



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

26 October 2026  
EMA/PRAC/227255/2026  
Human Medicines Division

## Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda for the meeting on 26 - 29 October 2026

Chair: Ulla Wändel Liminga – Vice-Chair: Liana Martirosyan

26 October 2026 09:30 – 19:30, virtual meeting

27 October 2026 08:30 – 19:30, virtual meeting

28 October 2026 08:30 – 19:30, virtual meeting

29 October 2026 08:30 – 16:30, virtual meeting

### Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also change during the course of the review. Additional details on some of these procedures will be published in the PRAC meeting highlights once the procedures are finalised.

Of note, this agenda is a working document primarily designed for PRAC members and the work the Committee undertakes.

### Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to ongoing procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents ([EMA/127362/2006 Rev.1](#)).



## Table of contents

|           |                                                                                                                                           |           |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| <b>1.</b> | <b>Introduction</b>                                                                                                                       | <b>10</b> |
| 1.1.      | Welcome and declarations of interest of members, alternates and experts.....                                                              | 10        |
| 1.2.      | Agenda of the meeting on 26–29 October 2026.....                                                                                          | 10        |
| 1.3.      | Minutes of the previous meeting on 28 September–01 October 2026.....                                                                      | 10        |
| <b>2.</b> | <b>EU referral procedures for safety reasons: urgent EU procedures</b>                                                                    | <b>10</b> |
| 2.1.      | Newly triggered procedures .....                                                                                                          | 10        |
| 2.2.      | Ongoing procedures .....                                                                                                                  | 10        |
| 2.3.      | Procedures for finalisation.....                                                                                                          | 10        |
| <b>3.</b> | <b>EU referral procedures for safety reasons: other EU referral procedures</b>                                                            | <b>10</b> |
| 3.1.      | Newly triggered procedure .....                                                                                                           | 10        |
| 3.1.1.    | Melitracen hydrochloride, flupentixol hydrochloride (NAP) – EMA/REF/0000382942.....                                                       | 10        |
| 3.2.      | Ongoing procedures .....                                                                                                                  | 11        |
| 3.3.      | Procedures for finalisation.....                                                                                                          | 11        |
| 3.4.      | Re-examination procedures.....                                                                                                            | 11        |
| 3.5.      | Others .....                                                                                                                              | 11        |
| <b>4.</b> | <b>Signals assessment and prioritisation</b>                                                                                              | <b>11</b> |
| 4.1.      | New signals detected from EU spontaneous reporting systems and/or other sources .....                                                     | 11        |
| 4.1.1.    | Human normal immunoglobulin - DEQSIGA (CAP); FLEBOGAMMA DIF (CAP); HIZENTRA (CAP); HYQVIA (CAP); KIOVIG (CAP); PRIVIGEN (CAP), NAP .....  | 11        |
| 4.2.      | Signals follow-up and prioritisation .....                                                                                                | 12        |
| 4.2.1.    | Cefpodoxime (NAP).....                                                                                                                    | 12        |
| 4.2.2.    | Lithium (NAP) .....                                                                                                                       | 12        |
| 4.2.3.    | Oseltamivir – TAMIFLU (CAP) - EMEA/H/C/000402/SDA/107; zanamivir – DECTOVA - EMEA/H/C/004102/SDA/019 (CAP) .....                          | 12        |
| 4.3.      | Variation procedure(s) resulting from signal evaluation .....                                                                             | 12        |
| <b>5.</b> | <b>Risk management plans (RMPs)</b>                                                                                                       | <b>13</b> |
| 5.1.      | Medicines in the pre-authorisation phase .....                                                                                            | 13        |
| 5.1.1.    | Bilayer engineered collagen hydrogel containing living autologous keratinocytes and fibroblasts (CAP MAA) - EMEA/H/C/006357, Orphan ..... | 13        |
| 5.1.2.    | Deuruxolitinib (CAP MAA) - EMEA/H/C/006812 .....                                                                                          | 13        |
| 5.1.3.    | Enlicitide (CAP MAA) - EMEA/H/C/006815 .....                                                                                              | 13        |
| 5.1.4.    | Enlicitide (CAP MAA) - EMEA/H/C/007131 .....                                                                                              | 13        |
| 5.1.5.    | Hexaminolevulinate (CAP MAA) - EMEA/H/C/006878 .....                                                                                      | 13        |
| 5.1.6.    | Ianalumab (CAP MAA) - EMEA/H/C/006748.....                                                                                                | 13        |

