

15 May 2024  
EMA/187783/2024  
Stakeholders and Communication Division

## Joint Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) working parties meeting

EMA meeting room: EMA 2A / Webex

Co-Chairs: Juan Garcia Burgos (EMA), Marko Korenjak (PCWP), Rosa Giuliani (HCPWP)

### Joint PCWP-HCPWP – Part 1 - 2 July 2024, 14:00-18:15 CEST

| Time                                                        | Topics                                                                                   | Speakers                               |
|-------------------------------------------------------------|------------------------------------------------------------------------------------------|----------------------------------------|
| 13:45                                                       | <i>Joining and technical checks</i>                                                      |                                        |
| 14:00                                                       | Welcome and introduction / Health and safety information                                 | Juan Garcia Burgos (EMA)               |
| <b>1. European Medicines Agency Network (EMAN) Strategy</b> |                                                                                          |                                        |
| 14:10                                                       | 1.1. Extension of the EMAN strategy to 2028                                              | Melanie Carr (EMA)                     |
| 14:25                                                       | Q&A                                                                                      |                                        |
| <b>2. Members' voice</b>                                    |                                                                                          |                                        |
| 15:00                                                       | 2.1. PCO: Analysis on Medicines Overviews for CHMP opinions                              | François Houyez (EURORDIS)             |
| 15:10                                                       | 2.2. HCPO: Roles and Responsibilities of the GP in Prescribing in the Health Care System | Mary McCarthy (UEMO)                   |
| 15:20                                                       | Q&A                                                                                      |                                        |
| <b>3. Clinical trial activities</b>                         |                                                                                          |                                        |
| 15:30                                                       | 3.1. Clinical trials raw data pilot – interim results                                    | Frank Pétavy and Marcia Rückbeil (EMA) |
| 15:45                                                       | Q&A                                                                                      |                                        |

| Time                                                                                              | Topics                                                                                                                                                   | Speakers                                                                   |
|---------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| 15:50                                                                                             | 3.2. Update on ACT EU and Multistakeholder Platform                                                                                                      | Ana Zanoletty (EMA)<br>Denis Lacombe (EORTC)                               |
| 16:00                                                                                             | Q&A                                                                                                                                                      |                                                                            |
| 16:10                                                                                             | <i>Coffee break</i>                                                                                                                                      |                                                                            |
| <b>4. Product Information</b>                                                                     |                                                                                                                                                          |                                                                            |
| 16:25                                                                                             | 4.1. Update of the QRD template of the package leaflet                                                                                                   | Monica Buch (EMA)                                                          |
| 16:35                                                                                             | Q&A                                                                                                                                                      |                                                                            |
| <b>5. Revision of EMA Guideline on Risk Assessment of Medicines on Reproduction and Lactation</b> |                                                                                                                                                          |                                                                            |
| 16:45                                                                                             | 5.1. Concept paper on the revision of the Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling | Dinah Duarte (EMA)<br>Karel Allegaert (EAP)                                |
| 17:00                                                                                             | Q&A                                                                                                                                                      |                                                                            |
| <b>6. Transparency activities</b>                                                                 |                                                                                                                                                          |                                                                            |
| 17:10                                                                                             | 6.1. Re-start of Clinical Data Publication – Update on transparency activities                                                                           | Silvia Garrido-Lestache (EMA)                                              |
| 17:20                                                                                             | Q&A                                                                                                                                                      |                                                                            |
| 17:30                                                                                             | 6.2. Revised CTIS transparency rules                                                                                                                     | Francesca Scotti (EMA)                                                     |
| 17:40                                                                                             | Q&A                                                                                                                                                      |                                                                            |
| <b>7. Update on biosimilars</b>                                                                   |                                                                                                                                                          |                                                                            |
| 17:45                                                                                             | 7.1. Outcome of biosimilars surveys to patients, healthcare professionals, industry and Heads of Medicines Agencies (HMA)                                | Rosa Gonzalez-Quevedo (EMA)<br>Diederik de Cock (EMA collaborating expert) |
| 18:00                                                                                             | Q&A                                                                                                                                                      | All                                                                        |
| <b>8. AOB</b>                                                                                     |                                                                                                                                                          |                                                                            |
| 18:10                                                                                             | AOB                                                                                                                                                      |                                                                            |
| 18:15                                                                                             | <i>End of Joint PCWP-HCPWP plenary part 1</i>                                                                                                            |                                                                            |

