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Oss, December 22, 2011

Re : Commission guidelines on Good Distribution Practice of Medicinal Products for Human Use

Dear Madam, Sir,

Merck & Co., Inc, known as MSD outside the United States and Canada, is a global healthcare leader. Through a combination of the best science and state-of-the-art medicine, Merck has produced many important medicines and vaccines. Today the company is continuing to actively develop a broad portfolio of small molecules, vaccines and biologics products, including biosimilars to significantly improve worldwide patient access to important/life-saving therapies.

Merck has reviewed the above referenced document and is providing the following comments for your consideration. Merck welcomes guidance from the Commission and we appreciate this opportunity to comment on the subject document and hope that you will take our comments into consideration.

On a general note, we would like to emphasize that it is important that the exact scope of the guideline is clearly and unambiguously defined as to which activities are within the scope and which are outside the scope. Furthermore, although we are supportive of the general principles and aim of the guidance, we are concerned that several of the requirements are unrealistic from a practical perspective and unnecessarily stringent as the same level of safety could in our view be obtained through other means. Our detailed comments are summarised in tabular format below.

Should you need additional information or wish to hold further discussions with our company experts, do not hesitate to contact me.

Yours sincerely,

Lisette Vromans
Encl.

<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:

Name of organisation or individual
Merck Sharp & Dohme

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)*
	<u>Scope of the guideline</u> Under INTRODUCTION the exact scope of the guideline should be more clearly and unambiguously defined as to which activities are within the scope and which are outside the scope, e.g. • (direct) distribution by a manufacturer versus distribution by a wholesale distributor; • storage (static) versus transport (dynamic); • trade only with distribution contracted out versus physical handling of products. <u>24 hours criterion for hubs or transfer facilities</u> The requirement for a wholesale distribution licence for hubs or intermediate storage facilities for the storage of cold chain products (or for any products when stored for more than 24 hours) is excessive and not realistic. Major problems will be encountered e.g. over the weekend (when in some countries no trucks are allowed on the highways) or during midweek public holidays. The 3rd sentence stipulates requirements which will virtually be impossible to meet. In consequence e.g. all airports worldwide will require wholesale	

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	distribution authorisations to simply execute a transfer of cold chain products. <u>Segregation requirements for special product categories.</u> Although we are supportive of physical separation between 'legitimate stock' and a number of other categories of product stock ('special cases' like e.g. rejects, returns, recalled product, suspected falsified medicines), we do not support the requirement to also separate all special categories between themselves. With segregation requirements for all these special categories, in addition to the proposed (but not realistic, see above) segregation of EU/non-EU and cold chain products, the number of segregated storage areas would become completely impractical and have huge cost impact. Apart from the above considerations validated computer systems could be used to manage these different categories of segregated products, also when they are stored in the same area. <u>Batch numbers</u> Under 4.10, 5.29 and 5.32 it is stated that the batch number should be included in the documentation, *where required*. This is very	

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	confusing as no clarification is given as to when inclusion of the batch number would or would not be required. To avoid unharmonised interpretation/implementation between Member States, the requirement on inclusion of the batch number should be unambiguous. It is proposed to either specify in which case(s) the batch number is required, or delete *'where required'*. <u>Storage conditions during transportation (chapter 9 – Principle; articles 9.1-9.3).</u> Storage conditions during transportation as a general principle should be according to the approved storage labelling, <u>unless otherwise justified.</u> In many instances during product development companies have done stability studies under different conditions of temperature/humidity, which would support storage/transportation under other than the approved conditions for a limited period of time. These studies are especially intended to accommodate short time excursions e.g. during intermediate storage or transportation. Therefore, transportation under conditions other than the labelled storage conditions should be	

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	allowed, where stability data are available demonstrating that product quality is not affected.	

