



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

**29.12.2010**

## 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

Polish Industrial Gases Association, WG-4 "Medical Gases"

*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 <i>(To be completed by the Agency)</i>	General comment (if any)	Outcome (if applicable) <i>(To be completed by the Agency)</i>
	<p>The document doesn't reflect specific storage and transportation conditions related do medicinal gases. These are strictly combined with specific safety (ADR or fire protection) requirements.</p> <p>In some member countries the proposed regulations can be taken directly and when there will be no exception for medicinal gases in some particular paragraphs there will be not possible to meet all requirements and perform all activities as required by different legal regulations.</p>	

## 2. Specific comments on text

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
Page 12, lines 12-17		<p>Comment: Storage areas for medical gases due to safety reasons are not temperature conditioned and can vary i.e. from -30°C to 60°C</p> <p>Proposed change (if any): In the beginning of the Para 3.13 should be added "<i>Where specific storage conditions are required</i>".</p>	
Page 17, lines 18-19		<p>Comment: It should be specified where cleaning of the containers should take place. On the vehicle or inside the warehouse, in which area?</p>	
Page 17, lines 26-28		<p>Comment: Some containers with medical gases (portable vessels with liquid gases) due to their construction are stored directly on the floor.</p> <p>Proposed change (if any): The requirement should be removed or added "<i>Where it is possible</i>" or "<i>Except of medical gases</i>".</p>	
Page 18, line 18		<p>Comment: Transportation conditions of medical gases in pallets do not</p>	

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
		<p>allow to have sealed containers during the entire transportation time.</p> <p>Proposed change (if any): The requirement should be removed or should be added "<i>Where it is possible</i>" or "<i>Except of medical gases</i>".</p>	
Page 28, lines 4-8		<p>Comment: Safety reasons do not allow to have "closed space" during transportation of medical cases (fire or asphyxiation risk), so usage of thermal packing or thermal controlled containers is not possible</p> <p>Proposed change (if any): There should be added an exception for medical gases.</p>	

Please add more rows if needed.