



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 May 2015  
EMA/801592/2012 rev. 5  
Stakeholders and Communication Division

## Application/Re-evaluation form for the involvement of patients' and consumers' organisations in the activities of the European Medicines Agency (EMA)

This application form is for the collection of information necessary to allow the Agency to (re)-evaluate whether a specific patient/consumer organisation fulfils the eligibility criteria<sup>1</sup> to join the group of EMA eligible organisations, as defined by the Agency Management Board. The Agency will also evaluate information gathered from the organisations' website to ensure compliance with the aforementioned criteria.

When completing the form, please refer to the guidance document here:

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2015/05/WC500187018.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/05/WC500187018.pdf)

### Organisation

**Name and acronym:**

**Website:**

---

<sup>1</sup> [Criteria to be fulfilled patients' and consumers' organisations involved in European Medicines Agency \(EMA\) activities](#)



<b>Head of organisation</b>	
<b>Name:</b>	
<b>Position:</b>	
<b>Professional address:</b>	
<b>Telephone:</b>	
<b>E-mail address:</b>	

<b>Contact person/coordinator (for EMA related activities)</b>	
<b>Name:</b>	
<b>Position:</b>	
<b>Professional address:</b>	
<b>Telephone:</b>	
<b>E-mail address:</b>	

*Please notify the Agency of any subsequent change of contact details.*

Definition			
<b>Patient organisation:</b> non-profit, patient-focused organisation	Yes		No
Describe the focus of the organisation (taking into account the definition on page 2 of the guidance document):			
Patients and/or carers represent the majority of members in governing bodies	Yes		No
If not, please provide further information:			
Please insert link to your website containing information of the representation in governing bodies, if available:			
Include link to registered status/bylaws/constitution/terms of reference on your website:			
Include link to non-profit status on your website:			
<b>Consumer organisation:</b> non-profit organisation which defends and promotes the general interests of European consumers as purchasers and users of goods and services	Yes		No

Legitimacy			
Organisation is registered within the EU/EEA	Yes		No
Organisation has a branch or office operating within the EU/EEA	Yes		No

## Activities

Please provide information on the organisations' activities relating to:

- Medicines:
- The organisation's mission and objectives:
- The EU focus and outreach:
- For current eligible organisations, reference to the EMA work can also be included:

Include link to the annual activity report/or other forms of reporting on your website:

## Representation

Please explain how the organisation represents patients/consumers throughout the EU/EEA:

Include link to list of member associations on your website:

Include link to geographical distribution of individual members on your website, if applicable/available:

## Structure

Please explain how the governing bodies of the organisation are elected:

Do corporate members, if part of the governing bodies, have voting rights?

Yes

No

If yes, please provide further information (including link to list of corporate members on your website):

## Accountability and consultation methods

Please explain how the organisation's statements and opinions reflect the views and opinions of its members:

Include link to the description of policy and decision-making procedures on your website, if available:

## Accountability and consultation methods

Please explain what are the organisation's methods of communication from and towards its members:

## Transparency

Please complete the attached funding sources form with the names of all funding sources (both public and private) and their individual financial contribution in terms of percentage of the overall income<sup>2</sup>.

### Include links to your website to:

- Latest annual financial statement, if available (if not available online, please attach in an email):
- List of all sponsors:
- Overall proportion of industry and non-industry income:
- Percentage of the highest contribution from a single company:
- Proof that the organisation's accounts are annually audited, if available:
- Code of conduct/policy regulating the organisation's relationship with and independence from sponsors, if available:
- Reference to any other transparency initiative by the organisation (e.g., publication of declaration of interests of members of governance bodies; registration with the transparency Register etc.):

## Mission/Objectives

Please provide link to your website containing information of the organisation's mission and objectives:

### For current eligible organisations :

- only fill in this section of the form if you wish to provide new/updated information (see here for current information published on EMA website [eligible organisations](#)).

### For organisations applying for the first time:

- please fill in this part of the form by providing a written summary of the organisation, which, if the application is successful, would be published on the EMA website (see here for examples [eligible organisations](#)). The summary should include the following headings:

---

<sup>2</sup> Please note that the EMA reviews the financial details of the eligible organisations on a yearly basis.

## Mission/Objectives

- **Introduction** (max. 30 words):
- **Representation** (max. 30 words):
- **Vision** (max. 30 words):
- **Mission and objectives** (max. 75 words):

## Undertaking

We commit to take an active part in the interaction with the EMA and its activities.

We commit to advise the EMA immediately of any change to the information provided herein, including financial information that might impact on current eligibility status.

Date submitted:

Signature:

Full name:

Position:

## Application form to be submitted:

• by email:

[PCWPSecretariat@ema.europa.eu](mailto:PCWPSecretariat@ema.europa.eu)

• by post:

European Medicines Agency  
Stakeholders and Communication Division  
Patients and Healthcare Professionals Department  
30 Churchill Place  
Canary Wharf  
London E14 5EU  
United Kingdom

## Patients' and consumers' organisation funding sources

**NAME OF ORGANISATION:** <insert name of organisation>

**YEAR:** <2014>

Industry <sup>1</sup> related income <sup>2</sup>		
Name of company/ funder	Amount of income	% of overall organisation's income
<insert name of company>	<insert amount>	<insert %>
<insert name of company>	<insert amount>	<insert %>
<insert name of company>	<insert amount>	<insert %>
<i>Add lines as necessary</i>		
<b>Subtotal:</b>	<insert subtotal>	<insert subtotal %>
Non-industry related income		
Source of funding <sup>3</sup>	Amount of income	% of overall organisation's income

<sup>1</sup> Industry is defined as commercial manufacturers of healthcare products and services, including distributors and wholesalers, etc.

<sup>2</sup> This should reflect the overall funding received from industry, including, e.g. projects, conferences, etc.



<insert source of funding>	<insert amount>	<insert %>
<insert source of funding>	<insert amount>	<insert %>
<insert source of funding>	<insert amount>	<insert %>
<insert source of funding>	<insert amount>	<insert %>
<i>Add lines as necessary</i>		
<b>Subtotal:</b>	<insert subtotal>	<insert subtotal %>
<b>TOTAL<sup>4</sup>:</b>	<insert total>	<insert total %>

**Comments/explanatory notes:**

<sup>3</sup> E.g. membership fees, donations.

<sup>4</sup> In case the total figures in this table do not match those in the financial statement, please provide justification (attached here or as an email).