EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<06 December 2011>

Submission of comments on 'Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use' (SANCO/C8/AM/anD(2010)380358)

Comments from:

Name of organisation or individual
GIRP – European Association of Pharmaceutical Full-line Wholesalers

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).

7 Westferry Circus •CanaryWharf•London E14 4HB •United Kingdom
Telephone +44 (00 7418 8400 **Facsimile** +44 (0)20 7418 8416
-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Good Distribution Practice (GDP) Guidelines aim to ensure that a harmonised level of quality is maintained throughout the distribution chain in all EU Member States, so that medicines distributed to retail pharmacists and other healthcare professionals dispensing medicines to the general public are safe and of unaltered, genuine quality. GDPs therefore are of particular interest to wholesale distributors. The current draft however covers a series of provisions which are only applicable to pharmaceutical manufacturers and are Good Manufacturing Practice (GMP) orientated standards. GIRP is of the view that principles of GDP should not include GMP requirements, especially when wholesale distribution authorisation holders are not permitted to interfere in any way with the actual medicinal product, but are only handling, storing and delivering medicinal products in their secondary packaging. A distinction has to be made between provisions applicable to manufacturers, distributing their products and wholesale distributors. Furthermore, it should be made clear which provisions are only applicable to wholesale distributors of Active Pharmaceutical Ingredients (APIs), as naturally different GDP Guidelines are necessary for this purpose. The proposal in its current state therefore goes far beyond what is necessary to ensure the safe handling, storage and transportation of medicines. Some of the proposed new requirements are overly burdensome to achieve a relatively limited step forward in overhauling a currently well-functioning quality system. Furthermore, the current proposal would lead to major additional costs for wholesale distributors that cannot be covered by current margins, which have	

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	significantly declined throughout the years and lately have been cut severely in several EU countries as part of general austerity measures. Given the fact that Member States and economic operators find themselves in the midst of the worst economic and financial crisis of the past 80 years, neither the economic hardship nor the consequential decrease in service level arising from the proposed new obligations can be justified. While the GDP Guidelines are not necessarily categorised as a formal legislative instrument, they will, as is already the case with the current GDP Guidelines, be implemented into national legislation. Therefore GIRP and its members urge that an impact assessment is carried out prior to the revision of the GDP guidelines in order to be able to weigh the benefits of the suggested measures against their costs. In light of reference in the draft proposal to 'delivery' of medicinal products throughout Chapter 5 and 'transport' of medicinal products in Chapter 9, GIRP would like to see the meaning of both expressions clarified and clearly separated in dedicated Chapters. In this context transport or transportation could be defined as the movement of medicinal products over long distances in bulk quantities from production centers to distribution hubs or warehouses. Delivery could refer to the micro distribution of medicinal products over short distances and within a short time frame from a warehouse or distribution center to persons authorized to distribute medicinal products to the public. Finally, we believe that enumerations ending with vague additions such as "not limited to" should be taken out of the text. Repetitions of text parts, which are already reflected in the Falsified Medicines Directive should also be avoided. The inclusion of definitions to clarify which part of the distribution process is addressed	

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	would be useful as well. Concerning the terms 'container' and 'refrigerated vehicle', we suggest the following: ▪ Transit container: any container used between manufacturer and wholesaler ▪ Delivery container: any container used between wholesale distributor and pharmacy ▪ Refrigerated vehicle: vehicle whose storage area remains constantly between 2 and 8 °C We have taken the liberty to adopt the second column of the below table for our own purposes, by adding the numbers 1 to 3, which reflects a prioritisation of our comments (i.e. a provision numbered 1 would have our highest priority and is of greatest importance to GIRP members due to the high additional cost implication).	

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 … It is necessary to exercise control over the entire chain of distribution objectives by observing good manufacturing practice of medicinal products.	1	Comment: Instead of good manufacturing practice of medicinal products, good distribution practice of medicinal products is applicable. Proposed change (if any): It is necessary to exercise control over the entire chain of distribution objectives by observing good ~~manufacturing~~ ***distribution*** practice of medicinal products.	
1.2 A responsible person should be appointed by the management for each distribution site, who should have defined authority and responsibility for ensuring that a quality system is implemented and maintained.	1	Comment: This requirement does not exist in many EU Member States and would involve major additional costs for wholesale distributors. As GIRP members operate over 1,600 warehouses in Europe, this provision could lead to an annual cost increase of approximately 20 million Euro (detailed calculation can be provided), without improving the current well-functioning system. This provision should be moved to Chapter 2. Proposed change (if any): 1.2 ***The company R***~~r~~esponsible ***P***~~p~~erson should ~~be appointed by the management for each distribution site, who should~~ have defined authority and responsibility for ensuring that a quality system is implemented and maintained ***for all distribution sites***.	
1.4 The size and complexity of distributor's activities should be taken into consideration when developing the quality management system or modifying an existing one.	2	Comment: GDP guidelines have to ensure that every holder of a wholesale distribution authorisation adheres to the same standards and ensures the same quality independently of the size and complexity of the activities as risk is not related to size.	

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		Proposed change (if any): 1.4 ~~The~~ ***Independent of the*** size and complexity of ***a*** distributor's activities ***a quality management system*** should be ***implemented.*** ~~taken into consideration when developing the quality management system or modifying an existing one.~~	
1.7 A change control system should be in place for management of changes to critical processes. This system should incorporate quality risk management principles.	3	Comment: This relates to product quality management in terms of production and is not related to distribution activities. Wholesale distributors are storing, handling and distributing finished products and there is a much lower risk of the actual product being damaged. This requirement refers only to API producers and distributors. Quality risk management principles are part of GMP and should not be included in GDP. Proposed change (if any): 1.7 A change control system should be in place for management of changes to critical processes. ~~This system should incorporate quality risk management principles~~.	
1.8 The quality system should ensure that: i) medicinal products are procured, held, supplied or exported in a way that is compliant with the requirements of GDP; ii) management responsibilities are clearly specified; iii) products are delivered to the right recipients within a satisfactory time period; iv) quality related activities are recorded at the time they are performed; v) deviations from established procedures are documented and investigated;	3	Comment: Comment for vi): The principles of "corrective and preventive actions (CAPA)" are not defined within the current GDP proposal and therefore they should be deleted. This is not needed for GDP purposes as this is a specific instrument related to GMP. Proposed change (if any): v) deviations from established procedures are documented~~, and~~ investigated ***and further actions decided to correct deviations and avoid their re-occurrence.***	