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)*
1.8 iii)		Comment: *´…within a satisfactory time period´* is considered inaccurate wording. The time period agreed e.g. in a contract is acceptable and satisfactory. Proposed change: *'...delivered to the right recipients within ~~a satisfactory~~ the time period agreed between parties;´*	
1.9 i)		Comment: It is advised to use consistent wording and role designations throughout the entire text. Proposed change: *´…the suitability and competence of the contract acceptor ~~other party~~ to carry out…´*	
1.11		Comment: It is not defined to whom the outcome of the review shall be communicated. It is proposed to spread this information company internally only (acc. ICH Q7 2.41). Proposed change: *´…should be timely and effectively communicated to responsible management.´*	
Ch. 2 - Principle		Comment: Inaccurate wording. Proposed change: *'…and the ~~correct~~ distribution of medicinal products…´*	
2.1		Comment: To avoid different interpretations between Member States it should be clarified what is meant with 'permanently available'.	

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)*
		Proposed change: As a minimum requirement it should be sufficient if the Responsible Person can be reached by phone 24 hours/7 days per week.	
2.1 & 2.3		Comment: Last sentence in 2.1 and first sentence in 2.3 have the same meaning and content. Proposed change: Delete last sentence from 2.1.	
2.1 & 2.4		Comment: Second sentence in 2.1 and first sentence in 2.4 have the same meaning and similar content. Proposed change: Modify 2.4 to read *´The Responsible Person should carry out his/her duties ~~activities personally~~ in order to ensure…´*	
2.4		Comment: It is not clear what public service obligations are meant by *´…and that public service obligations are met.´* Proposed change: Clarify what is exactly meant with 'public service obligations'.	
2.5		Comment: Regulatory guidance should include a conclusive enumeration of applicable or minimal requirements. In that context the wording *´…include, but are not limited to: ´* is not accurate. Proposed change: Omit second part of statement to read: *´…GDP responsibilities include~~, but are not limited to~~:´*	
2.5 iii)		Comment: The wording 'distribution activities' may be misinterpreted to only include activities related to actual	

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		distribution, which probably is not the intention. Proposed change: '*.. for all personnel involved in ~~distribution~~ GDP related activities;´*	
2.5 iv)		Comment: Over-prescriptive wording. Based on outcome of the risk assessment a recall may need to be done in a time frame other than ´promptly´. Proposed change: '*…and timely performing ~~promptly~~ any recall operations…´*	
2.5 xi)		Comment: This article is not aligned with article 6.11, which assigns a stronger role to the RP than just being 'involved'. Proposed change: Suggestion to strengthen the role of the RP beyond just being 'involved', based on his/her personal responsibility and accountability.	
2.14		Comment: An assessment on practical effectiveness of training is not covered/allowed in all member countries based on legal constraints. The minimum should be to document and assess training (Acc. ICH Q7 3.12) Proposed change: '*…and the ~~practical~~ effectiveness of training should be periodically assessed and documented.´*	
2.16		Comment: Proposed change: '*The storage and consumption of food, drink,….´*	
3.4		Comment: There does not seem to be any rationale for	

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		keeping medicines not intended for the EU market in segregated areas. With modern stock management systems we allow QC/QP released stock to be held next to unreleased material, which is a far greater risk, and we allow the system to control the disposition. Then why should goods for different markets, which is a lower risk, need to be physically separated? Besides products for different end markets have different product codes/numbers and different country specific finishes, which minimize the chances for a mix-up. Proposed change: Delete article 3.4.	
3.10		Comment: Cleaning agents should be included as well. Proposed change: *'Cleaning equipment and cleaning agents …'*	
3.13		Comment: Regulatory guidance should include a conclusive enumeration of applicable or minimal requirements. See also 3.5 where it is stated "where required". Proposed change: *´Environmental factors to be considered may include temperature, humidity and cleanliness of the premises.´*	
3.16 & 3.17		Comment: Both paragraphs include elements of calibration and verification of functionality. It is	