## Joint PCWP-HCPWP – Part 2 - 3 July 2024, 09:00-12:15 CEST

| Time                                            | Topics                                                                                                                                                                           | Speakers                                                         |
|-------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>9. Update on shortage related activities</b> |                                                                                                                                                                                  |                                                                  |
| 9:00                                            | 9.1. Presentation of the activities of the Joint Action Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network (Chessmen)      | Nuno Simões (Infarmed)<br>Domenico Di Giorgio (AIFA)             |
| 09:10                                           | Q&A                                                                                                                                                                              |                                                                  |
| 09:20                                           | 9.2. Report on progress of the Subgroup on the implementation of the Good practice guidance for patient and healthcare professional organisations on the prevention of shortages | Inga Abed (EMA)                                                  |
| 09:30                                           | Q&A                                                                                                                                                                              |                                                                  |
| 09:40                                           | 9.3. Update and feedback on Multistakeholder workshop on GLP-1 RAs shortages                                                                                                     | Klaus Kruttwig (EMA)                                             |
| 09:50                                           | Q&A                                                                                                                                                                              |                                                                  |
| 10:00                                           | 9.4. Report on “Union List of Critical Medicines” development activities                                                                                                         | Joao Ferreira (EMA)                                              |
| 10:10                                           | Q&A                                                                                                                                                                              |                                                                  |
| 10:20                                           | <i>Coffee break</i>                                                                                                                                                              |                                                                  |
| <b>10. Vaccine related activities</b>           |                                                                                                                                                                                  |                                                                  |
| 10:40                                           | 10.1. Reinitiation of the vaccines outreach strategy                                                                                                                             | Melanie Carr and Marco Cavaleri (EMA)                            |
| 10:55                                           | 10.2. Update on the European Vaccination Information Portal (EVIP)                                                                                                               | Nicolas White (ECDC)<br>Cécile Henrot and Christopher Gadd (EMA) |
| 11:15                                           | Q&A                                                                                                                                                                              |                                                                  |
| 11:55                                           | 10.3. Presentation of the Vaccine Monitoring Platform                                                                                                                            | Catherine Cohet and Alessandra Buoninfante (EMA)                 |
| 12:05                                           | Q&A                                                                                                                                                                              |                                                                  |

| Time  | Topics                      | Speakers |
|-------|-----------------------------|----------|
| 12:10 | AOB                         |          |
| 12:15 | <i>End of joint meeting</i> |          |

# Healthcare Professionals Working Party (HCPWP) meeting

EMA meeting room: EMA 2A / Webex

Co-Chairs: Juan Garcia Burgos (EMA), Rosa Giuliani (HCPWP)

## HCPWP plenary - 3 July 2024, 13:10–16:00 CEST

| Time                                                            | Topics                                                                                                                                                                                                                       | Speakers                                           |
|-----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| 13:00                                                           | <i>Joining and technical checks</i>                                                                                                                                                                                          |                                                    |
| 13:10                                                           | Welcome and introduction / Health and safety information                                                                                                                                                                     | Rosa Giuliani (HCPWP) and Juan Garcia Burgos (EMA) |
| <b>1. Healthcare professional involvement in EMA activities</b> |                                                                                                                                                                                                                              |                                                    |
| 13:15                                                           | 1.1. Update of framework of interaction with HCPs                                                                                                                                                                            | Ivana Silva (EMA)                                  |
| 13:30                                                           | 1.2. Remuneration of experts for involvement in EMA activities                                                                                                                                                               | Ivana Silva (EMA)                                  |
| 13:40                                                           | Q&A                                                                                                                                                                                                                          |                                                    |
| 13:55                                                           | 1.3. Update on CHMP early dialogue process                                                                                                                                                                                   | Cécile Henrot (EMA)                                |
| 14:00                                                           | Q&A                                                                                                                                                                                                                          |                                                    |
| <b>2. HCPWP operations</b>                                      |                                                                                                                                                                                                                              |                                                    |
| 14:15                                                           | 2.1. Outcome of the survey on the joint PCWP/HCPWP workplan actions and discussion on HCPWP-specific actions                                                                                                                 | Ivana Silva (EMA)                                  |
| 14:30                                                           | 2.2. Update on HCP POG drafting groups                                                                                                                                                                                       | Ivana Silva (EMA)                                  |
| 14:45                                                           | Q&A                                                                                                                                                                                                                          |                                                    |
| 15:00                                                           | <i>Coffee break</i>                                                                                                                                                                                                          |                                                    |
| <b>3. Topics suggested by members</b>                           |                                                                                                                                                                                                                              |                                                    |
| 15:15                                                           | 3.1 Current practices for communication and uptake of risk minimisation measures by healthcare professionals - Example of risk of lactic acidosis after iodinated contrast media administration in patients taking metformin | Olivier Clément (ESR)                              |
| 15:25                                                           | Q&A                                                                                                                                                                                                                          |                                                    |
| 15:35                                                           | Open discussion with HCPWP                                                                                                                                                                                                   | HCPWP                                              |
| 16:00                                                           | <i>End of HCPWP plenary</i>                                                                                                                                                                                                  |                                                    |