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vi) appropriate corrective and preventive actions (CAPA) are taken to correct deviations and prevent them in line with the principles of quality risk management.		~~vi) appropriate corrective and preventive actions (CAPA) are taken to correct deviations and prevent them in line with the principles of quality risk management.~~	
1.9 The quality management system should extend to the control and review of any outsourced activities. These processes should incorporate quality risk management and include:	3	Comment: The quality management system should only extend to the control and review of outsourced activities, which are related to medicines distribution, storage and handling and not include other necessary business activities (tax advice, accounting, legal advice, etc.). Quality risk management principles are part of GMP and should not be included in GDP. Proposed change (if any): 1.9 The quality management system should extend to the control and review of any outsourced activities ***related to the handling, storage and distribution of finished products***. These processes should ~~incorporate quality risk management and~~ include:	
1.10 Senior management should have a formal process for reviewing the quality management system on a periodic basis. The review should include: i) Measurement of achievement of quality management system objectives; ii) Assessment of performance indicators that can be used to monitor the effectiveness of processes within the quality management system, such as complaints, deviations, CAPA, changes to processes; feedback on outsourced activities; self-assessment processes including risk assessments, and audits; external assessments such as regulatory inspections and findings and customer	3	Comment: Comment for ii): The principles of "corrective and preventive actions (CAPA)" are not defined within the current GDP proposal and therefore they should be deleted. This is not needed for GDP purposes as this is a specific instrument related to GMP. Proposed change (if any): ii) Assessment of performance indicators that can be used to monitor the effectiveness of processes within the quality management system, such as complaints, deviations, ~~CAPA,~~ changes to processes; feedback on outsourced activities; self-assessment processes including risk assessments, and audits; external assessments such	

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audits.		as regulatory inspections and findings and customer audits.	
1.11 The outcome of this management review of the quality management system should be timely and effectively communicated.	3	Comment: It has to be clarified to whom this communication should be addressed. Proposed change (if any): 1.11 The outcome of this management review of the quality management system should be timely and effectively communicated ***internally***.	
1.13 Quality risk management should ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient. The level of effort, formality and documentation of the process should be commensurate with the level of risk. Examples of the processes and applications of quality risk management can be found inter alia in the EU Guidelines to Good Manufacturing Practice5 or publications of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ('ICH').	3	Comment: As distributors are not in direct contact with the patient and are not responsible for the effect of the product on the patient, they can only protect the integrity of the product and thereby be responsible for the product's safety. Quality risk management in this context can only refer to medicinal products in their secondary packaging and be carried out according to the instruction of the marketing authorisation holder. Proposed change (if any): 1.13 Quality risk management should ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the ***product*** ~~patient~~. The level of effort, formality and documentation of the process should be commensurate with the level of risk. ~~Examples of the processes and applications of quality risk management can be found inter alia in the EU Guidelines to Good Manufacturing Practice5 or publications of the International Conference on Harmonisation of Technical~~	

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		~~Requirements for Registration of Pharmaceuticals for Human Use ('ICH').~~	
2.1 The wholesale distributor must designate a person as Responsible Person. 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.	1	Comment: The current wording suggests the presence of the responsible person to be present on site 24 hours per day. The wording needs to be adjusted in order to reflect what is practically possible. There should be the possibility to delegate the responsibilities of the Responsible Person and the person should be reachable. Proposed change (if any): 2.1 The wholesale distributor must designate a person as ***company*** Responsible Person. The ***company*** Responsible Person should fulfil his/her responsibilities personally ***or otherwise appropriately delegate his/her tasks. The company Responsible Person or his/her delegated representative*** should be permanently ~~available~~ ***reachable***. The Responsible Person should meet the conditions provided for by the legislation of the Member State concerned.	
2.3 The qualifications of the Responsible Person should meet the conditions provided by the legislation of the Member State concerned and should be appropriate to fulfill the assigned duties. A degree in Pharmacy is desirable. He/she should have appropriate competence and experience as well as knowledge and training on GDP.	2	Comment: The Responsible Person has to be understood as their company Responsible Person, who can delegate tasks. Proposed change (if any): 2.3 The qualifications of the ***company*** Responsible Person should meet the conditions provided by the legislation of the Member State concerned and should be appropriate to fulfill the assigned duties. A degree in Pharmacy is desirable.	
2.4 The Responsible Person should carry out his/her activities personally in order to ensure the	1	Comment: The company Responsible Person has the right to	

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wholesale distributor can demonstrate GDP compliance and that public service obligations are met.		delegate tasks and remains personally responsible whereas he/she cannot carry out all tasks personally. Furthermore, Public Service Obligations are not in place in all EU Member States. Proposed change (if any): 2.4 The ***company*** Responsible Person should carry out his/her activities personally ***or otherwise appropriately delegate them*** in order to ensure the wholesale distributor can demonstrate GDP compliance and that public service obligations are met ***in countries where it is required by national legislation***.	
2.5 His/her responsibilities include, but are not limited to: … xi) being involved in any decision to quarantine or dispose of returned, rejected, recalled or falsified products; …	3	Comment: This should be seen in context with 2.4. concerning the delegation of responsibilities. Proposed change (if any): xi) being involved in ~~any~~ decision***s*** to quarantine or dispose of returned, rejected, recalled or falsified products;	
2.8 The responsibilities and roles of employees working in key positions to medicinal products quality should be defined in written job descriptions, in which the deputyship arrangements of employees are also laid out.	3	Comment: The term "medicinal products quality" is not relevant here as distributors cannot be made responsible for the quality of medicinal products. We therefore propose to delete this expression. Proposed change (if any): 2.8 The responsibilities and roles of employees working in key positions ~~to medicinal products quality~~ should be defined in written job descriptions, in which the deputyship arrangements of employees are also laid out.	

