. This is likely to have a major cost and time impact in the supply chain in terms of getting facilities licensed. Moreover distributors would have to comply with other Chapters of new EU GDP and as mentioned in Chapter 2.1: companies will need to get RPs in place, as businesses currently having Quality Management systems based on ISO 9001:2008 or ISO 13485:2003 will have Management Representatives and Quality Managers who may not be competent to be a Wholesale Licence Holder – their options would be to either get existing quality managers trained and qualified or to hire externally (not consistent across the EU as some member states do not allow consultants or externally employed personnel).	

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		The UK's MHRA has proposed training in 4 key elements over a time period which goes beyond the date of the proposals coming into operation. Other European DRAs see the Quality manager needing to be a Pharmacist – thus may require many businesses to have a Pharmacist on site at all such premises. This clause would have a major impact on parcel deliveries as this could mean that a number of parcel companies will have to licence their hubs. It is understood that the European Express Association will submit their views in this matter to try and get greater clarity around "normal" time limits. A maximum time limit of 24 hrs has created a lot of discussion and misunderstanding in the industry. Some read "normally" as if a hub is not designed to hold product for more than 24 hours but this only happens during bad weather, flight delays vehicle breakdowns, traffic accidents etc - then they are out of scope? Some have read this the other way if there is the potential for product to be stored as it could happen almost on a regular basis but is not expected or "normal" ie not designed to happen, then they are in scope which is technically every transport hub thus 24 hours is too short. There are numerous examples which would delay a delivery and need stock held securely at a site/hub pending a redelivery which could take longer than 24 hours, especially during weekends, bank holidays and or due to customs clearance delays.	

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		This would have a major impact on the numbers of licences that will be required for such companies if the definition of "normally" is based around the "potential" and not the "design" of the transport hub. Accordingly, DRAs like the MHRA inspectorate and licensing departments will have to cope with such a large number of new sites requiring licences and regular inspections. During the MHRA GDP conference in October 2011 it was indicated that it is likely that this requirement will not apply to Parcel companies such as Yodel, DHL Express and Parcel Force, however the clause as it is does not reflect that. Another clarification required is that the term "refrigerated product" excludes "passive" temperature controlled packaging such as Isothermic boxes and "active" temperature controlled packing such as Envirotainers, ocean freight reefer containers etc, Otherwise, every express transportation hub, freight forwarder site, airline warehouse and port could require a wholesale distribution license. Proposed change (if any): Clarity what is "normally": i) clarify what is meant by "normally" based on design to store or potential to store and ii) clarify that mail and transportation services (such as express, freight and freight forwarding) are excluded from the wholesale distribution requirement	

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		Clarification on what is refrigerated product specify this is for "active" chilled product only and not for product that has been qualified to be shipped for a specified time limit as a "passive" shipment or in an "active" temperature controlled packaging solution.	
Transportation (page 27) Clause 9.13		Comment: The Auditing of all hubs will need some further clarification - as does this apply only to those identified in 9.12? Or hubs which do not require any wholesale license authorisation? - those sites that would fall currently from a contract logistics perspective under 9.12 should not be a major problem as that would be the norm – the issue comes whether parcel carriers, freight forwarders, airlines, etc are in scope as that could be a huge challenge (staff, workload, compliance etc) + cost impact will be significant. In addition to increased costs of having to do audits there is the practicability of this process being undertaken as every company that uses a transport depot which could be all pharmaceutical manufacturers x by the number of distributors/logistics providers x the number of wholesalers etc ; thus thousands of additional audits could be required. Proposed change (if any): Focus and prioritise audits on new players entering the market who do not have wholesale authorisations	

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		Clarify what terminals and hubs are in scope Have a certification programme so auditing is only required for new providers – similar to VAWD in the USA	
Transportation Containers, packaging and labelling (page 27) Clause 9.15		Comment: Further clarification is needed. Definition of "container" is unclear: does this refer to packaging, trailers, airline unit load devices, ocean freight containers, etc.? Would this mean that normal cardboard boxes (shippers) will need validation? Or is this only related to isothermic boxes ("passive" temperature controlled packaging) and shipment containers for large volume of product (i.e. pallet loads sent from the manufacturing sites (overseas) to the wholesalers via air/sea/road freight. Proposed change (if any): Define the terms for Containers and Packaging in the Annex of Glossary of Terms	
Transportation Containers, packaging and		Comment: Clarification is needed for this clause as again, we believe that this is only expected for in-bound shipments in large	