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		proposed to separate the two topics into each of the two paragraphs. Proposed change: *´3.16 Equipment used to control or to monitor the environment of the medicinal product should be calibrated. Calibration should be traceable to a primary standard. ~~and their correct operation and suitability for purpose verified at defined intervals by the appropriate methodology.~~* *3.17 ~~Calibration of equipment should be traceable to a primary standard.~~ Appropriate alarm systems should be in place to provide alerts when there are deviations from pre-defined storage conditions. Alarm levels should be appropriately set and alarms and their suitability should be regularly ~~tested~~ verified at defined intervals by the appropriate methodology to ensure adequate functionality.´*	
3.19		Comment: Relevant equipment should be determined based on risk considerations which shall include and focus on potential impact on product quality. Proposed change: *'Relevant pieces of equipment should be determined based on risk considerations and the potential impact on product quality. These would include at least ~~(but not be limited to)~~ cold stores, refrigerators,*	

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		thermo hygrometers, or other temperature and humidity recording devices, air handling units and any equipment utilised in conjunction within the onward supply chain.'	
3.21 – 3.25		Comment: The content proposed in these sections is closely linked with the requirements laid down in Annex 11. Any redundancy or duplication with a slightly modified meaning would lead to ambiguous interpretation of requirements in GDP (& GMP): Proposed change: It is proposed to place a reference to Annex 11 and/or to align with wording of Annex 11.	
3.23		Comment: Fraud and sabotage committed by company personnel itself shall not be included in a guidance document. It is proposed to align with wording according to Annex 11, 7.1. Proposed change: *'…by physical and electronic means against ~~wilful or accidental~~ damage.'*	
3.26		Comment: According to Annex 15 qualification should be planned and documented. Proposed change: *'The scope and extent of such qualifications and/or validations should be determined by a documented risk based approach. Qualification and/or validation activities should be planned and documented. ...'*	
3.27		Comment: Common terminology applied suggests to validate processes and to qualify systems and	

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		equipment to verify their correct installation and operation. Proposed change: Change to read: *'…, systems should be qualified ~~validated~~ to ensure correct installation and operation.'*	
3.28		Comment: Annex 15 suggests including the responsible for quality, i.e. the RP into the approval process. Proposed change: *'… should be ~~produced~~ collected by appropriate personnel and approved by the Responsible Person ~~appropriate personnel~~.'*	
4.8		Comment: It is assumed that 'Records' has the same title layout as 'General'. Proposed change: Change layout properties for title.	
4.10		Comment: Customer should be included here as well. Proposed change: *'name and address of the supplier, customer, broker or consignee, as appropriate;'*	
4.10, 5.29 and 5.32		Comment: It is unclear why the batch number should only be included 'where required'. Proposed change: Either specify in which case(s) inclusion of the batch number is required, or delete *'where required'*.	
5.7		Comment: The examples given are considered to be over-prescriptive. It is the risk assessment which should identify and address potential risks. Those might be considerably different from the limited examples given	

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		here. It is proposed to present these examples in a Q&A document at a later stage, as appropriate. Proposed change: Change to read: *'A risk based approach should be used. ~~for this purpose considering: i) searches for the new supplier's reputation or reliability and its authorised activities; ii) certain medicinal products are more likely to be target of falsification; iii) large offers of medicinal product which are generally only available in limited quantities; iv) out of range prices.'~~*	
5.9		Comment: It is unclear whether customers here would include local pharmacies and hospital pharmacies. Proposed change: Clarify wording as to whether or not public and hospital pharmacies are in the scope of this article.	
5.14		Comment: The suspect of any falsification might include more than one (single) batch. It is advised to include the entire consignment as a whole. Proposed change: *'In the event of any suspicion of falsified medicinal product, the consignment or shipment ~~batch~~ affected should immediately be segregated and …'*	
5.18		Comment: The term 'container' has different meanings, including e.g. specific form of primary packaging. 'Outer packaging' or 'goods´ might be more appropriate.	