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2.10 All personnel involved in wholesale distribution activities should be qualified in GDP requirements by training and should have the appropriate competence and experience prior to commencing their tasks.	2	Comment: The idea stated in the Principles of Chapter 2 "All personnel should be aware of the principles of GDP that affect them and should receive initial and continuing training relevant to their responsibilities" should be reflected in this provision. GDP training should focus on the parts relevant for the specific person. Proposed change (if any): 2.10 All personnel involved in wholesale distribution activities should be ~~qualified~~ ***trained*** in ***the*** GDP requirements ***that affect them*** ~~by training~~ and should have the appropriate competence and experience prior to commencing their tasks.	
3.5 Where specific storage conditions are required, control should be adequate to maintain all parts of the relevant storage area within defined temperature, humidity or light parameters.	1	Comment: Storage conditions should only refer to the specific requirements of the products stored. Constant humidity conditions are not required and extremely costly for a whole warehouse. Proposed change (if any): 3.5 Where specific storage conditions are required, control should be adequate to maintain all ***relevant*** parts of the ~~relevant~~ storage area ~~within defined temperature, humidity or light parameters~~ ***according to the required specific conditions***.	
3.9 Unauthorised access to all areas of the authorised premises should be prevented. Prevention measures would usually include, but not be limited to, a monitored intruder alarm system and appropriate access control.	3	Comment: The use of specific security systems such as a monitored intruder alarm system should not be laid down in the GDP guidelines, but rather be adjusted to the specific situation. Proposed change (if any):	

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		3.9 Unauthorised access to all areas of the authorised premises should be prevented~~. Prevention measures would usually include, but not be limited to, a monitored intruder alarm system and~~ ***by*** appropriate access control ***measures***.	
Temperature and Environment Control 3.13 Suitable equipment and procedures should be in place to ensure adequate control of the environment of medicinal products during storage. Environmental factors to be considered include, but are not limited to, temperature, humidity, and cleanliness of the premises.	1	Comment: Humidity control is a disproportionate measure and therefore currently not employed in wholesale distributor warehouses. Wholesale distributors are handling medicines in secondary packaging, which provides sufficient protection against environmental influences inside their facilities. In this respect, humidity control is not necessary and such a provision is Europe-wide not justified. Proposed change (if any): **Temperature~~and Environment~~ Control** 3.13 Suitable equipment and procedures should be in place to ensure adequate control of the ~~environment~~ ***storage area*** of medicinal products~~ during storage~~. Environmental factors to be considered include~~, but are not limited to,~~ temperature, ~~humidity~~, and cleanliness of the premises.	
3.14 Storage areas should be temperature mapped under representative conditions and should take into account seasonal variations. An initial mapping should be carried out prior to the commencement of use. The mapping exercise should be repeated according to the results of a risk assessment exercise or whenever significant modifications are made to the facility or the temperature controlling	1	Comment: Temperature mapping serves to qualify the permanent temperature monitoring should only be carried out once the warehouse is in operation, as this is the only way to map under real conditions. In this respect, critical areas in the warehouse should be tracked and later on captured by the temperature monitoring (worst case analysis). Once the temperature monitoring system is installed, deviations	

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equipment. Temperature monitoring equipment should be located according to the results of the mapping exercise.		from the target temperature are captured and corrected. In this respect, a review of the permanent and seasonal temperature mapping is not necessary. Therefore we would propose the following rewording of the paragraph. Proposed change (if any): 3.14 Storage areas should be temperature mapped under representative conditions~~ and should take into account seasonal variations~~. An initial mapping should be carried out ~~prior to the commencement of use~~***once the warehouse is in operation***. The mapping exercise should be repeated ~~according to the results of a risk assessment exercise or~~ whenever significant modifications are made to the facility or the temperature controlling equipment. Temperature monitoring equipment should be located according to the results of the mapping exercise.	
3.16 Equipment used to control or to monitor the environment of the medicinal product should be calibrated and their correct operation and suitability for purpose verified at defined intervals by the appropriate methodology.	1	Comment: Only the sensors of the temperature monitoring system have to be calibrated, which is not the case for the sensors in the control system such as the air-conditioning. This is not necessary because the result is checked through the temperature monitoring system. Proposed change (if any): 3.16 Equipment used ~~to control or to~~ monitor the environment of the medicinal product, should be calibrated and their correct operation and suitability for purpose verified at defined intervals by the appropriate methodology.	
3.19 Adequate records of repair, maintenance and calibration activities for key equipment should be made and the results should be retained. Relevant	1	Comment: We assume that "equipment utilised in conjunction within the onward supply chain" is used to check temperatures	

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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.		during transport. We would like to see the "but not to be limited to" part deleted as it is too vague and the GDPs should provide a clear standard. Humidity recording devices as well as air handling units are extremely expensive and therefore currently not employed. We believe that such equipment is out of proportion for finished medicines in their secondary packaging. Proposed change (if any): 3.19 Adequate records of repair, maintenance and calibration activities for key equipment should be made and the results should be retained. Relevant pieces of equipment would include ~~(but not be limited to)~~ cold stores, refrigerators, thermo hygrometers, or other temperature recording devices~~, air handling units~~ and any equipment utilised in conjunction within the ~~onward~~ supply chain ***under the responsibility of the wholesale distributor***.	
3.24 Data should be protected by backing up at regular intervals. Back up data should be stored for a period stated in national legislation but at least 5 years at a separate, secure location.	3	Comment: "Data" should be understood only as data relevant for the compliance with Good Distribution Practice. "Separate" refers to a mandatory storage at another location, whereas the same level of security can be achieved through back-up systems. The provision should contain the necessary flexibility. Proposed change (if any): 3.24 Data should be protected by backing up at regular intervals. Back up data should be stored for a period stated in national legislation but at least 5 years at a ~~separate,~~ secure location.	

