



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Rules of engagement for patients' organisations and their representatives in repurposing activities and impact on involvement in EMA activities

## 1. Objective

The objective of this document is to define the rules of engagement for patients' organisations and their representatives involved in repurposing activities with a focus on the impact on their participation in future EMA activities.

These rules build on the principles established in the European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts<sup>1</sup> and the related procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form (for scientific committees' members and experts)<sup>2</sup>.

This document is separate from the Framework of interaction of EMA with patients and their organisations<sup>3</sup>, which describes how the Agency involves patients' organisations and individuals in its activities.

## 2. Repurposing activities

Repurposing can be described as the process of identifying a new use for an existing medicine – out of regulatory protection - in an indication that is not registered in its marketing authorisation.

Repurposing activities in the context of the Safe and Timely Access to Medicines for Patients (STAMP) proposed framework include the use of scientific advice as the main regulatory tool.

### Champions

**The champion for the repurposing of a medicinal product** is defined as a non-profit stakeholder developing or gathering evidence, including the use of scientific advice as the main regulatory tool, for the repurposing of a medicinal product that can be e.g. a patient organisation, academia, collaborative groups or European Reference Networks (ERNs).

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<sup>1</sup> [European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts](#)

<sup>2</sup> [Procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form \(for scientific committees' members and experts\)](#)

<sup>3</sup> [Revised framework for interaction between the European Medicines Agency and patients and consumers and their organisations](#)



A champion is typically:

- a) able to coordinate and/or foster the research programme up until the point of full engagement by a pharmaceutical company
- b) initially responsible for liaising and leading the interactions with regulatory authorities and pharmaceutical companies/other stakeholders
- c) transparent regarding interactions with relevant pharmaceutical company(ies) in charge of filing the initial request for scientific/regulatory advice on the basis of the available data.

When a patient organisation acts as a champion, the following three scenarios are considered:

#### **Patient organisation acting as champion alone**

When a patient organisation acts as a champion for the repurposing of a medicine, which includes seeking scientific advice, and where there is no interaction with pharmaceutical industry.

#### **Patient organisation collaborating with academia as champion**

In the case where a patient organisation is collaborating with an academic partner, where the latter is acting as the champion for the repurposing project, and where there is no interaction with pharmaceutical industry.

#### **Patient organisation collaborating with pharmaceutical industry:**

In the case where a patient organisation is collaborating with a pharmaceutical company for the repurposing of a medicine.

### **3. Patient involvement in EMA activities**

Community legislation mandates EMA, its Management Board and its Scientific Committees to develop contacts with its various stakeholders<sup>4</sup>. Patients and consumers are members (and alternates) of some of the Agency's scientific committees and of the Agency's Management Board<sup>5,6,7,8</sup>.

#### **Patients as representatives of their organisation**

Patients may, as representatives of a specific organisation, be consulted and participate in Agency discussions to express the views of their organisation on a specific issue. Organisations involved should be fully transparent with regard to their activities and funding sources<sup>9</sup>.

#### **Patients as individual experts**

Patients also contribute to the EMA's activities as individual experts, where they bring their individual expertise and experience on a specific issue. They must declare any individual competing interests in pharmaceutical industry and abide by the Agency's Code of Conduct<sup>10</sup>. This is reflected in the rules of involvement of members of patients and consumers' organisations in EMA activities<sup>11</sup>.

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<sup>4</sup> [Regulation \(EC\) No 726/2004](#) - Articles 78 (1 and 2)

<sup>5</sup> [Regulation \(EC\) No 141/2000](#) - Article 4 (3) of

<sup>6</sup> [Regulation \(EC\) No 1901/2006](#) - Article 4 (1.b)

<sup>7</sup> [Regulation \(EC\) No 1394/2007](#) - Article 21 (1.d)

<sup>8</sup> [Regulation \(EU\) No 1235/2010](#) - Articles 61a (d)

<sup>9</sup> [https://www.ema.europa.eu/en/documents/other/assessment-patient-consumer-healthcare-professional-organisations-compliance-ema-eligibility\\_en.pdf](https://www.ema.europa.eu/en/documents/other/assessment-patient-consumer-healthcare-professional-organisations-compliance-ema-eligibility_en.pdf)