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		Proposed change: *'Incoming goods ~~containers of medicinal products~~ should be cleaned…'*	
5.20		Comment: FEFO may not always be appropriate. Where customers require single batch supply (tenders, military supplies, some hospital groups) or where site supplies batches out of order (batch release held up for some reason), so later product may be available before older product is released and available. Proposed change: It is proposed to 'qualify' the FEFO statement or to modify to state that this would be the usual or normally expected practice.	
5.25		Comment: The requirement for physical segregation between all these 'special categories' is excessive and impractical (see also under General Comments). Proposed change: *'Where physical segregation is needed, the products and the areas concerned shall be appropriately identified and secured.'*	
5.27		Comment: It is within the scope and purpose of pertinent national laws on environmental protection to address safe and harmless disposal and handling of medicinal products. Proposed change: *'Destruction of medicinal products should be in accordance with national or international requirements for handling, transport and disposal of such products~~, and with due consideration to the~~*	

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		~~*protection of the environment*~~*.'*	
5.29		Comment: FEFO may not always be appropriate. Where customers require single batch supply (tenders, military supplies, some hospital groups) or where site supplies batches out of order (batch release held up for some reason), so later product may be available before older product is released and available. See also under 5.20. Proposed change: It is proposed to 'qualify' the FEFO statement or to modify to state that this would be the usual or normally expected practice.	
5.30		Comment: The sub-heading Packing is not correct, because it suggests to also applying to primary and/or secondary packaging, which obviously is not the intention here. Clarification is required also with regards to the definition of 'sealing', as this would be the transport packaging or tertiary packaging. Proposed change: *'Packing <u>for shipment</u>.'*	
5.33		Comment: The meaning and the context of the term 'free zone' can not be understood. Proposed change: *'<u>This also applies to an exporting wholesale distributor operating from a duty free zone or warehouse.</u>* ~~*This is also the case if the exporting wholesale distributor is operation from a free zone.'*~~	
5.34		Comment: It is unclear how (quality) oversight will be	

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		assured whether a supplier not requiring a wholesale distribution authorisation will comply with the applicable rules for wholesale distribution. Proposed change: Clarify the article.	
6.2		Comment: According to 2.5.v) the Responsible Person is responsible to ensure that customer complaints are dealt with. The text as proposed may bear too high requirements for small distributors/wholesalers. Proposed change: '~~*A person*~~ *Appropriately qualified personnel should be appointed for handling the complaints* ~~*with sufficient supporting personnel to assist him/her.*~~*'*	
6.3		Comment: The wording ´without delay' calls for a requirement which never can be met. The applicable timelines are based on risks involved and are laid down in the respective recall guidance documents. Proposed change: *'The national competent authority should be notified* ~~*without delay*~~ *in a timely manner.'*	
6.4		Comment: 'Any product distribution complaint….' means in practice that all complaints originating from distribution events should be investigated (e.g. damaged packaging). Propose to restrict or further clarify to significant incidents, such as events with direct risk or impacting product quality. Proposed change: *'Any significant product distribution*	

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		complaint, i.e. with potential impact on product quality, should be ….'	
6.9 ii)		Comment: It is not understandable why the limit for returned goods is set to a fixed time of 5 days. Clarification would be welcomed if this refers to calendar days or working days. Based on the product concerned the risks may be higher or lower, resulting in different return times to be considered as reasonable. Proposed change: a rationale for the 5 days is required or the timeframe has to be set based on risk considerations for each product.	
6.9. iii)		Comment: Specifications and predefined conditions 'by definition' include the adjective proper. Proposed change: Change to read: *'…handled under ~~proper specified/predefined conditions~~ their specific storage requirements;'*	
6.9. v)		Comment: Two typographical errors. Proposed change: *'…reasonable evidence that the product was supplied to that customer and…'*	
6.10		Comment: Include appropriate temperature records for transportation and storage. Proposed change: *'- appropriate temperature records for transportation and storage.'*	
6.11		Comment: Disposal would not need approval by the Responsible Person, only return to saleable stock would.	

