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31 December 2011

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European Medicines Agency (EMA)
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Reference: *Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use, Brussels, SANCO/C8/AM/an D(2010) 380358, 15 July 2011.*

To: Responsible Person: European Commission, Pharm. Unit
To: Responsible Person: EMEA Inspections Sector

PDA is pleased to have the opportunity to comment on the revised Guideline on Good Distribution Practice. Attached you will find our general and specific comments in the standard EMA comment matrix. Our general comments include:

**Scope of the guideline:** We recommend addition of a Scope section giving information on the types of products and the responsibilities of persons covered by the guideline (Comment 1).

**Risk based concepts:** We recommend the guideline embody risk-based thinking and decision making which will allow flexibility and validated solutions to transport issues (Comments 2-3).

**Definitions & terminology:** We recommend use of existing definitions consistent with ICH and/or other sources, and a review/ deletion of qualifiers such as 'any' and 'all' on a case-by-case basis (Comments 4 & 6).

**Consultation and deadline for coming into operation:** Considering the magnitude of this revision we recommend consideration of a second round of consultation and an extension of the 'coming into operation' deadline to at least 18 months (Comment 5).

**Industry technical resources:** In support of the revision process we are sharing with the Commission and the drafting group copies of four PDA Technical Reports (Nos. 39, 46, 52 & 53) which are directly related to GDP technical issues. They will be sent to the EC and EMA contacts under separate email cover (Comment 7).

Please contact me, or James Lyda of the PDA staff (lyda@pda.org), if you have any questions.

With very best regards,

Georg Roessling, Ph.D.
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cc: S. Rönninger, S. Schniepp, R. Levy, J. Lyda, R. Dana

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 December 2011

Submission of comments on

# "Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use,"

SANCO/C8/AM/an D(2010) 380358

**Comments from:**

Parenteral Drug Association (PDA)
James C. Lyda (lyda@pda.org)

*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

| Stake-holder number | PDA # | General comment (if any) | Outcome (if applicable) |
|---|---|---|---|
| | 1 | **Scope of the guideline:**<br>*Items/products:* It is our understanding, and preference, that this GDP guideline should be applicable only to the distribution of finished medicinal products for commercial distribution. It should not apply, for example, to active pharmaceutical ingredients, the distribution requirements for which are described in paragraph 10 of EU GMP Part II. Neither do we interpret it to apply to Investigational Medicinal Products (IMPs), which are distributed in small, controlled quantities through 'non-commercial' distribution systems.<br><br>*Parties involved in distribution*: We recommend that the various parties in the supply chain to whom the requirements of the Good Distribution Practice guideline apply should be stated more clearly. For example, in referring to ''distributor', Article 80 (g) of Directive 2001/83 is referenced. This Article refers specifically to 'Holders of the distribution authorization'. However there are many other parties in the distribution chain, and the Introduction to the guideline describes ''actors'' engaging in activities such as exporting and holding or storing medicinal products. It also states that ''the relevant sections of the guideline should be considered for implementation by e.g. governments, regulatory bodies, international procurement agencies and donor agencies as well as all parties involved in any aspect of distribution of medicinal products.''<br><br>**Recommendation 1A:** We recommend that the term 'distributor' be completely defined and described in the Annex: Glossary of Terms (beyond just a reference to another directive).<br><br>**Recommendation 1B:** We recommend creation of a new Scope section in the guideline clarifying the types of products and materials which are covered by the guideline, and identifying the persons, parties and entities which are required to comply with the guideline. This will be helpful as the requirements must be understood by parties involved in distribution around the globe.<br><br>**Recommendation 1C:** For similar reasons, it will be helpful if the new Scope section includes the legal rationale for application to the various parties involved in distribution of medicinal products. | |
| | 2 | **Storage and transport conditions – Risk based approach:**<br>We believe that transport conditions do not necessarily need to be identical to label storage conditions. Medicinal products may be transported at specified temperature ranges (which differ from label conditions) for defined transport durations when | |

