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Targeted Stakeholders' consultation on the GMP Annex 22: Artificial Intelligence

Fields marked with * are mandatory.

* Name of organisation

European Federation of Pharmaceutical Industries and Associations (EFPIA) and Vaccines Europe (VE)

* Email

kateryna.khmilevska@efpia.eu

Introduction to the EU Survey tool

Please click here to be redirected to the draft guideline text. The public consultation is launched on 7 July 2025 and will be closed on 7 October 2025.

Those participating in the public consultation are asked to please submit comments via the EU Survey tool, **by downloading the attached template excel file (see below) and uploading the file when completed**; login is not required to fill in the survey.

When you have filled in the EU Survey, please use the submission button at the end of the form to submit the comments to the European Medicines Agency.

Before submission, a draft of the comments can be saved in the EU Survey tool. Once submitted, comments can be edited (by 6 October 2025) by clicking on "Edit contribution" in the link https://ec.europa.eu/eusurvey/ and entering your ID contribution that can be found on the pdf copy of your submission sent via email.

You are invited to provide your organisation or name, country and email address below for the purpose of this public consultation (for further information, please see EMA's Data Protection Statement below).

EMA Privacy Statement

All personal data provided within this survey will be processed in accordance with Regulation (EU) 2018/1725 on the protection of individuals regarding the processing of personal data by the Union Institutions and bodies on the free movement of such data.

For more details on how EMA processes personal data, please refer to the EMA Data Protection Notice for surveys conducted via EUSurvey: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-conducting-surveys-eusurvey_en.pdf

If you have any questions, complaints or concerns about the processing of your personal data, you can contact EMA's Data Protection Officer at dataprotection@ema.europa.eu

You can contact the Internal Controller at datacontroller.humanmedicines@ema.europa.eu

You may also lodge a complaint with the European Data Protection Supervisor: edps@edps.europa.eu

* Please confirm that you have read and understood the Data Protection notice and that you consent to the processing of your personal data.
  - (●) Yes

* Please confirm that you consent to possibly be contacted by EMA in relation to your survey responses to support the finalisation of the document subject this EU Survey.
  - (●) Yes
  - ( ) No

Please be aware that the sender of the comments is responsible to not disclose any personal data of third parties in the comments.

For additional information, please consult EMA's privacy statement.

Download

Stakeholder_Comments_-_Annex_22_EMA_PICs.xlsx

Please download the template excel file attached above. Once completed, please upload the excel file with your comments by clicking on the tab below.

Please upload your file(s)

6da045c0-6549-4beb-b239-29f0975f98d0/EFPIA_Vaccines_Europe_Comments_Annex_22_EMA_PICs.xlsx

Please give any feedback you may have on this pilot-phase of the new survey format. Thank you.

	Feedback
1	We appreciate EMA’s efforts to enhance the consultation process. The use of the Excel file greatly facilitates the collection of comments within trade associations. However, we would appreciate the removal of the character limit in the template, as it restricts the ability to provide comprehensive comments and proposals.

Thank you for your contribution.

Contact

Contact Form