



European Medicines Agency

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SUBMISSION OF COMMENTS ON

The EMEA Transparency Policy

Draft for Public Consultation

COMMENTS FROM:

Name of Organisation or individual
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Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

Comments should be sent to the EMEA electronically and in word-format (not pdf).

1. GENERAL COMMENTS

Stakeholder No. <i><to be completed by EMEA></i>	General Comment (if any)	Outcome (if applicable) <i><to be completed by EMEA></i>
	<p>The Genetic Interest Group (GIG) is a UK umbrella organisation acting on behalf of 138 member organisations who support and care for patients and their families affected by health conditions with a genetic component. Many of the conditions supported by our members are severe and lack a cure or treatment.</p> <p>GIG is a member of the European Genetic Alliances Network (EGAN). Our Director, Alastair Kent is a member of the Committee for Advanced Therapies (CAT), and our Policy Analyst, Nick Meade is the alternate member. Mr Kent and Mr Meade represent the CAT on the Patient and Consumer Working Party.</p> <p>As part of our preparation for this consultation, we performed a short and simple consultation of our members. Our intention was to gain an understanding of how our members (a heterogeneous group ranging from "expert" patients, and researchers in the employ of our members, to patients with little or no experience of the drug development pathway or the regulatory process) regard the EMEA and its current communication techniques.</p> <p>The full questionnaire and results are in an annex attached to this submission; we would ask that you keep the results of this survey, other than those mentioned in this response, confidential as we have no</p>	

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	<p>permission from our members to use their answers for anything but this response. EMEA may of course use the results internally. We had 38 respondents of which approximately 30 answered each question.</p> <p>The first part of our survey examined our member's knowledge about the EMEA. Just a third of the respondents knew what "EMEA" stands for, and just a third of the respondents knew what EMEA's function is. This is an important issue, to properly communicate with its stake holders, the population of the EU; EMEA must ensure that they are aware of what EMEA is and what EMEA does.</p> <p>We surveyed disease specific patient organisations operating on a national level. Interaction between EMEA and these organisations is rightfully done on their behalf by Europe-wide umbrella organisations such as EGAN. This model of communication in which EMEA interacts with a group of suitable parties is appropriate for mechanisms such as the Patient & Consumers' Working Party, and patient involvement on expert committees, where EMEA requires patient input; but this model cannot be considered as a sole solution for communication in the opposite direction.</p> <p>The second part of our survey assessed, again in a quick and simple manner, the current communication methods employed by EMEA in communicating with patients. We deliberately did not question our members on the usability of EMEA's website, as we understand this is undergoing a redesign process. Our survey presented our members with a European Public Assessment Report (EPAR) and secondly with a negative opinion; these were on Cerezyme and Milnacipran respectively.</p> <p>We asked our members how easy the documents were to understand,</p>	

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	<p>whether they wished to know anything more and whether they understood what the drug was intended to do. 80% of our members rated the EPAR easy or very easy to understand, and almost all knew what Cerezyme was intended to do. Our members found the negative opinion for Milnacipran harder to understand, but only one member found it difficult or very difficult. There were many specific comments made, frequently regarding dosage information, these are listed in the annex.</p> <p>We believe this second part of our survey has demonstrated that EMEA's existing communication techniques are sound and suitable for their target audience.</p> <p>GIG applauds EMEA's move towards greater transparency, but would strongly encourage EMEA to consider its public profile if it is to reach all of its stakeholders.</p> <p>We are grateful for the opportunity to comment and will be happy to expand on any of these comments if required.</p>	

2. SPECIFIC COMMENTS ON TEXT

Line No of the first line(s) affected. <e.g. Line 20-23>	Stakeholder No. <to be completed by EMEA>	Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using “track changes”>	Outcome <to be completed by EMEA>
109		<p>Comments: The Genetic Interest Group particularly supports the measures described in this paragraph. We have identified that the EMEA is not well understood by some of its stakeholder groups. It is important that when stakeholders, in this case patients, discover EMEA, they can quickly understand its structure and its purpose.</p> <p>Proposed change (if any):</p>	
		<p>Comments:</p> <p>Proposed change (if any):</p>	
		<p>Comments:</p> <p>Proposed change (if any):</p>	

Please feel free to add more rows if needed.

2. SPECIFIC COMMENTS ON ANNEX 1

Objective No and key transparency initiative No. <e.g. 2.7 >	Stakeholder No. <to be completed by EMEA>	Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using “track changes”>	Outcome <to be completed by EMEA>
		<p>Comments:</p> <p>Proposed change (if any):</p>	
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Please feel free to add more rows if needed.