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| | | adequate stability data are available.<br><br>**Recommendation 2:** For this reason, the concept of risk-based decisions for storage and transportation conditions throughout the distribution chain should be embodied in this GDP guideline. Such decisions should be science-based and consider the known characteristics of the product. Comments related to this issue will be found in the specific comments section of this matrix. | |
| | 3 | **Temperature monitoring of shipments – Risk based approach:**<br>It is not necessary to require temperature monitoring of all shipments. As an alternative to temperature monitoring, and with the use of risk-based principles, it is feasible to use temperature-control systems that employ validated packaging configurations for temperature maintenance over a pre-defined transport duration. As such, a validated temperature-control system will provide adequate assurance that the temperature of the medicinal product is controlled.<br><br>**Recommendation 3:** We recommend the guideline, embodying risk-based principles, be sufficiently flexible to allow the use of validated temperature-control systems when appropriate, rather than requiring temperature monitoring data for all shipments. Reference to this issue will be found in some specific comments below. | |
| | 4 | **Definitions:**<br>Some terminology in the GDP guideline is inconsistent with ICH Q10; with proposed revisions to Part I, Chapter 1 of the EU GMP; and is internally inconsistent. For example, current ICH Q10 uses the term "Pharmaceutical Quality System," while Chapter 1, GMP Part I, is being revised to define the "Quality Management System." In the GDP guideline, Chapter 1 discusses "Quality Management" and describes a "Quality System." In GDP Chapter 10, "Specific Provisions for Brokers," the term "Quality Management System" is used. The Annex: Glossary of Terms in the guideline describes a Quality System using the ICH Q9 definition.<br><br>**Recommendation 4A:** For Quality Management System, we recommend either the ICH Q10 definition or the definition used in the proposed revision of Chapter 1, GMP Part I.<br><br>Similarly, GDP Chapter 1 discusses "Management of Outsourced Activities," (consistent with ICH Q10 and proposed Part I, Chapter 7) whereas GDP Chapter 7 uses the term "Contract Operations."<br><br>**Recommendation 4B**: We recommend use of the ICH Q10 term, "Management of Outsourced Activities." | |

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| | 5 | **Consultation and deadline for coming into operation:**<br>The scope, applicability and impact of this guideline are expanded from past requirements (the previous guidance was 4 pages in length, while the current draft is 32 pages.) We suggest it is unrealistic to expect a six month implementation date after final publication. For the same reasons, and to make the most 'fit for use' final guideline, we suggest there be more than a single round of consultation before the adoption of a final version.<br><br>**Recommendation 5A**: We recommend consideration of a second round of consultation after the first stakeholder comments are reviewed.<br><br>**Recommendation 5B:** We recommend the 'deadline for coming into operation,' be lengthened to a more appropriate timeframe, e.g., 18 months. | |
| | 6 | **Use of terms 'all' and 'any':**<br>Experience has shown that absolute terminology such as 'any' and 'all' may have unintended consequences, and may underestimate the compliance impact on those parties subject to the guideline. Such terminology also may not distinguish between truly critical risks and those which may be more tenuous in nature. Such words can frequently be deleted with no dilution of the expectation for protection of the medicinal product supply. Three examples are cited below, with the proposed deletion of all or any:<br><br>**Example a:** Introduction, p4: "The relevant sections of these guidelines should also be considered for implementation by, among others, governments, regulatory bodies, international procurement organisations and donor agencies, as well as ~~all~~ **other** parties involved in ~~any~~ aspect**s** of distribution of medicinal products."<br><br>**Example b:** Section 3.19, Equipment, p13: "Relevant pieces of equipment would include (but not be limited to) cold stores, refrigerators, thermo hygrometers, or other temperature and humidity recording devices, air handling units and ~~any~~ equipment utilised in conjunction within the onward supply chain."<br><br>**Example c:** Section 5.14, Operations, p17: "In the event of ~~any~~ suspicion of falsified medicinal product, the batch should immediately be segregated and reported to the national competent authority and, where applicable to the marketing authorisation holder," | |