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3.26 Wholesale distributors should identify what qualification and/or validation work is necessary to demonstrate control of key aspects of their activities. The scope and extent of such validations should be determined by a documented risk assessment approach. Validation activities should be planned and documented. The plan should specify acceptance criteria.	1	Comment: Not all systems have an impact on product quality, for example IT systems. Wholesale distributors should determine which of their processes may affect product quality and therefore require qualification and/or validation, as otherwise this provision could lead to extremely high additional costs. Acceptance criteria cannot be specified before a validation plan is in place. Proposed change (if any): 3.26 Wholesale distributors should identify what qualification and/or validation work is necessary to demonstrate control of key aspects of their ~~activities~~ ***storage and transport processes***. The scope and extent of such validations should be determined by a ~~documented~~ risk assessment approach. Validation activities should be planned and documented. ~~The plan should specify acceptance criteria.~~	
3.27 Prior to implementation and after any significant changes or upgrades, systems should be validated to ensure correct installation and operation.	1	Comment: This article should be rephrased to keep the wording adopted in the previous provision consistent. We furthermore suggest replacing "Prior" by "Accompanying" as this wording correlates with the change from "systems" to "processes". Proposed change (if any): 3.27 ***Accompanying*** ~~Prior to~~ implementation, ~~and after~~ any significant changes or upgrades ***to storage and transport processes***~~, systems~~ should be validated to ensure correct installation and operation.	
3.28 A validation report should be prepared summarising the results obtained and commenting	1	Comment: Wholesale distributors are not in a position to anticipate	

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on any observed deviations. The principles of corrective and preventive actions (CAPA) should be applied where necessary. Evidence of satisfactory validation and acceptance of a process or piece of equipment should be produced and approved by appropriate personnel.		deviations from established processes. Preventive action does therefore not apply. Furthermore, the principles of "corrective and preventive actions (CAPA)" are not set out in the GDPs. Proposed change (if any): 3.28 A validation report should be prepared summarising the results obtained and commenting on any observed deviations. ~~The principles of corrective and preventive actions (CAPA) should be applied where necessary.~~ Evidence of satisfactory validation and acceptance of a process or piece of equipment should be produced and approved by appropriate personnel. ***Deviations from established procedures should be documented and further actions decided to correct deviations and avoid their re-occurrence.***	
4 Good documentation constitutes an essential part of the quality management system. Clearly written documentation prevents errors from spoken communication and permits tracing of batch history. Instructions, procedures, and records should be free from errors and each employee should have access to such instructions and procedures concerning his or her activities at any time.	2	Comment: Reference to the "tracing of batch history" by means of documentation is an inappropriate requirement in GDP, as batch recording requirements are laid down in the Directive and/or national legislation. This would be a step beyond legislative requirements. Proposed change (if any): 4 Good documentation constitutes an essential part of the quality management system. Clearly written documentation prevents errors from spoken communication ~~and permits tracing of batch history~~. Instructions, procedures, and records should be free from errors and each employee should have access to such instructions and procedures concerning his or her activities at any time.	
4.3 Documentation should be approved, signed and	3	Comment:	

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dated by appropriate authorised persons, as required. It should not be hand-written; although, where documents require the entry of data, sufficient space should be provided for such entries.		Certain records require hand written completion. Proposed change (if any): 4.3 Documentation should be approved, signed and dated by appropriate authorised persons, as required. ***Preferably, the documentation*** ~~It~~ should not be hand-written***.*** ~~; although, ~~***W***~~w~~here documents require the entry of data ***by hand***, sufficient space should be provided for such entries.	
4.10 Records should include the following information: date; name of the medicinal product; quantity received, supplied or brokered; name and address of the supplier, broker or consignee, as appropriate; and batch number where required.	3	Comment: It should be added that the batch number be recorded where required by legislation. Proposed change (if any): 4.10 Records should include the following information: date; name of the medicinal product; quantity received, supplied or brokered; name and address of the supplier, broker or consignee, as appropriate; and batch number where required ***by legislation***.	
4.11 Records should be made at the time each operation is taken and in such a way that all significant activities or events are traceable.	2	Comment: Technically speaking an index must be prepared each time any activity or event occurs otherwise it is not possible to trace events or activities. This is not feasible and significantly disproportionate to the intended aim. Therefore, this should only apply to "significant" activities or events and be related only to GDP. Proposed change (if any): 4.11 Records should be made ***without undue delay*** ~~at the time each operation is taken and~~ in such a way that all significant activities or events ***related to the wholesale distribution of medicines can be followed*** ~~are traceable~~.	

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5 All actions taken by the distributor should ensure that the identity of the medicinal product is not lost and that wholesale distribution of medicinal products is handled according to the specifications given on the packaging information. The wholesale distributor should use all means available to ensure that the source of all arriving products is known to minimise the risk of falsified medicinal products entering the legal supply chain.	2	Comment: The proposal appears to be missing two concepts: first the identification of the medicinal products and second the checking of whether the product is falsified or not. The process for verifying the identity of the medicinal products will be set out in the Delegated Acts of the Falsified Medicines Directive. Which records have to be kept is defined by law so that there is no need for this provision, which can only lead to confusion. The same applies for the source of the arriving product as the procedure of source verification is laid down by law. A pre-requisite for handling products according to the information given on the package is that there are harmonised definitions available especially concerning temperature. It should be clarified that wholesale distributors are only able to read information from the outer packaging. Proposed change (if any): 5 All actions taken by the distributor should ensure that the ~~identity of the medicinal product is not lost and that wholesale distribution of~~ ***immediate source of the*** medicinal products is ***known and that the products are checked*** ~~handled~~ according to the ~~specifications~~ ***information*** given on the ***outer*** packaging***,*** ~~information~~ ***as defined in the relevant legislative instruments***. The wholesale distributor should use all means available ~~to ensure that the source of all arriving products is known~~ to minimise the risk of falsified medicinal products entering the legal supply chain.	
5.2 Where the medicinal product is obtained from another wholesale distributor, wholesale distributors must verify compliance with the	2	Comment: Once the EurdraGDP Community database is established, it should be possible for wholesale distributors to verify	