|             |                                                                                                                                                       |           |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 5.1.7.      | Omalizumab (CAP MAA) - EMEA/H/C/006687 .....                                                                                                          | 13        |
| 5.1.8.      | Ponatinib (CAP MAA) - EMEA/H/C/006894.....                                                                                                            | 14        |
| 5.1.9.      | Regadenoson (CAP MAA) - EMEA/H/C/006848.....                                                                                                          | 14        |
| 5.1.10.     | Veligrotug (CAP MAA) - EMEA/H/C/006813 .....                                                                                                          | 14        |
| <b>5.2.</b> | <b>Medicines in the post-authorisation phase – PRAC-led procedures.....</b>                                                                           | <b>14</b> |
| 5.2.1.      | Canakinumab - ILARIS (CAP) – EMA/VR/0000368030 .....                                                                                                  | 14        |
| 5.2.2.      | Etanercept - BENEPALI (CAP) – EMA/VR/0000365721 .....                                                                                                 | 14        |
| 5.2.3.      | Ipilimumab - YERVOY (CAP); Nivolumab - OPDIVO (CAP) – EMA/VR/0000362961.....                                                                          | 15        |
| 5.2.4.      | Siponimod - MAYZENT (CAP) – EMA/VR/0000317924.....                                                                                                    | 15        |
| <b>5.3.</b> | <b>Medicines in the post-authorisation phase – CHMP-led procedures .....</b>                                                                          | <b>15</b> |
| 5.3.1.      | 5-aminolevulinic acid - GLIOLAN (CAP) – EMA/VR/0000365302 .....                                                                                       | 15        |
| 5.3.2.      | Adagrasib - KRAZATI (CAP); NAP – EMA/X/0000358567.....                                                                                                | 16        |
| 5.3.3.      | Alglucosidase alfa - MYOZYME (CAP) – EMA/VR/0000368063 .....                                                                                          | 16        |
| 5.3.4.      | Asciminib - SCEMBLIX (CAP) – EMA/VR/0000342126 .....                                                                                                  | 16        |
| 5.3.5.      | Atidarsagene autotemcel - LIBMELDY (CAP) – EMA/VR/0000368167 .....                                                                                    | 16        |
| 5.3.6.      | Dengue tetravalent vaccine (live / attenuated) - DENGUE TETRAVALENT VACCINE (LIVE, ATTENUATED) TAKEDA (ART 58); QDENG (CAP) – EMA/VR/0000323434 ..... | 17        |
| 5.3.7.      | Denosumab - WYOST (CAP) – EMA/VR/0000363226 .....                                                                                                     | 17        |
| 5.3.8.      | Deutivacaftor / Tezacaftor / Vanzacaftor - ALYFTREK (CAP) – EMA/X/0000358872.....                                                                     | 17        |