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| | | **Recommendation 6:** We recommend that the terms 'any' and 'all' be examined as they are currently used in the guideline, and deleted/ modified where not deemed necessary. If desired PDA is willing to help with this exercise. | |
| | 7 | **Industry Technical Resources:** To the extent useful, the guideline should consider and be consistent with existing industry guidance, 'points to consider,' and consensus-based technical information relating to good distribution practice.<br><br>In support of the drafting process, PDA is sharing with the EC and EMA four of our published Technical Reports which should be helpful for the guideline drafting group. They are:<br><br>- PDA Technical Report No. 39, Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment, 2007.<br><br>- PDA Technical Report No. 46, Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End User, 2009.<br><br>- PDA Technical Report No. 52, Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain, 2011<br><br>- PDA Technical Report No. 53, Guidance for Industry: Stability Testing to Support Distribution of New Drug Products, 2011<br><br>Note: These reports will be forwarded in PDF format under separate email cover. | |

## 2. Specific comments on text

| Sec No. | PDA Number | Comment and rationale; proposed changes<br>*(If changes to the wording are suggested, they should be highlighted using 'track changes')* | Outcome<br>*(To be completed by the Agency)* |
|---|---|---|---|
| Intro | 8 | ***Comment:***<br>Current text reads, "It is necessary to exercise control over the entire chain of distribution objectives by observing good manufacturing practice of medicinal products. This policy ensures that products manufactured in, or imported into the European Union are of the appropriate quality. This level of quality should be maintained throughout the distribution network without any alteration". This section of the guideline is confusing. See proposed revision which is closer to current wording of EU GDP.<br><br>***Proposed Change:***<br>Replace the existing section with the following:<br><br>**Products manufactured in, or imported to the European Union are produced in accordance with GMPs to ensure that they are of the appropriate quality ~~safe and effective~~. It is necessary to exercise control over the entire chain of distribution activities in order to maintain the quality of medicinal products through to the end-user.** | |
| 1.10 (iv) | 9 | ***Comment:***<br>For clarity we have proposed appropriate rewording of this section to reflect innovations in the distribution system, not the quality system, which we believe is the actual intent of this section.<br><br>***Proposed Change:***<br>Change article iv to read:<br><br>(iv) ~~Innovations that might enhance the quality management system~~; **innovations that may enhance the security and integrity of the distribution system.** | |
| 2.1 | 10 | ***Comment:***<br>Re: Responsible Person: We propose that personal accountability is maintained but that delegation of responsibility may be allowed as per 2.5 (point x) which describes 'delegating his/her duties when absent…''. | |

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| | | ***Proposed Change:***<br>Please changes this section as follows:<br><br>"The wholesale distributor must designate a person as Responsible Person **who has clearly defined personal accountability.** ~~The Responsible Person should fulfil his/her responsibilities personally and should be permanently available~~. The Responsible Person should meet the conditions provided for by the legislation of the Member State concerned." | |
| 2.3 | 11 | ***Comment:***<br>There are other academic qualifications other than pharmacy which may be equally suitable for this function.<br><br>***Proposed Change:***<br>We recommend deletion of this sentence and allow reference to appropriate Member State legislation to stand as the requirement.<br><br>~~A degree in Pharmacy is desirable.~~ | |
| 2.5 (xi) | 12 | ***Comment:***<br>This sentence says the RP is responsible for, "being involved in... any decision to quarantine…,"etc. This is ambiguous and does not make clear what the function of the RP is to be. We recommend a change to make the RP role more clear.<br><br>***Proposed Change:***<br>Change line xi replacing "being involved in" with "overseeing":<br><br>xi) ~~being involved in~~ **overseeing** any decision to quarantine or dispose of returned, rejected, recalled or falsified products;" | |
| 3.3 | 13 | ***Comment:***<br>It is stated that ''There should be segregated areas designated for the storage of products awaiting further decisions as to their fate." It is not current GMP requirement that goods not yet released for use be physically segregated. Rather, it is current practice that, for example, incoming goods and products from manufacturing that are awaiting a release decision may be | |