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labelling (page 27) Clause 9.16		quantities (pallets) from the manufacturing sites, however for outbound parcel deliveries only chill product is identified with the storage/handling requirements but not "ambient" products. Also out-bound parcels are only identified as "healthcare or medicinal" products, and the delivery documents that are attached to the parcel have information about the content of the box but the actual content is frequently not identified with a "visible" label as directly identifying the contents is seen as a risk for theft and not GPSP (Good Pharmaceutical Security Practice) e.g. GHIV (Good with High Illicit Value, Controlled Substances etc. Confirmation is needed to ensure that the attached delivery note is sufficient. Proposed change (if any): Include that for parcel/small deliveries the attached delivery note would be sufficient to comply with this requirement. The same applies for shipping documents in the freight forwarding environment.	
Transportation Temp. control during Transport (page 28) Clause 9.19		Comment: This would be a major change for our transport partners such as Yodel and Parcel Force as their small vehicles are not temperature controlled and the investment to comply with this clause would be quite large. Many parcel companies may not be interested in going down the route of having temperature controlled vans for what is a relatively small business for them (transporting medicinal products).	

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		Not seen as a problem with this clause for chill transportation as we are already in compliance with this and our transport partner who also have wholesale authorisations from DRAs. Validation of equipment (trailer, containers etc): challenges for DHL Freight and a significant cost impact, in particular if this means validation according to GMP annex 15 (DQ, IQ, OQ, PQ etc). If a more pragmatic solution/wording could be found (e.g. as in the food industry where ATP certification is used as a harmonized validation approach) then of course fine If temperature controlled packaging solutions (active or passive) are utilized, must the temperature controlled truck still be validated? This impacts parcel and freight forwarding operations. Proposed change (if any): Clarify if this applies to "dedicated" vehicles only and/or if it is applicable in conjunction with temperature controlled packaging solutions. Suggest removing the "if requested" from the end of the sentence, as temperature data should always be available	
Transportation Temp. control during Transport (page 28)		Comment: The annual calibration mentioned in clause 9.20 appears to refer to calibration of equipment. However the start of the	

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Clause 9.20		following sentence states "This includes temperature mapping under representative conditions …." Hence clarification is required: is temperature mapping performed in the same way as warehouses and refrigerators as defined in a validation master plan and then remapped every 2-3 years or when there is a change to that equipment? If this is aimed as mentioned above at just dedicated vehicles, or all temperature controlled vehicles? For shipments with temperature controlled packaging? As described in previous comments, this will have significant cost impact for parcel and freight forwarding operations if this clause is understood to apply across the board. Temp mapping/ and including seasonal variations could be a significant challenge for freight operations and carry a significant cost impact. If a more pragmatic solution/wording could be found (e.g. as in the food industry where ATP certification is used as a harmonized validation approach) then the challenge + cost can be reduced. Regardless, a harmonized approach to "what is temperature mapping and trailer/container validation" - should be found as otherwise we may have as many interpretations of this as there are LSHC companies (maybe multiplied by their number of auditors as it would then come down to an individual interpretation). Proposed change (if any): Align mapping studies of vehicles to other equipment eg HVAC Make reference to current equipment vehicle specification,	

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		e.g. ATP Certification Produce an annex to the GDP which details for auditors what is good and bad practice to avoid individual interpretation – also it is understood all EU DRAs will need to have their GDP inspectors go through the same audit inspection training to ensure consistency so the industry knows what "good looks like". In addition a list of what would constitute a Critical, Major or Minor regulatory observation would be useful.	
Glossary of Terms (page 31)		Comment: *Industry is invited to provide a list –* The term medicinal product has led to some confusion around what products are in scope: e.g. OTCs, raw materials, clinical trial IMPs (Investigational Medicinal Products) etc. One view is to class these as pharmaceutical products but as the EU does have definitions which have been amended it would be good to have the term defined in the glossary too. As there are borderline products that can fall under the definition of a "medicinal product" these needs to be distinguished from medical devices, cosmetics and food supplements. Directive 2011/62/EU has amended in Article 1 Active Substance and Excipients; thus would be to define medicinal products covered by EU GDP:	

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		Proposed change (if any): Use latest medicinal product definition as Directive 2001/83/EC that was amended by Directive 2004/27/EC in Article 1 as follows: *(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or* *(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.'*	

Please add more rows if needed.