| 5.3.9.      | Dolutegravir - TIVICAY (CAP) – EMA/VR/0000351003 .....                                                                                                | 17        |
| 5.3.10.     | Dolutegravir / Lamivudine - DOVATO (CAP) – EMA/X/0000335457 .....                                                                                     | 18        |
| 5.3.11.     | Eravacycline - XERAVA (CAP) – EMA/VR/0000343900 .....                                                                                                 | 18        |
| 5.3.12.     | Furosemide - BOPEDIAT (CAP) – EMA/X/0000358405 .....                                                                                                  | 18        |
| 5.3.13.     | Givinostat - DUVYZAT (CAP) – EMA/VR/0000343703.....                                                                                                   | 19        |
| 5.3.14.     | Givinostat - DUVYZAT (CAP) – EMA/VR/0000343737.....                                                                                                   | 19        |
| 5.3.15.     | Glofitamab - COLUMVI (CAP) – EMA/VR/0000348695.....                                                                                                   | 19        |
| 5.3.16.     | Ipilimumab - YERVOY (CAP); Nivolumab - OPDIVO (CAP) – EMA/VR/0000350392.....                                                                          | 19        |
| 5.3.17.     | Lebrikizumab - EBGLYSS (CAP) – EMA/X/0000358474 .....                                                                                                 | 20        |
| 5.3.18.     | Mavacamten - CAMZYOS (CAP) – EMA/VR/0000343906 .....                                                                                                  | 20        |
| 5.3.19.     | Methylphenidate hydrochloride - TUZULBY (CAP) – EMA/X/0000327555 .....                                                                                | 20        |
| 5.3.20.     | Osilodrostat - ISTURISA (CAP) – EMA/VR/0000315678, Orphan .....                                                                                       | 20        |
| 5.3.21.     | Repotrectinib - AUGTYRO (CAP) – EMA/X/0000357212.....                                                                                                 | 21        |
| 5.3.22.     | Rezafungin - REZZAYO (CAP) – EMA/VR/0000363537 .....                                                                                                  | 21        |
| 5.3.23.     | Risankizumab - SKYRIZI (CAP) – EMA/VR/0000360512 .....                                                                                                | 21        |
| 5.3.24.     | Risankizumab - SKYRIZI (CAP) – EMA/VR/0000370015 .....                                                                                                | 22        |
| 5.3.25.     | Teplizumab - TEIZEILD (CAP) – EMA/VR/0000363763 .....                                                                                                 | 22        |
| 5.3.26.     | Teprotumumab - TEPEZZA (CAP) – EMA/VR/0000370302 .....                                                                                                | 22        |
| 5.3.27.     | Ustekinumab - STELARA (CAP) – EMA/VR/0000363450 .....                                                                                                 | 23        |
| 5.3.28.     | Vosoritide - VOXZOGO (CAP) – EMA/VR/0000343152.....                                                                                                   | 23        |