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principles and guidelines of good distribution practices by the supplying wholesale distributor. This includes verifying whether the supplying wholesale distributor holds a wholesale distribution authorisation.		compliance of the supplying wholesale distributor with the principles and guidelines of good distribution practices by checking that the supplying wholesale distributor holds a wholesale distribution authorisation and complies with the principles and guidelines in the GDP. Proposed change (if any): 5.2 Where the medicinal product is obtained from another wholesale distributor, wholesale distributors must ***check the Community database to*** verify compliance with the principles and guidelines of good distribution practices by the supplying wholesale distributor. This ~~includes~~ ***means*** verifying whether the supplying wholesale distributor holds a ***valid*** wholesale distribution authorisation.	
5.4 Purchase of medicinal products should be controlled by written procedures. The supply chain of medicinal products should be known and documented.	3	Comment: As a result of this sentence, wholesale distributors would have to look for the pedigrees of all medicines. Therefore this part of the sentence should be deleted. Proposed change (if any): 5.4 Purchase of medicinal products should be controlled by written procedures. ~~The supply chain of medicinal products should be known and documented.~~	
5.5 Appropriate qualification should be performed prior to any procurement. The selection, including qualification and approval of suppliers is an important operation. This operation should be controlled by a standard operating procedure and the results documented and periodically rechecked.	3	Comment: Once the EurdraGDP Community database is established, it should be possible for wholesale distributors to verify compliance of the supplying wholesale distributor with the principles and guidelines of good distribution practices by checking that the supplying wholesale distributor holds a wholesale distribution authorisation and complies with the principles and guidelines in the GDP. Proposed change (if any):	

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		5.5 Appropriate qualification should be performed prior to any procurement. The selection, including qualification and approval of suppliers is an important operation. ***Verification of such can be achieved through checking the EudraGDP database.*** This operation should be controlled by a standard operating procedure and the results documented and periodically rechecked.	
5.7 Due-diligence should be carried out by the distributor when entering a new contract with new suppliers in order to assess the suitability, competence and the reliability of the other party to supply medicinal products. 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.	2	Comment: Due-diligence only needs to be carried out by the distributor when entering a contract with new suppliers other than the marketing or the manufacturing authorisations holder. Proposed change (if any): 5.7 Due-diligence should be carried out by the distributor when entering a new contract with new suppliers ***other than marketing or manufacturing authorisations holder*** in order to assess the suitability, competence and the reliability of the other party to supply medicinal products. ~~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.~~	
5.10 Wholesale distributors should monitor their transactions and investigate any irregularity in sale patterns to avoid diversion of medicinal products at risks of being misused and to ensure fulfilling any public service obligation imposed upon	2	Comment: It is not within the responsibility of wholesale distributors to enforce the legislation and to investigate irregularities. However, this can be envisages for specific product categories.	

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them.		Furthermore, Public Service Obligations are not in place in all EU Member States. Proposed change (if any): 5.10 Wholesale distributors should monitor their transactions and investigate any irregularity in sale patterns ***of narcotics, explosive or other dangerous substances*** to avoid diversion of medicinal products at risks of being misused and to ensure fulfilling any public service obligation ***in countries where national law*** imposed~~***s such***~~ upon them.	
5.12 The purpose of the receiving function is to ensure that the arriving consignment is correct, the medicinal products originate from approved suppliers and that they have not been damaged or altered during transportation.	3	Comment: It is not feasible for the receiver to ensure that the consignment is correct in terms of having to check that products have not been exposed to high temperature or radioactivity for example. Proposed change (if any): 5.12 The purpose of the receiving function is to ensure that the ***details of the*** arriving consignment ***are*** ~~is~~ correct, the medicinal products originate from ~~approved~~ ***licensed*** suppliers and that they have not been ***visibly*** damaged ~~or altered~~ during transportation.	
5.15 Batches of medicinal products intended for the Union market should not be transferred to saleable stock before assurance has been obtained in accordance with written procedures, that they are authorised and released for sale for the market in question.	1	Comment: This does not apply to wholesalers as it is the responsibility of manufactures in the first instance. Proposed change (if any): 5.15 ***Manufacturers should not transfer b***~~B~~atches of medicinal products intended for the Union market ~~should not be transferred~~ to saleable stock before assurance has been obtained in accordance with written procedures, that they are authorised and released for sale for the market in question.	

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5.17 Medicinal products should be stored separately from other products and protected from harmful effects of light, temperature, moisture or other external factors. Particular attention should be paid to products where specific storage conditions are required.	1	Comment: This requirement is impossible to implement as currently products in the warehouses are stored according their frequency in demand and the business of full-line wholesalers focuses of delivering to pharmacies all products they need. Medical product should however be protected from harmful effects of light, temperature, moisture or other external factors. Proposed change (if any): 5.17 Medicinal products should be ~~stored separately from other products and~~ protected from harmful effects of light, temperature, moisture or other external factors. Particular attention should be paid to products where specific storage conditions are required.	
5.20 Steps should be taken to ensure stock rotation according to the expiry dates of batches of medicinal products.	2	Comment: This requirement is impractical and not workable unless changes are made to requirements for manufactures to deliver according to FEFO. Proposed change (if any): 5.20 Steps should be taken to ensure stock ~~rotation~~ ***organisation*** according to the expiry dates ~~of batches~~ of medicinal products ***if deliveries can be received from the supplier in this way***.	
5.21 Medicinal products should be handled and stored in such a manner as to prevent spillage, breakage, contamination and mix-ups. Medicinal products should not be stored directly on the floor.	2	Comment: Medicinal products in secondary packaging should not be stored directly on the floor. Proposed change (if any): 5.21 Medicinal products should be handled and stored in such a manner as to prevent spillage, breakage,	