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| | | assigned a quarantine status via an electronic inventory system. Only returned goods, goods to be rejected or destroyed, or goods suspected to be falsified, should be stored in a segregated area (as noted in 5.25 of the guideline.)<br><br>***Proposed Change:***<br>Modify this section as follows:<br><br>~~"There should be segregated areas designated for the storage of products awaiting further decisions as to their fate. These include any product suspected of falsification, returned products, rejected product, product awaiting disposal and recalled product.~~<br>**Segregation should be provided for the storage of rejected, expired, recalled or returned products and suspected falsified medicinal products. The products and the areas concerned shall be appropriately identified.** | |
| 3.4 | 14 | ***Comment:***<br>We find no justification why, 'products not intended for the (European) Union market' should be kept in segregated areas. Such products should be stored in the same manner as all products destined for export, as described in section 3.3.<br><br>***Proposed Change:***<br>Please revised this section as follows:<br><br>Medicinal products not intended for the European Union/ market should be ~~kept in segregated areas.~~ **appropriately identified as such and stored in a manner to avoid distribution in the EU/ EEA.** | |
| 3.19 | 15 | ***Comment:***<br>Security and alarm systems for intruders should also be included here as well as in section 3.9.<br><br>***Proposed Change:***<br>Revise section 3.19 as follows:<br><br>"Relevant pieces of equipment would include (but not be limited to) cold stores, **monitored intruder alarm and access control systems,** refrigerators, thermo hygrometers, or other temperature and humidity recording devices, air handling units and any | |

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| | | equipment utilised in conjunction within the onward supply chain. | |
| 3.27 | 16 | ***Comment:***<br>The term "system" could incorrectly be understood as a whole system, instead of only validating the subsystems affected by changes or upgrades.<br><br>***Proposed Change:***<br>Please revised 3.27 as follows:<br><br>"Prior to implementation and after any significant changes or upgrades, **the affected** systems **or subsystems** should be validated. ~~to ensure correct installation and operation.~~ **A risk based approach can be used to determine if the change is significant.** | |
| 4.8 | 17 | ***Comment:***<br>Item 4.8 references the word "Records" and appears to be an incomplete entry.<br><br>***Proposed Change:***<br>Either correct or delete this section. | |
| 5.1 | 18 | ***Comment:***<br>The meaning of the following is unclear: "wholesale distributors must obtain their supplies of medicinal products only from persons who are themselves in possession of a wholesale distribution authorisation or … a manufacturing authorisation…" What is the expectation regarding distributors who obtain their supplies from outside the EU and where there may not be a wholesale distribution authorization of this type available?<br><br>***Proposed Change:***<br>We suggest clarification of this section to address possibilities for legitimate supply of medicinal products originating outside the EU. Such explanation would also be useful in a new 'Scope' section. | |
| 5.5 | 19 | ***Comment:*** | |

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| | | For clarity add 'medicinal products' to this section.<br><br>***Proposed Change:***<br>Revise section 5.5 to read:<br><br>"Appropriate qualification should be performed prior to any procurement **of medicinal products**. | |
| 5.8 | 20 | ***Comment:***<br>Typographical error.<br><br>***Proposed Change:***<br>Delete 'must' from sentence as shown:<br><br>"Wholesale distributors must ensure they ~~must~~ supply medicinal products only to persons …" | |
| 5.13 | 21 | ***Comment:***<br>Consistent with our general comment #2, we support the possibility of distributing products outside of label conditions when data and validated systems are used.<br><br>***Proposed Change:***<br>Please add the following sentence to this section:<br><br>Where medicinal products require special storage … after appropriate checks have been conducted. **It may be acceptable to ship/ receive product outside of temperature storage label claim when supported by stability data or justification.** | |
| 5.16 | 22 | ***Comment:***<br>While the term "Third Country" may be understood in the EU/EEA, it may be misunderstood in other parts of the world.<br><br>***Proposed Change:***<br>Add a definition or reference to the term 'Third Country' in the guideline section 5.16. | |