## 6. Periodic safety update reports (PSURs) 23

### 6.1. PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) only 23

|         |                                                                                                  |    |
|---------|--------------------------------------------------------------------------------------------------|----|
| 6.1.1.  | Albendazole / Ivermectin - IVERMECTIN/ALBENDAZOLE CAP (ART 58) – EMA/PSUR/0000350272 .....       | 23 |
| 6.1.2.  | Atogepant - AQUIPTA (CAP) – EMA/PSUR/0000358983 .....                                            | 24 |
| 6.1.3.  | Avelumab - BAVENCIO (CAP) – EMA/PSUR/0000359018.....                                             | 24 |
| 6.1.4.  | Belantamab mafodotin - BLENREP (CAP) – EMA/PSUR/0000359028.....                                  | 24 |
| 6.1.5.  | Betaine - AMVERSIO (CAP); CYSTADANE (CAP) – EMA/PSUR/0000358994 .....                            | 24 |
| 6.1.6.  | Certolizumab pegol - CIMZIA (CAP) – EMA/PSUR/0000358998.....                                     | 24 |
| 6.1.7.  | Clascoterone - WINLEVI (CAP) – EMA/PSUR/0000359039.....                                          | 24 |
| 6.1.8.  | Concizumab - ALHEMO (CAP) – EMA/PSUR/0000359010.....                                             | 25 |
| 6.1.9.  | COVID-19 vaccine (recombinant / adjuvanted) - BIMERVAX (CAP) – EMA/PSUR/0000359030 .....         | 25 |
| 6.1.10. | Dabigatran etexilate - PRADAXA (CAP) – EMA/PSUR/0000358991.....                                  | 25 |
| 6.1.11. | Deutetrabenazine - AUSTEDO (CAP) – EMA/PSUR/0000359045.....                                      | 25 |
| 6.1.12. | Dupilumab - DUPIXENT (CAP) – EMA/PSUR/0000359022.....                                            | 25 |
| 6.1.13. | Eftrenonacog alfa - ALPROLIX (CAP) – EMA/PSUR/0000359006, Orphan.....                            | 26 |
| 6.1.14. | Emtricitabine / Rilpivirine / Tenofovir alafenamide - ODEFSEY (CAP) – EMA/PSUR/0000359014 .....  | 26 |
| 6.1.15. | Enalapril maleate - AQUMELDI (CAP) – EMA/PSUR/0000358992.....                                    | 26 |
| 6.1.16. | Enfuvirtide - FUZEON (CAP) – EMA/PSUR/0000359005.....                                            | 26 |
| 6.1.17. | Epcoritamab - TEPKINLY (CAP) – EMA/PSUR/0000358986 .....                                         | 26 |
| 6.1.18. | Erdafitinib - BALVERSA (CAP) – EMA/PSUR/0000359040 .....                                         | 26 |
| 6.1.19. | Futibatinib - LYTGobi (CAP) – EMA/PSUR/0000358985 .....                                          | 27 |
| 6.1.20. | Glofitamab - COLUMVI (CAP) – EMA/PSUR/0000358982.....                                            | 27 |
| 6.1.21. | Idecabtagene vicleucel - ABECMA (CAP) – EMA/PSUR/0000359025.....                                 | 27 |
| 6.1.22. | Immunestrant - INLURIYO (CAP) – EMA/PSUR/0000359013 .....                                        | 27 |
| 6.1.23. | Inavolisib - ITOVEBI (CAP) – EMA/PSUR/0000359036 .....                                           | 27 |
| 6.1.24. | Levacetylleucine - AQNEURSA (CAP) – EMA/PSUR/0000359011.....                                     | 28 |
| 6.1.25. | Lutetium ( <sup>177</sup> Lu) vipivotide tetraxetan - PLUVICTO (CAP) – EMA/PSUR/0000359032 ..... | 28 |
| 6.1.26. | Maralixibat - LIVMARLI (CAP) – EMA/PSUR/0000359029 .....                                         | 28 |
| 6.1.27. | Marstacimab - HYMPAVZI (CAP) – EMA/PSUR/0000359043.....                                          | 28 |
| 6.1.28. | Mirikizumab - OMVOH (CAP) – EMA/PSUR/0000358984.....                                             | 28 |
| 6.1.29. | Naldemedine - RIZMOIC (CAP) – EMA/PSUR/0000359023 .....                                          | 28 |
| 6.1.30. | Nintedanib - OFEV (CAP) – EMA/PSUR/0000359009.....                                               | 29 |
| 6.1.31. | Niraparib - ZEJULA (CAP) – EMA/PSUR/0000359021 .....                                             | 29 |
| 6.1.32. | Olipudase alfa - XENPOZYME (CAP) – EMA/PSUR/0000359026 .....                                     | 29 |
| 6.1.33. | Pemigatinib - PEMAZYRE (CAP) – EMA/PSUR/0000359031, Orphan.....                                  | 29 |