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		contamination and mix-ups. Medicinal products **in secondary packaging** should not be stored directly on the floor.	
5.23 Stock inventories should be performed regularly. Timings should be defined using a risk based approach. Irregularities should be investigated and documented.	3	Comment: The frequency and timing of inventories are sometimes required by law and are also partly carried out at the discretion of each wholesaler (e.g. for expensive products, etc.) This freedom should be maintained. Proposed change (if any): 5.23 Stock inventories should be performed regularly***, in line with national requirements.*** ~~Timings should be defined using a risk based approach. Irregularities should be investigated and documented.~~	
5.24 If required, medicinal products should be stored in segregated areas, which are clearly marked and their access restricted to authorised personnel. Any system replacing physical segregation such as electronic segregation based on a computerised system shall provide equivalent security and should be validated.	1	Comment: This requirement is impossible to implement as currently products in the warehouses are stored according their frequency in demand and the business of full-line wholesalers focuses of delivering to pharmacies all products they need. Deviations are laid down in national law for products such as narcotics and cold chain products. Proposed change (if any): 5.24 ~~If required,~~ ***~~m~~ Medicinal*** products should be stored ***separately from each other*** ~~in segregated areas, which are clearly marked~~ and ~~their~~ access ***to storage areas should be*** restricted to authorised personnel. Any system replacing physical segregation such as electronic segregation based on a computerised system shall provide equivalent security ~~and should be validated~~.	
5.29 Controls should be in place to ensure the	3	Comment:	

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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. The batch number should be recorded, where required.		This requirement is impractical and not workable unless changes are made to requirements for manufactures to deliver according to FEFO. Proposed change (if any): 5.29 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. The batch number should be recorded, where required~~. ***Preferably, the product should be picked on a first expired first out basis. Where required by national legislation the batch number should be recorded.***	
5.30 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 sealed.	3	Comment: It should be clarified that this requirement is aimed at the shipment from production sites to wholesale distributors. It is not workable that the delivery units sent to pharmacy customers are sealed. A definition of container or transit container should be added. Proposed change (if any): 5.30 Products should be packed in a way to avoid breakage, contamination and theft ***whilst in transit***. The packing should be adequate to maintain ***the quality of the medicinal products during*** ~~the storage conditions of the product during~~ transport. The ***transit*** containers in which medicinal products are shipped should be sealed.	
5.32 For all supplies to a person authorised or entitled to supply medicinal product to the public, 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;	1	Comment: The investment to implement a tracking of deliveries is prohibitive and therefore this should apply only for bulk deliveries and medicinal products in transit. The applicable transport and storage conditions should be on the pack of the medicinal product.	

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quantity supplied; name and address of the supplier, name and delivery address of the consignee (actual physical storage premises, if different) and applicable transport and storage conditions. Records should be kept so that the actual physical journey undertaken by the product can be tracked.		Proposed change (if any): 5.32 For all supplies to a person authorised or entitled to supply medicinal product to the public, 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~~ ***as*** required ***by Directive 2011/62/EU***; quantity supplied; name and address of the supplier, name and delivery address of the consignee (actual physical storage premises, if different) ~~and applicable transport and storage conditions. Records should be kept so that the actual physical journey undertaken by the product can be tracked.~~ ***This information can be also transmitted electronically to the client. Records should be kept so that the receiver of products carrying safety features can be identified.***	
6.9 Medicinal products which have left the premises of the distributor should only be returned to saleable stock if: i) the medicinal products are in their unopened and undamaged secondary packaging and in good condition; 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 of original dispatch; iii) it is demonstrated that the medicinal products have been transported, stored and handled under proper specified/predefined conditions; iv) they have been examined and assessed by a sufficiently trained and competent person authorised to do so;	1	Comment: It is not acceptable that the distributing wholesaler should carry the commercial risk in case of returns as in case the conditions i)-v) are not fulfilled, he cannot return the products to saleable stock. Whereas he should not be allowed to accept them as returns if conditions i), iii), iv) and v) are not fulfilled. Provision v) will make it very hard to accept returns from pharmacies. Proposed change (if any): 6.9 Medicinal products which have left the premises of the distributor should only be ***accepted as*** return***s*** ~~ed to saleable stock~~ if: ii) medicinal products return~~s~~***ed*** from a customer not holding a wholesale distribution authorisation should only be ***accepted as returns*** ~~returned to saleable stock~~ if	

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v) the distributor has reasonable evidence that the product was supplied to that customer and the batch number of the dispatched product is known, that a copy of the original delivery note is attached and that there is no reason to believe that the product has been falsified.		they ~~were~~ ***are*** returned within five days of original dispatch. ***The customer returning the medicinal products should guarantee that the product was correctly handled and did not leave his/her premises during the time under his/her control;*** iii) it is demonstrated ***by the customer*** that the medicinal products have been transported, stored and handled under proper specified/predefined conditions; v) the distributor has reasonable evidence that the product was supplied to that customer ***by him*** and ~~the batch number of the dispatched product is known,~~ ***a reference to the delivery note (number) is made or*** a copy of the original delivery note is attached and that there is no reason to believe that the product has been falsified ***by verifying the status of the medicinal product in the repository***.	
6.10 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. This evidence should include but is not limited to the following: - delivery to customer - opening of the packaging - examination of the product - returning of the product to the packaging and sealing of the packaging - collection and return to the distributor - return to the distribution site refrigerator	2	Comment: It is not possible to verify that medicinal products requiring low temperature storage conditions have been kept all the time within the required storage conditions. Therefore medicinal products requiring special storage conditions cannot be accepted as returns. Proposed change (if any): 6.10Medicinal products ***with special storage conditions should not be accepted as returns from customers.*** ~~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. This evidence should include but is not limited to the following:~~	

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		~~- delivery to customer~~ ~~- opening of the packaging~~ ~~- examination of the product~~ ~~- returning of the product to the packaging and sealing of the packaging~~ ~~- collection and return to the distributor~~ ~~- return to the distribution site refrigerator~~	
6.20 The distribution records should be readily available to the person(s) responsible for the recall, and should contain sufficient information on distributors and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batches and quantities delivered), including those for exported products and medicinal product samples.	3 first part 1 second part	Comment: The first change concerns recall procedures and it is important to mention that it is faster and safer to inform all customers (as done in all recall cases). The second proposed change relates to ensuring consistency of the GDP with the Falsified Medicines Directive. Proposed change (if any): 6.20 The distribution records should be readily available to the person(s) responsible for the recall, and should contain sufficient information on distributors and ~~directly supplied~~ all customers (with addresses, phone and/or fax numbers inside and outside working hours, batches ***for medicinal products bearing safety features as required by legislation*** and quantities delivered), including those for exported products and medicinal product samples.	
6.22 The progress of the recall process should be recorded and a final report issued, including reconciliation between the delivered and recovered quantities of the medicinal products.	3	Comment: The commercial aspects related to this requirement are not clear and wholesale distributors should not have to incur the cost of the procedure. Reconciliation of delivered and recovered quantities can only be validly made by the manufacturer of the medicinal products. Proposed change (if any): 6.22 The progress of the recall process should be	

