



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Looking ahead into 2022

Meeting dates, new mandate and annual eligibility re-evaluation

Presented by Nathalie Bere on 22 September 2021
Public and Stakeholders Engagement

An agency of the European Union





Upcoming PCWP/HCPWP meeting dates:

2021

- 24 November : Annual training day (*virtual*)
- 25 November: PCWP/HCPWP meeting with all eligible organisations (*virtual*)

2022

- 2 and 3 March PCWP/HCPWP meeting (*virtual*)
- *1 and 2 June PCWP/HCPWP meeting (*virtual*)
- *21 and 22 September PCWP/HCPWP meeting (*physical – election of Co-Chairs*)
- *15 and 16 November PCWP/HCPWP meeting with all eligible organisations (*physical*)

**New working party mandate 2022-2025*



New mandate 2022-2025; key milestones

1 to 31 March 2022

Call open to all eligible organisations

May 2022

Executive Director decision

1 June 2022

1st meeting of new mandate

21 September 2022

Election of co-chairs



Launch of annual re-assessment of eligibility:

Important steps and dates:

Step 1: Email with **unique link** to online form will be sent to all on **30 September**

- Sent to main contact for eligibility purposes at your organisation
- Let us know if your organisation has not received it (*NB: may go to your SPAM box*).

Step 2: Completion of electronic 'self-declaration' form between **1-30 October**

Step 3: Acknowledgement email received following submission of online form

Step 4: EMA will verify information received

Step 5: Confirmation email including certificate as PDF

Step 6: Updated list of eligible organisations on EMA website

[Patient/Consumer organisation](#) [Healthcare professional organisation](#)





Example email (please check your SPAM folder)

From: ☐ StakeholdersDB
To: ☐ Radu Raluca
Cc:
Subject: Eligibility Questionnaire Invitation

Dear Raluca Radu

As an EMA eligible organisation you are required to undergo an annual re-evaluation of eligibility to confirm compliance with EMA eligibility criteria. To support this process, you will find herein a link to a prefilled 'self-declaration' form which includes information previously provided by your organisation:

<https://fmapps.ema.europa.eu/stakeholders/eligibilityorg.php?id=RXVyb3BlyW4qTWVkaWNpbmVzIEFnZW5jeQ99737250971113400322>

You are kindly asked to confirm that the information contained in the form remains valid and provide updates where applicable, including links to the latest financial information to comply with EMA eligibility criteria.

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2018/06/WC500250539.pdf

Please note that you are responsible for the information provided and this will be monitored by EMA through a randomised assessment of organisations to ensure compliance.

If you require any assistance with this process please email StakeholdersDB@ema.europa.eu.

Kind regards,
Public Engagement Department

EMA eligibility criteria:

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/12/WC500018099.pdf



Submission of form:

- Complete / submit **electronic 'self-declaration' form** between 1-30 October 2021:
 - Some parts **pre-filled** from previous submission
 - **Confirm compliance** with each [eligibility criteria](#)
 - **Provide links to public information**, where applicable, including funding sources (**2020 financial**)
 - For **full details** see [guidance](#)
- From each group, **20%** of organisations will be **randomly selected for a full check** and informed accordingly
- Please don't hesitate to email us if you have any questions:
 - Patient/Consumer organisations – pcwpsecretariat@ema.europa.eu
 - Healthcare professional organisations – hcpsecretariat@ema.europa.eu