|             |                                                                                                                                                 |           |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 6.1.34.     | Pertussis vaccine (recombinant / acellular / component / adsorbed) - VACPERTAGEN (CAP) – EMA/PSUR/0000359017 .....                              | 29        |
| 6.1.35.     | Retifanlimab - ZYNYZ (CAP) – EMA/PSUR/0000359042 .....                                                                                          | 30        |
| 6.1.36.     | Rezafungin - REZZAYO (CAP) – EMA/PSUR/0000358987.....                                                                                           | 30        |
| 6.1.37.     | Selumetinib - KOSELUGO (CAP) – EMA/PSUR/0000359038 .....                                                                                        | 30        |
| 6.1.38.     | Serplulimab - HETRONIFLY (CAP) – EMA/PSUR/0000359033 .....                                                                                      | 30        |
| 6.1.39.     | Sotatercept - WINREVAIR (CAP) – EMA/PSUR/0000359035 .....                                                                                       | 30        |
| 6.1.40.     | Tepotinib - TEPMETKO (CAP) – EMA/PSUR/0000359027 .....                                                                                          | 30        |
| 6.1.41.     | Tipiracil / Trifluridine - LONSURF (CAP) – EMA/PSUR/0000359015 .....                                                                            | 31        |
| 6.1.42.     | Tucatinib - TUKYSA (CAP) – EMA/PSUR/0000359024 .....                                                                                            | 31        |
| 6.1.43.     | Vibegron - OBGEMSA (CAP) – EMA/PSUR/0000359037.....                                                                                             | 31        |
| 6.1.44.     | Vilobelimab - GOHIBIC (CAP) – EMA/PSUR/0000359044.....                                                                                          | 31        |
| 6.1.45.     | Zolbetuximab - VYLOY (CAP) – EMA/PSUR/0000359034 .....                                                                                          | 31        |
| <b>6.2.</b> | <b>PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) and nationally authorised products (NAPs) .....</b> | <b>32</b> |
| 6.2.1.      | Bimatoprost – LUMIGAN (CAP), NAP – EMA/PSUR/0000359007 .....                                                                                    | 32        |
| 6.2.2.      | Gozetotide - LOCAMETZ (CAP), NAP – EMA/PSUR/0000359041 .....                                                                                    | 32        |
| <b>6.3.</b> | <b>PSUR single assessment (PSUSA) procedures including nationally authorised products (NAPs) only .....</b>                                     | <b>32</b> |
| 6.3.1.      | Aprotinin – EMA/PSUR/0000358989.....                                                                                                            | 32        |
| 6.3.2.      | Bicalutamide – EMA/PSUR/0000358990.....                                                                                                         | 32        |
| 6.3.3.      | Butoconazole – EMA/PSUR/0000358999 .....                                                                                                        | 32        |
| 6.3.4.      | Cyproterone acetate / estradiol valerate – EMA/PSUR/0000358995 .....                                                                            | 33        |
| 6.3.5.      | Cystine / pyridoxine hydrochloride – EMA/PSUR/0000358969 .....                                                                                  | 33        |
| 6.3.6.      | Diclofenac sodium / orphenadrine citrate – EMA/PSUR/0000358996 .....                                                                            | 33        |
| 6.3.7.      | Diethylamine-salicylate / escin – EMA/PSUR/0000359012.....                                                                                      | 33        |
| 6.3.8.      | Dimeticone / guaiazulene – EMA/PSUR/0000358993 .....                                                                                            | 33        |
| 6.3.9.      | Ethinylestradiol / gestodene – EMA/PSUR/0000359001 .....                                                                                        | 33        |
| 6.3.10.     | Ethosuximide – EMA/PSUR/0000359002.....                                                                                                         | 34        |
| 6.3.11.     | Fluconazole – EMA/PSUR/0000359008 .....                                                                                                         | 34        |
| 6.3.12.     | Furazidine – EMA/PSUR/0000359046 .....                                                                                                          | 34        |
| 6.3.13.     | Gliclazide – EMA/PSUR/0000359000 .....                                                                                                          | 34        |
| 6.3.14.     | Human plasma (pooled and treated for virus inactivation) – EMA/PSUR/0000359003 .....                                                            | 34        |
| 6.3.15.     | Nicorandil – EMA/PSUR/0000359019.....                                                                                                           | 35        |
| 6.3.16.     | Nitrofurantoin, nitrofurantoin / pyridoxine hydrochloride – EMA/PSUR/0000358997 .....                                                           | 35        |
| 6.3.17.     | Perchlorates – EMA/PSUR/0000359020 .....                                                                                                        | 35        |
| 6.3.18.     | Piperacillin – EMA/PSUR/0000359004.....                                                                                                         | 35        |
| 6.3.19.     | Rabies vaccine – EMA/PSUR/0000358988.....                                                                                                       | 35        |
| 6.3.20.     | Tenoxicam – EMA/PSUR/0000359016 .....                                                                                                           | 35        |
| <b>6.4.</b> | <b>Follow-up to PSUR/PSUSA procedures .....</b>                                                                                                 | <b>36</b> |