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		recorded and a final report issued~~, including reconciliation between the delivered and recovered quantities of the medicinal products~~.	
7 Contract Operations When outsourcing activities a written contract should be drawn up. Both the contract giver and the contract acceptor must hold a distribution authorisation. The written and signed contract should cover all wholesale distribution activities and clearly establish the duties and responsibilities of each party. Written contracts should be established for any activity likely to impact on GDP related activities.	1	Comment: Outsourced activities subject to this requirement should be limited to activities relevant for distribution, storage and handling of medicinal products only. A distribution authorisation should not be necessary for the contract acceptor when the activities are not directly related to the core activities connected to the medicinal products (a notable example of an activity is the sub-contracting of pure transport activities, another example is cleaning activities, etc.). Proposed change (if any): 7 Contract Operations When outsourcing activities a written contract should be drawn up. Both the contract giver and the contract acceptor***, when his activities require a wholesale distribution authorisation by law,*** must hold a distribution authorisation. The written and signed contract should cover all ***outsourced*** wholesale distribution activities and clearly establish the duties and responsibilities of each party. Written contracts should be established for any activity likely to impact on GDP related activities.	
7.2 The Contract Giver is responsible for assessing the competence of the Contract Acceptor to carry out successfully the work required and for ensuring by means of the contract and through audits that the principles and guidelines of GDP are followed. An audit of the Contract Acceptor should be performed before the beginning of the outsourced	3	Comment: Auditing contract acceptors for all activities is an impractical and disproportionate measure – it is not workable/not necessary that all contract acceptors be audited (cleaning contracts). Proposed change (if any):	

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activities and afterwards audits should be done periodically.		7.2 ***In relevant circumstances*** T***t***he Contract Giver is responsible for assessing the competence of the Contract Acceptor to carry out successfully the work required and for ensuring by means of the contract and through audits that the principles and guidelines of GDP are followed ***if the Contract Acceptor has no distribution authorisation***. An audit of the Contract Acceptor should be performed before the beginning of the outsourced activities and afterwards audits should be done periodically.	
7.6 The Contract Acceptor should not pass to a third party any of the work entrusted to him under the contract without the Contract Giver's prior evaluation and approval of the arrangements and an audit of the third party. Arrangements made between the Contract Acceptor and any third party should ensure that the wholesale distribution information is made available in the same way as between the original Contract Giver and Contract Acceptor.	3	Comment: An audit is these circumstances is not necessary and a disproportionate measure. Proposed change (if any): 7.6 The Contract Acceptor should not pass to a third party any of the work entrusted to him under the contract without the Contract Giver's prior evaluation and approval of the arrangements and an audit of the third party ***by the Contract Acceptor***. Arrangements made between the Contract Acceptor and any third party should ensure that the wholesale distribution information is made available in the same way as between the original Contract Giver and Contract Acceptor.	
8.3 Audit of subcontracted activities should be a part of the self-inspection programme.	3	Comment: It is important that the audit is limited to activities directly related to wholesale distribution. Proposed change (if any): 8.3 Audit of subcontracted activities ***concerning handling, storage and transport of medicinal products*** should be a part of the self-inspection programme.	

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8.4 All self-inspections should be recorded. Reports should contain all the observations made during inspections. A copy of the report should be provided to the senior management and other relevant persons. In the event that irregularities and/or deficiencies are observed, their causes should be determined and the CAPA should be documented and followed-up.	2	Comment: Different quality standards are applied in different countries and the CAPA should not be mandated. Proposed change (if any): 8.4 All self-inspections should be recorded. Reports should contain all the observations made during inspections. A copy of the report should be provided to the senior management and other relevant persons. In the event that irregularities and/or deficiencies are observed, their causes should be determined ~~and the CAPA should be documented and followed-up~~.	
9 It is the responsibility of the wholesale distributor that, during the supply of medicinal products, the transport conditions are such as to maintain the quality of the product, to protect against breakage, adulteration and theft, and to ensure appropriate environmental conditions are maintained during transport. Adequate precautions should be taken to this effect. Medicinal products should be transported in accordance with the storage conditions indicated on the packaging information.	1	Comment: There is no direct link between storage and transport temperature. For the purposes of transportation it is important that the specific transportation conditions as determined by the manufacturer are kept. It also has to be taken into account that the transportation times for wholesale distributors are very short. Proposed change (if any): 9 It is the responsibility of the wholesale distributor that, during the supply of medicinal products, the transport conditions are such as to maintain the quality of the product, to protect against breakage, adulteration and theft, and to ensure appropriate ~~environmental~~ ***temperature*** conditions are maintained during transport. Adequate precautions should be taken to this effect. Medicinal products should be transported in accordance with the~~ storage~~ ***transport*** conditions indicated~~ on the packaging information.~~ ***by the manufacturer. Due***	

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		account should be taken of the temperature parameters of the stability data of the medicinal product.	
9.1 The required storage conditions for medicinal products should be maintained during transportation within the defined limits as described on the packaging information.	1	Comments: A distinction should be between 'storage temperature' and 'transportation temperature' for the purposes of defining the requirements for transportation. There is no direct link between storage and transport temperature. For the purposes of transportation it is important that the specific transportation conditions as determined by the manufacturer are kept. It also has to be taken into account that the transportation times for wholesale distributors are very short. Proposed change (if any): 9.1 The ~~required storage~~ ***transportation*** conditions for medicinal products should be maintained during transportation within the defined limits as described ~~on the packaging information~~ ***by the manufacturer***.	
9.2 If a deviation has occurred during transportation, this should be reported to the distributor and recipient of the affected medicinal products.	3	Comment: Due to short delivery durations minor deviations are not detrimental to the medicinal products and only significant deviations need to be reported. Proposed change (if any): 9.2 If a ***significant*** deviation ***from the delivery duration*** has occurred during transportation, this should be reported to the ***wholesale*** distributor and recipient of the affected medicinal products.	
9.7 Equipment used for temperature monitoring during transport within vehicles and/or containers, should be maintained and calibrated at regular	2	Comment: At the wholesale distribution level, the delivery container provides sufficient protection to fulfil this requirement.	

