



The Consumer Voice in Europe

Public hearings

BEUC response to the EMA public consultation

Contact: **Ilaria Passarani** – health@beuc.eu

Ref.: BEUC-X-2014-075 - 14/10/2014

Stakeholder number <i>(To be completed by the Agency)</i>	Comment	Outcome (if applicable) <i>(To be completed by the Agency)</i>
General comment	<p>Public hearings can be an excellent tool to provide more information on the actual use of medicine and to apply risk minimization measures that are better suited for consumers. To allow for broader participation and to maximise the use of resources, EMA should ensure that all public hearings are systematically live-broadcast and web streamed.</p> <p>It is important to take into account that not all consumers have the economic capacity to travel where the meeting is held, if this is not in their own country. If travel costs are not covered only affluent individuals and organizations can participate.</p>	
Lines 42 - 44	<p>Comment: To enhance stakeholders' and consumers' participation is convenient to take advantage of digital technological achievements.</p> <p>Proposed change (if any): Different modalities of participation, physical attendance and online participation, will help to ensure that as many citizens as possible....</p>	
Lines 54 - 55	<p>Comment: It would be useful to open the discussion also to non- English speaking people. Not everybody speaks English or understands it. Conducting the hearings in English only will undermine their added value and would exclude a large number of interested individuals and organizations.</p> <p>Proposed change (if any): Public hearing could be held in national agencies in their own language and the views are sent to PRAC. Translation at least in the 3 working languages</p>	

Stakeholder number <i>(To be completed by the Agency)</i>	Comment	Outcome (if applicable) <i>(To be completed by the Agency)</i>
	<p>of the European Commission (English, French and German) should be foreseen. A summary of the views discussed should be translated and published in several EU languages.</p>	
Line 71	The proposal of one of the members of the PRAC to organise a public hearing should be reported in the minutes of the PRAC.	
Line 88	It should be specified how much in advance the hearing should be announced to allow those interested to properly arrange their participation.	
Line 89	<p>Comment: National Agencies could contribute to disseminate the information about public hearings. On their web sites, newsletters etc. They can also organize discussions in the national arena and gather, in advance, concerns and views from citizens of their country in order to pass them to EMA during the public hearings.</p> <p>Proposed change (if any): The announcement of the hearing should be published also on the National Agencies websites, together with a calendar of the steps to follow prior to the public hearing. Organizations representing consumers, patients, health care professionals, victims of medicines and academics in the disease should be proactively informed.</p>	
Line 93	The exact link to the Web page where the hearing will be broadcasted should be provided.	
Line 99	<p>Comment: Digital technology should always provide the means for participation online.</p> <p>Proposed change: remove “when feasible”</p>	

Stakeholder number <i>(To be completed by the Agency)</i>	Comment	Outcome (if applicable) <i>(To be completed by the Agency)</i>
Line 107	<p>Intervention via teleconference facilities should always be feasible</p> <p>Proposed change: remove "where possible and feasible"</p>	
Line 116	<p>Comment: Observed video broadcast should be always feasible</p> <p>Proposed change: remove " when technically feasible"</p>	
Line 140	<p>A definition of confidential data should be clearly stated in the document or a reference should be added to the relevant definition applied by EMA in this context</p>	
Line 148	<p>As above , remove " when technically feasible"</p>	
Line 151	<p>A budget should be foreseen to cover the travel expenses of individuals and public interests organizations speakers whose contribution is considered particularly relevant for the hearing</p>	
Line 154	<p>The information should be added to the minutes of the hearing</p>	
Line 162	<p>The modalities of the lottery should be defined</p>	
Line 177	<p>Comment: The decision to cancel the meeting should be justified with a detailed explanation. If the public hearing is postponed for technical reasons the other date should be announced.</p>	

Stakeholder number <i>(To be completed by the Agency)</i>	Comment	Outcome (if applicable) <i>(To be completed by the Agency)</i>
Line 188	Proposed change: All attendees, being in place or online, should register prior to the beginning of the public hearing Comment: registrations should be also made via web if broadcast video or other forms allows participation.	

END