|             |                                                                     |           |
|-------------|---------------------------------------------------------------------|-----------|
| 6.4.1.      | Baloxavir marboxil - XOFLUZA (CAP) – EMA/PAM/0000365599 .....       | 36        |
| 6.4.2.      | Semaglutide – OZEMPIC (CAP) – EMA/PAM/0000338018 .....              | 36        |
| 6.4.3.      | Semaglutide – RYBELSUS (CAP) – EMA/PAM/0000337900 .....             | 36        |
| 6.4.4.      | Semaglutide – WEGOVY (CAP) – EMA/PAM/0000337800.....                | 36        |
| <b>6.5.</b> | <b>Variation procedure(s) resulting from PSUSA evaluation .....</b> | <b>37</b> |
| 6.5.1.      | Levofloxacin - QUINSAIR (CAP) – EMA/VR/0000365289 .....             | 37        |
| 6.5.2.      | Rotavirus vaccine, live - ROTARIX (CAP) – EMA/VR/0000368203 .....   | 37        |
| <b>6.6.</b> | <b>Expedited summary safety reviews .....</b>                       | <b>37</b> |

## **7. Post-authorisation safety studies (PASS) 37**

|             |                                                                                                       |           |
|-------------|-------------------------------------------------------------------------------------------------------|-----------|
| <b>7.1.</b> | <b>Protocols of PASS imposed in the marketing authorisation(s).....</b>                               | <b>37</b> |
| 7.1.1.      | Beremagene geperpavec - VYJUVEK (CAP) – EMA/PASS/0000287685 .....                                     | 37        |
| 7.1.2.      | Ciltacabtagene autoleucel - CARVYKTI (CAP) – EMA/PASS/0000372428 .....                                | 38        |
| 7.1.3.      | Donanemab - KISUNLA (CAP) – EMA/PASS/0000339391 .....                                                 | 38        |
| 7.1.4.      | Donanemab - KISUNLA (CAP) – EMA/PASS/0000339404 .....                                                 | 38        |
| 7.1.5.      | Doxecitine / Doxribtimine - KYGEVVI (CAP) – EMA/PASS/0000372539 .....                                 | 38        |
| <b>7.2.</b> | <b>Protocols of PASS non-imposed in the marketing authorisation(s) .....</b>                          | <b>39</b> |
| 7.2.1.      | Aficamten - MYQORZO (CAP) – EMA/PAM/0000368228 .....                                                  | 39        |
| 7.2.2.      | Bimekizumab - BIMZELX (CAP) – EMA/PAM/0000365441.....                                                 | 39        |
| 7.2.3.      | Brensocatic - BRINSUPRI (CAP) – EMA/PAM/0000368428.....                                               | 39        |
| 7.2.4.      | Bupropion hydrochloride / Naltrexone hydrochloride - MYSIMBA (CAP) –<br>EMA/PAM/0000363244.....       | 39        |
| 7.2.5.      | Chikungunya vaccine (live) - IXCHIQ (CAP) – EMA/PAM/0000341603.....                                   | 40        |
| 7.2.6.      | Donanemab - KISUNLA (CAP) – EMA/PAM/0000338752.....                                                   | 40        |
| 7.2.7.      | Nipocalimab - IMAAVY (CAP) – EMA/PAM/0000358660 .....                                                 | 40        |
| 7.2.8.      | Setmelanotide - IMCIVREE (CAP) – EMA/PAM/0000368955.....                                              | 40        |
| <b>7.3.</b> | <b>Results of PASS imposed in the marketing authorisation(s).....</b>                                 | <b>41</b> |
| <b>7.4.</b> | <b>Results of PASS imposed and non-imposed in the marketing authorisation(s).....</b>                 | <b>41</b> |
| 7.4.1.      | Imiglucerase - CERZYME (CAP) – EMA/VR/0000362491 .....                                                | 41        |
| 7.4.2.      | Infliximab - FLIXABI (CAP) – EMA/VR/0000358948.....                                                   | 41        |
| 7.4.3.      | Mexiletine - NAMUSCLA (CAP) – EMA/VR/0000365999 .....                                                 | 41        |
| 7.4.4.      | Sonidegib - ODOMZO (CAP) – EMA/VR/0000357142 .....                                                    | 42        |
| 7.4.5.      | Tofacitinib - XELJANZ (CAP) – EMA/VR/0000368202 .....                                                 | 42        |
| <b>7.5.</b> | <b>Interim results and other post-authorisation measures for imposed and non-imposed studies.....</b> | <b>42</b> |
| 7.5.1.      | COVID-19 mRNA vaccine - COMIRNATY (CAP) – EMA/PAM/0000359120.....                                     | 42        |
| 7.5.2.      | Idecabtagene vicleucel - ABECMA (CAP) – EMA/PAM/0000365985 .....                                      | 42        |
| 7.5.3.      | Lecanemab - LEQEMBI (CAP) – EMA/PAM/0000339581 .....                                                  | 43        |
| 7.5.4.      | Naldemedine - RIZMOIC (CAP) – EMA/PAM/0000320323 .....                                                | 43        |
| 7.5.5.      | Solriamfetol - SUNOSI (CAP) – EMA/PAM/0000349991.....                                                 | 43        |