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intervals at least once a year.		No calibration is necessary because of short delivery times at wholesale level. There should be no obligation for full active temperature monitoring within vehicles on wholesale level, because it is out proportion. Proposed change (if any): 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 Deliveries should be made directly to the address stated on the delivery note and must be handed into the care of the consignee. Medicinal products should not be left on alternative premises.	1	Comment: Wholesale distributors deliver products to several pharmacies during their delivery route and not directly from the distribution centre to individual pharmacists. If wholesale distributors have an obligation to deliver directly into the hands of the pharmacists this will prevent wholesale distributors from delivering over-night and using existing methods for deliveries such as leaving the deliveries inside the pharmacist premises through night time delivery hatches. Delivery times would significantly increase. Proposed change (if any): 9.9 Deliveries should be made ~~directly~~ to the address stated on the delivery note and must be ~~handed~~ ***delivered*** into the care ***or the premises*** of the consignee. Medicinal products should not be left on alternative premises.	
9.11 If transportation is sub-contracted to a third party then the contract should encompass the requirements contained within Chapter 7. In addition the contractors should be fully aware of all	1	Comment: Only general information is provided to sub-contractors, no details on medicinal products are given for security reasons.	

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relevant conditions applicable to the storage and transportation of medicinal products.		Wholesale distributors are not in a position to give contractors used for transportation full details of the contents of the container. Proposed change (if any): 9.11 If transportation is sub-contracted to a third party then the contract should encompass the requirements contained within Chapter 7. In addition the contractors should be fully ~~aware of all relevant conditions applicable to the storage and transportation of medicinal products~~***informed by the wholesale distributor of all relevant transport conditions of the actual delivery.***	
9.12 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. Where medicinal products are held on the premises for longer than this defined time limit, the hub will be deemed to be acting as a storage site and required to obtain a wholesale distribution authorisation. For refrigerated product any storage at a transportation hub for any period of time would require that premises to hold a wholesalers distribution authorisation.	1	Comment: In countries with long distances and sparse population there is a lack of practical possibilities to handle distribution without any transit storage over weekends. It should therefore be clarified that transit storage at hubs over weekends is allowed without a wholesaler distribution authorisation for that hub, while correct temperature conditions must be assured regardless. Proposed change (if any): 9.12 Where transportation hubs are utilised in the supply chain, a maximum time limit of normally 24 hours***, excluding weekends,*** should be set to await the next stage of the transportation route. Where medicinal products are held on the premises for longer than this defined time limit, the hub will be deemed to be acting as a storage site and required to obtain a wholesale distribution authorisation. For refrigerated product ***all cross-docking*** ~~any storage~~ at a transportation hub for any period of time would require ~~that premises to hold a wholesalers distribution authorization~~ ***facilities and routines for securing***	

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		required storage conditions.	
9.14 Medicinal products should be transported in containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination.	3	Comment: Adverse effects are strictly defined by law. For the purpose of GDP it is only relevant to ensure that the quality of the products is maintained. Proposed change (if any): 9.14 Medicinal products should be transported in ~~containers~~ ***a way*** that ~~have no adverse effect on~~ ***maintains*** the quality of the products, and that offer adequate protection from external influences, including contamination.	
9.16 Containers should bear labels providing sufficient information on handling and storage requirements and precautions to ensure that the products are properly handled and secured at all times. The containers should enable identification of the contents of the containers and the source.	2	Comment: The last sentence should be deleted for security reasons. At the wholesale distribution levels containers may also refer to delivery containers and it is more precise for such requirements to refer to transit containers. Proposed change (if any): 9.16 ***Transit*** ~~C~~***containers*** should ~~bear labels~~ ***provide***~~*ing*~~ sufficient information on handling and storage requirements and precautions to ensure that the products are properly handled and secured at all times. ~~The containers should enable identification of the contents of the containers and the source.~~	
9.19 Validated temperature-control systems (e.g. thermal packaging, temperature-controlled containers, and refrigerated vehicles) should be used to ensure correct transport conditions are maintained between the distributor and customer. Customers should be provided with a temperature data to demonstrate that products remained within the required temperature storage conditions during	1	Comment: Equipment has to be qualified, but should not have to be validated. Wholesale distributors transport under GDP conditions, so no temperature data to customers are necessary. Furthermore, this is a problem of time and volume. Wholesale distributors are not in a position to give monitoring values for their deliveries to customers. Due	

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transit, if requested.		to the fact that many customers are delivered within a very short time fram, the requirement to provide temperature data to customers will have an impact on the speed of delivery. Proposed change (if any): 9.19 ***For cold chain products qualified equipment*** ~~Validated temperature control systems~~ (e.g. thermal packaging, temperature-controlled containers, ~~and~~ **or** refrigerated vehicles ***(2-8 degrees)***) should be used to ensure correct transport conditions are maintained between the ***manufacturer,*** distributor and customer. ~~Customers should be provided with a temperature data to demonstrate that products remained within the required temperature storage conditions during transit, if requested.~~	
9.20 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. This includes temperature mapping under representative conditions and should take into account seasonal variations. Customers should be provided with data to demonstrate that products remained within the required temperature storage conditions during transportation, if requested.	1	Comment: There should be no distinction between passive and insulated vehicles and active temperature controlled and refrigerated vehicles. Proposed change (if any): 9.20 If refrigerated ***(2 – 8 degrees)*** 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. This includes temperature mapping under representative conditions and should take into account seasonal variations. ~~Customers should be provided with data to demonstrate that products remained within the required temperature storage conditions during transportation, if requested.~~	

Please add more rows if needed.