<sup>10</sup> [https://www.ema.europa.eu/en/documents/other/european-medicines-agency-code-conduct\\_en.pdf](https://www.ema.europa.eu/en/documents/other/european-medicines-agency-code-conduct_en.pdf)

<sup>11</sup> [https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/rules-involvement-members-patients/consumers-healthcare-professionals-organisations-committee-related-activities\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/rules-involvement-members-patients/consumers-healthcare-professionals-organisations-committee-related-activities_en.pdf)

## 4. Impact of involvement in EMA activities based on different scenarios

Involvement of patients' organisations and their representatives in the repurposing of a medicinal product is considered as an interest to be declared in the declaration of interest of the individual expert:

- Direct interest: involvement of the expert in the repurposing of a medicinal product where his/her organisation is acting as the champion of the repurposing of this medicinal product or is collaborating with the champion of the repurposing of this medicinal product.
- Indirect interest: involvement of the expert's organisation in the repurposing of a medicinal product where his/her organisation is acting as the champion of the repurposing of a medicinal product or is collaborating with the champion of the repurposing, but where the individual expert is not involved in the repurposing.

The consequences of the application of the principles laid down in Policy 0044 in terms of allowable interests are summarised in annex 1<sup>1</sup> and are represented in parentheses ( ) below.

### Patient organisation acting as champion:

#### EMA Declaration of Interest (DOI):

A patient representative whose organisation is acting as champion in repurposing activities and who is **involved in the repurposing**:

- This activity represents a direct interest and restrictions applied at the level of this patient representative for involvement in EMA activities are similar to those applied for an interest declared as lead role in the development of a medicinal product.

A patient representative whose organisation is acting as champion in repurposing activities, but who as an individual is **not involved in the repurposing**:

- This activity represents an indirect interest and restrictions applied at the level of this patient representative for the involvement in EMA activities related to that specific repurposing project, are similar to those applied for an interest declared as principal investigator.

#### Restrictions for involvement at EMA:

##### Committee member representing patients:

A patient representative currently serving as committee member nominated by the European Commission (EC) cannot be involved in repurposing activities (X).

A patient representative who, has **no current or past involvement with repurposing activities** and belongs to a patient organisation that is currently, or has in the past been, champion for the repurposing of a medicinal product and, was later nominated as a committee member by the EC during, or after the end of the repurposing activity, cannot be involved in any regulatory/assessment procedures that relate to the same medicinal product. This represents an indirect interest and will apply as long as the repurposing activity is ongoing and for up to 3 years after the cessation of the repurposing activity, e.g. up to 3 years after the Commission Decision for a new marketing authorisation or variation of the medicine (XP-XRPP).

##### Invited expert:

A patient representative that belongs to a patient organisation that is currently acting as champion for the repurposing of a medicinal product and **who is involved in the repurposing activities**, cannot

be involved as an individual expert for any EMA activities (X). This represents a direct interest and will apply as long as the repurposing activity is ongoing. After the cessation of the repurposing activity, the patient representative can be involved in EMA activities, but not in any regulatory/assessment procedures at the level of committees and working parties that relate to the same medicinal product during the whole product life cycle (XP). Participation only in discussions on the same medicinal product at scientific advisory group meetings would be possible (DP).

A patient representative who has **no current or past involvement with repurposing activities** and belongs to a patient organisation that is currently, or has in the past been, champion for a repurposing activity can be involved as an individual expert for EMA activities, but not in any regulatory/assessment procedures that relate to the same medicinal product. This represents an indirect interest and will apply as long as the repurposing project is ongoing and for up to 3 years after the cessation of the repurposing project, e.g. up to 3 years after the Commission Decision for a new marketing authorisation or variation of the medicine (XP). Participation only in discussions on the same medicinal product at scientific advisory group meetings would be possible after the cessation of the repurposing project (DP).