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| 5.28 | 23 | ***Comment:***<br>The maintenance of records for destroyed medicinal products should be in keeping with existing document retention policies and local requirements. It is not necessary to keep such records indefinitely.<br><br>***Proposed Change:***<br>Revise this section to read:<br><br>"Records of all destroyed medicinal products should be maintained **for a defined period**." | |
| 5.29 | 24 | ***Comment:***<br>Current practice and some national requirements define a minimum remaining shelf-life for products to be picked. We understand that meeting this requirement is an acceptable reason to deviate from FEFO practices.<br><br>***Proposed Change:***<br>Add phrase to this section as shown below:<br><br>"Controls should be in place to ensure the correct product is picked. The product should have an appropriate remaining shelf life when it is picked. It should be picked on a "first expired, first out" (FEFO) basis, **unless otherwise justified**. …." | |
| 5.30 | 25 | ***Comment:***<br>Packing can provide a level of product protection however it is not practical to expect packing to maintain storage conditions during transport. We feel section 9.14 adequately addresses this issue, and we recommend deletion of the second sentence of Section 5.30.<br><br>***Proposed Change:***<br>Revised 5.30 as follows:<br><br>"Products should be packed in a way to avoid breakage, contamination and theft. ~~The packing should be adequate to maintain the storage conditions of the product during transport.~~ The containers in which medicinal products are shipped should be | |

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| | | sealed." | |
| 5.32 | 26 | ***Comment***:<br>It is unclear why the batch number should be recorded only for those products bearing safety features, and we suggest that batch numbers be recorded for all medicinal products.<br><br>***Proposed Change:***<br>Please revise this section to read:<br><br>For all supplies … a document must be enclosed to ascertain the date; name and pharmaceutical form of the medicinal product, batch number ~~at least for products bearing the safety features~~, ~~where required;~~ quantity supplied; name and address of the supplier, … | |
| 5.34 | 27 | ***Comment:***<br>This section is important as it describes to whom the guideline applies and their obligations.<br><br>***Proposed Change:***<br>We recommend that this information on export, and similar information describing the requirements for different parties, be fully clarified and added to a new Scope section (See General comment #1). | |
| 5.35 | 28 | ***Comment:***<br>Same as comment #27.<br><br>***Proposed Change:***<br>We recommend that this information on export, and similar information describing the requirements for different parties, be fully clarified and added to a new Scope section (See General comment #1). | |
| Ch.6 Principle | 29 | ***Comment:***<br>Line 2 in the "Principle" states that, ''A special assessment of returned medicinal product should be performed….'' It is not clear what is meant by a ''special assessment." | |

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| | | ***Proposed Change:***<br>Delete the word 'special' from the sentence.<br><br>"A**n** ~~special~~ assessment of returned medicinal products should be performed before any approval for resale." | |
| 6.3 | 30 | ***Comment:***<br>Currently this section requires reporting any complaint concerning potential defects or potential falsified products without delay. It is not a customary or helpful practice to report potential defects before an investigation has been initiated. For example, if a patient complains about a different ink color on a medicinal product pack, this could be an indication of counterfeiting. But it could also be traceable to other issues including patient error. It is the manufacturer's responsibility to conduct a timely investigation and report to the authorities with available data once they have reasonably confirmed the nature of the problem. We recommend the requirement for reporting under this section be consistent with the expectations in EU GMP Part I, Chapter 8, section 8.8, as reflected in our proposed rewording.<br><br>***Proposed Change:***<br>Reword 6.3 as follows:<br><br>"Any complaint concerning a potential product defect or a potential falsified product should be recorded with all the original details and investigated. **If, as a result of this investigation, the MAH is considering action involving the subject medicinal product,** the national competent authority should be notified without delay." | |
| 6.9(ii) | 31 | ***Comment:***<br>Section 6.9, point (ii) stipulates a maximum time (5 days from dispatch) within which medicinal products must be returned if they are to be returned to saleable stock. The rationale for this time period is not explained. We recommend such decisions to be made on a risk management basis taking into consideration properties of the product concerned.<br><br>***Proposed Change:***<br>Revise section (ii) as follows: | |