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		Proposed change*: 'All handling of returned medicinal products including their return to saleable stock ~~or disposal~~ should …'*	
6.15		Comment: The statement may need rephrasing. The meaning of legitimate medicinal products is not defined and understandable (in reality quarantined, rejected etc. goods would be illegitimate too, when applying the same definition). Proposed change: *'Any suspected falsified medicinal products found in the supply chain should be immediately physically and securely segregated ~~from legitimate medicinal products~~.'*	
6.16		Comment: It is not intended to test the procedure itself, but to challenge the processes laid down in the procedure with so called 'fire drills'. Proposed change: *'The processes laid down in the recall procedure should be periodically tested.'*	
6.18-6.20		Comment: The content of delivery documents and records is extensively described already in paragraphs 4.10 and 5.32. It is proposed to add the remaining statement to paragraph 6.18. Distribution records (like delivery slips) conform article 4.10 do not contain all of the information mentioned here. At least a distribution history should be made available (together with other information like phone	

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		numbers etc.) to the Responsible Person. Proposed change: Change to read: *'6.18 The distributor must follow the instructions of a recall message, which should be approved, if required, by the competent authorities. The distribution records should be readily available to the person(s) responsible for the recall.'* Then delete article 6.20.	
8.4		Comment: CAPA is an acronym not familiar to all parties concerned; the meaning is stated in paragraph 3.28. Proposed change: *'...their causes should be determined and the corrective and preventive actions (CAPA) should be documented and followed-up.'*	
Ch. 9 - Principle		Comment: Provided supportive (stability) data are available maintaining the labelled storage condition during transportation seems like an excessive requirement. Proposed change: *'Medicinal products …. indicated on the packaging information, unless otherwise justified.'*	
9.1		Comment: Same as above under Principle. Proposed change*: '…..as described on the packaging information, unless otherwise justified.'*	
9.2		Comment: This article should only apply to significant deviations, which could potentially have an impact on product quality. Any significant deviations occurring	

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		during transportation should also be reported to the MAH/local representative for evaluation of product quality impact (not limited to distributor and recipient). In case of outsourced distribution also the Contract Giver should be informed. Proposed change: Limit to significant deviations only. Include reporting requirement also to the MAH/local representative/ Contract Giver, as appropriate.	
9.5		Comment: This requirement seems rather excessive and will be difficult to enforce. Would this same requirement also apply to e.g. airline pilots, captains of ships and drivers of parcel couriers like DHL, FedEx, TNT and UPS? Moreover there may be different interpretations as to what would be 'relevant areas of GDP.' Proposed change: Delete article 9.5.	
9.12		Comment: The 2nd statement demanding an authorisation on an involuntary basis is imposing a legal threat. Proposed change: Delete 2nd sentence.	
9.12		Comment: The requirement for a wholesale distribution licence for hubs or intermediate storage facilities for the storage of cold chain products (or for any products when stored for more than 24 hours) is excessive and not realistic. Major problems will be encountered e.g. over the weekend (when in some countries no trucks are	

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		allowed on the highways) or during midweek public holidays. The 3rd sentence stipulates requirements which will virtually be impossible to meet. In consequence e.g. all airports worldwide will require wholesale distribution authorisations to simply execute a transfer of cold chain products. Proposed change: Delete article 9.12.	
9.14		Comment: Reword to be clearer. Proposed change: *'Medicinal products should be transported in shipment containers …'* The header for this section then should read: *'Shipment: containers, packaging and labelling'*	
9.15		Comment: Transit storage is not limited to customs only. Transit storage is also happening at hubs and terminals. Proposed change: *'...; the estimated maximum time for transportation including transit storage at ~~customs~~ various locations and the validation status of the ~~packaging and~~ shipment packaging/containers.'*	
9.19		Comment: In order to ensure full visibility of the transport conditions to the Contract Giver (MAH/local representative), it should also be an obligation to provide them with temperature data upon request. This requirement should also be included in the contract.	

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		Proposed change: Include Contract Giver (MAH/local representative) as recipient of transport temperature data as well.	
9.20		Comment: Temperature mapping is considered to be an initial effort to qualify a certain type of refrigerated vehicle. It is proposed to align the wording with paragraph 3.14. Proposed change: '*Refrigerated vehicles should be temperature mapped under representative conditions and mapping should take into account seasonal variations. An initial mapping should be carried out prior to the commencement of use* ~~*This includes temperature mapping under representative conditions and should take into account seasonal variations.*~~*'*	
		Comment: Proposed change:	

Please add more rows if needed.