#### **Status as EMA eligible organisation:**

Criteria<sup>12</sup> that must be fulfilled to be considered as an EMA eligible organisation have been defined and adopted by the EMA Management Board and a patient organisation must comply with these criteria, which are assessed annually.

#### **Status as member of Repurposing Observatory Group:**

The involvement of a patient representative in the STAMP Repurposing Observatory Group does not constitute a competing interest *per se* and does not result in restrictions for involvement in EMA activities, unless other interests are declared.

### **Patient organisation collaborating with academia as champion**

#### **EMA Declaration of Interest (DOI):**

A patient representative collaborating with an academic partner, who is acting as champion, in repurposing activities and involved in the activity has a direct interest. Restrictions applied at the level of this patient representative for the involvement in EMA activities, are similar to those applied for an interest declared as consultancy.

#### **Restrictions for involvement at EMA:**

##### **Committee member:**

A patient representative currently serving as committee member nominated by the EC cannot be involved in repurposing activities (X).

A patient representative who collaborated with an academic partner that acted as champion for the repurposing of a medicinal product in the past and was later nominated as a committee member by the EC after the end of the activity, cannot be involved in any regulatory/assessment procedures that relate to the same medicinal product up to 3 years after the cessation of the repurposing project, e.g. up to 3 years after the Commission Decision for a new marketing authorisation or variation of the medicine (XP-XRpP).

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<sup>12</sup> [https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/criteria-be-fulfilled-patient-consumer-healthcare-professional-organisations-involved-european\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/criteria-be-fulfilled-patient-consumer-healthcare-professional-organisations-involved-european_en.pdf)

### **Invited expert:**

A patient representative who is **currently collaborating** with an academic partner for the repurposing of a medicinal product cannot be involved as an individual expert in any committee or working party related activities at the EMA (X), but can be involved in scientific advisory group meetings except if it relates to the same medicinal product (XP).

A patient representative who **has collaborated** with an academic partner for a repurposing activity:

- cannot be invited as an individual expert in any regulatory/assessment procedures at the level of committees and working parties that relate to the same medicinal product for up to 3 years after the cessation of the repurposing activity, e.g. up to 3 years after the Commission Decision for a new marketing authorisation or variation of the medicine (XP).
- can only participate in discussions on the same medicinal product at scientific advisory group meetings for up to 3 years after the cessation of the repurposing project, e.g. up to 3 years after the Commission Decision for a new marketing authorisation or variation of the medicine (DP).

## **Patient organisation collaborating with pharmaceutical industry**

### **EMA Declaration of Interest (DOI):**

A patient representative who is collaborating with a pharmaceutical company in the repurposing of a medicinal product and therefore involved in the repurposing activity is considered to have a direct interest and the activity is considered as consultancy for a medicinal product to a pharmaceutical company for this patient representative.

### **Restrictions for involvement at EMA:**

#### **Committee member:**

A patient representative currently serving as committee member nominated by the EC cannot be involved in repurposing activities (X).

A patient representative who collaborated with a pharmaceutical company in the past and was later nominated as a committee member by the EC after the end of that consulting activity regarding the repurposing cannot be involved in any regulatory/assessment procedures that relate to the same medicinal product up to 3 years after the cessation of the repurposing activity, e.g. up to 3 years after the Commission Decision for a new marketing authorisation or variation of the medicine (XP-XRpR).

#### **Invited expert:**

A patient representative who is **currently collaborating** with pharmaceutical industry for a repurposing activity cannot be involved as an individual expert in any committee or working party related activities at the EMA (X), but can be involved in scientific advisory group meetings except if it relates to the same medicinal product (XP).

A patient representative who **has collaborated** with a pharmaceutical company for a repurposing activity:

- cannot be invited as an individual expert in any regulatory/assessment procedures at the level of committees and working parties that relate to the same medicinal product for up to 3 years after the cessation of the repurposing project, e.g. up to 3 years after the Commission Decision for a new marketing authorisation or variation of the medicine (XP).
- can participate only in discussions on the same medicinal product at scientific advisory group meetings for up to 3 years after the cessation of the repurposing activity, e.g. up to 3 years after the Commission Decision for a new marketing authorisation or variation of the medicine (DP).