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| | | ii) medicinal products returns from a customer not holding a wholesale distribution authorisation should only be returned to saleable stock if they were returned ~~within five days~~ within a reasonable period of time from the ~~of~~ original dispatch **and the decision to return to stock is supported by the quality system and a risk management process.** | |
| 6.10 | 32 | ***Comment:***<br>Medicinal products may be returned to saleable stock if a stability profile or associated stability information is available to support exposure conditions that differ from the labelled storage conditions.<br><br>***Proposed Change:***<br>Revise section 6.10 as follows, deleting the individual bullet points as they are no longer necessary.<br><br>"Medicinal products requiring ~~low~~ temperature storage conditions can be returned to saleable stock only if the batch number of the dispatched product is known and there is evidence that ~~the product has been stored within the authorised storage conditions throughout the entire time~~ **appropriate conditions have been maintained throughout transport and storage of the product and there is no evidence that product integrity has been compromised.** ~~This evidence should include but is not limited to the following:~~<br>~~- delivery to customer~~<br>~~- opening of the packaging~~<br>~~- examination of the product~~<br>~~- returning of the product to the packaging and sealing of the packaging~~<br>~~- collection and return to the distributor~~<br>~~- return to the distribution site refrigerator"~~ | |
| Ch.9 Principle | 33 | ***Comment:***<br>Consistent with our general comment #2, we believe that label storage conditions do not necessarily have to be the same as storage conditions during transport. Such conditions can differ based on knowledge of product stability characteristics and other data. These decisions should be science and risk-based and recognize the known characteristics of the medicinal product. For temperature sensitive products, allowable exposure ranges and durations outside of labeled storage conditions should be permitted provided that this approach is supported by adequate stability data. | |

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| | | ***Proposed Change:***<br>We recommend changes to this part of the Principle as follows:<br><br>''Medicinal Products should be transported in accordance with ~~the~~ **appropriate** storage conditions ~~indicated on the packaging information~~ **which are supported by stability data and should be protected during transportation against harmful effects of temperature, and other adverse environmental factors. Shipping outside of labeled storage temperature requirement is acceptable if supported by appropriate stability studies.“** | |
| 9.1 | 34 | ***Comment:***<br>Consistent with our general comment #2, above, we believe that transport conditions need not be identical to labeled storage conditions. For temperature sensitive products, allowable exposure ranges and durations outside of labeled storage conditions should be permitted provided that this approach is supported by adequate stability data.<br><br>***Proposed Change:***<br>We recommend changes to part 9.1 as follows:<br><br>**Medicinal products should be protected during transportation against harmful effects of temperature and other adverse environmental factors.** The ~~required~~ storage conditions for medicinal products ~~should~~ **to** be maintained during transportation ~~within the defined limits as described on the packaging information~~ **should be defined by the manufacturer based on knowledge of the product characteristics and supported by stability data.** | |
| 9.5 | 35 | ***Comment:***<br>Training of personnel and driver qualification is the responsibility of the service provider. Terms of delivery will normally be defined in a contract/service level agreement (e.g. as per Ch. 7 EU GMP, “Outsourced Activities”). The term ‘delivery drivers’’ is also ambiguous since products may be transported throughout the supply chain via other modes of transport, e.g. rail and air.<br><br>***Proposed Change:***<br>We recommend deletion of section 9.5. | |

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| | | ~~Delivery drivers (including contract drivers) should be trained in the relevant areas of GDP.~~ | |
| 9.7 & 9.20 | 36 | ***Comment:***<br>Section 9.7 states a requirement to maintain and calibrate temperature monitoring equipment in vehicles "at least once a year." Rather than specifying a maximum time period, we recommend an interval for calibration and maintenance to be determined based on risk-management principles. As this approach is included in section 9.20, we recommend deletion of section 9.7.<br><br>***Proposed Change:***<br>Delete section 9.7:<br><br>~~9.7 Equipment used for temperature monitoring during transport within vehicles and/or containers, should be maintained and calibrated at regular intervals at least once a year.~~ | |
| 9.9 | 37 | ***Comment:***<br>Section 9.9 specifies that deliveries should be made directly to the address stated on the delivery note and should not be left on alternative premises. In practice, transport hubs (as stated in 9.12) are frequently used for goods in transit to final destination. Experience has shown that on occasion there is an unavoidable need for alternate delivery arrangements. We recommend section 9.9 be revised to reflect this reality.<br><br>***Proposed Change:***<br>Revise section 9.9 to read as follows"<br><br>"Deliveries should be made directly to the address stated on the delivery note and **should** be handed into the care of the consignee. Medicinal products should not be left on alternative premises **unless covered by procedures or prior agreement.** " | |
| 9.12 | 38 | ***Comment:***<br>Section 9.12 introduces a requirement to restrict transit time at transport hubs to ''a maximum time limit of normally 24 hours''. The rationale for this time limit is not explained and it appears to be arbitrary. | |

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| | | ***Proposed Change:***<br>We recommend deletion of the 24 hour reference, to read:<br><br>Where transportation hubs are utilised in the supply chain, a maximum time limit ~~of normally 24 hours~~ should be set to await the next stage of the transportation route. | |
| 9.19 | 39 | ***Comment:***<br>The first sentence of 9.19. The term "transport conditions" is too broad. The critical variable that is addressed in this sentence is temperature.<br><br>***Proposed Change:***<br>Revise section 9.19, first sentence, as follows:<br><br>Validated temperature-control systems (e.g. thermal packaging, temperature-controlled containers, and refrigerated vehicles) should be used to ensure **appropriate** ~~correct transport~~ conditions are maintained between the distributor and customer | |
| 9.19 | 40 | ***Comment:***<br>The second sentence of section 9.19 states that ''Customers should be provided with temperature data to demonstrate that products remained within the required temperature storage conditions during transit if requested.'' This statement could suggest that temperature data be available for all deliveries if requested. As an alternative to monitoring all shipments, we advocate the use of temperature control programs that employ validated packaging configurations for temperature maintenance over a pre-defined transport duration. A validated temperature-control system should provide adequate assurance that the temperature is maintained.<br><br>***Proposed Change:***<br>Revise section 9.19, second sentence, to read:<br><br>Customers should be provided with ~~a temperature data~~ **information** to demonstrate that products remained within the required ~~temperature~~ storage conditions during transit, if requested." | |

| Sec No. | PDA Number | Comment and rationale; proposed changes<br>*(If changes to the wording are suggested, they should be highlighted using 'track changes')* | Outcome<br>*(To be completed by the Agency)* |
|---|---|---|---|
| 9.20 | 41 | ***Comment:***<br>Section 9.20, first sentence, introduces a requirement to maintain and calibrate temperature monitoring equipment in vehicles "at a minimum of once a year." Rather than specifying a maximum time period, we recommend an interval for calibration and maintenance to be determined based on risk-management principles. We have recommended deletion of section 9.7 of the guideline which included a similar time frame.<br><br>***Proposed Change:***<br>Revise 9.20 to read:<br><br>If refrigerated vehicles are used, the temperature monitoring equipment used during transport should be maintained and calibrated at regular intervals ~~or at a minimum of once a year~~. | |
| 9.20 | 42 | ***Comment:***<br>Section 9.20, second sentence, requires that refrigerated vehicles be subject to "temperature mapping under representative conditions…" We believe this is an overly prescriptive requirement and the guideline should allow for other means of establishing and qualifying appropriate vehicles, e.g. certification to an industry standard.<br><br>***Proposed Change:***<br>Please revise sentence two of 9.20 to read:<br><br>"~~This includes temperature mapping under~~ **Qualification of vehicles should consider** representative conditions and should take into account seasonal variations." | |

Please add more rows if needed.