|        |                                                             |    |
|--------|-------------------------------------------------------------|----|
| 7.5.6. | Tofacitinib - XELJANZ (CAP) – EMA/PAM/0000334570 .....      | 43 |
| 7.5.7. | Velaglucerase alfa - VPRIV (CAP) – EMA/PAM/0000357579 ..... | 44 |
| 7.5.8. | Zilucoplan - ZILBRYSQ (CAP) – EMA/PAM/0000369248 .....      | 44 |

## **8. Renewals of the marketing authorisation, conditional renewal and annual reassessments 44**

### **8.1. Annual reassessments of the marketing authorisation ..... 44**

|         |                                                                                                               |    |
|---------|---------------------------------------------------------------------------------------------------------------|----|
| 8.1.1.  | Amino acids - MAAPLIV (CAP) – EMA/S/0000362071.....                                                           | 44 |
| 8.1.2.  | Evinacumab - EVKEEZA (CAP) – EMA/S/0000351184 .....                                                           | 44 |
| 8.1.3.  | Lonafarnib - ZOKINVY (CAP) – EMA/S/0000362361 .....                                                           | 45 |
| 8.1.4.  | Mecasermin - INCRELEX (CAP) – EMA/S/0000365495 .....                                                          | 45 |
| 8.1.5.  | Nelarabine - ATRIANCE (CAP) – EMA/S/0000360566.....                                                           | 45 |
| 8.1.6.  | Odevixibat - BYLVAY (CAP) – EMA/S/0000362582 .....                                                            | 45 |
| 8.1.7.  | rADAMTS13 - ADZYNMA (CAP) – EMA/S/0000363431 .....                                                            | 45 |
| 8.1.8.  | Smallpox and monkeypox vaccine (live modified vaccinia virus Ankara) - IMVANEX (CAP) – EMA/S/0000363676 ..... | 45 |
| 8.1.9.  | Tofersen - QALSODY (CAP) – EMA/S/0000349866 .....                                                             | 46 |
| 8.1.10. | Vestronidase alfa - MEPSEVII (CAP) – EMA/S/0000363212 .....                                                   | 46 |

### **8.2. Conditional renewals of the marketing authorisation ..... 46**

|        |                                                                   |    |
|--------|-------------------------------------------------------------------|----|
| 8.2.1. | Exagamglogene autotemcel - CASGEVY (CAP) – EMA/R/0000365884 ..... | 46 |
|--------|-------------------------------------------------------------------|----|

### **8.3. Renewals of the marketing authorisation ..... 46**

|         |                                                                                                                     |    |
|---------|---------------------------------------------------------------------------------------------------------------------|----|
| 8.3.1.  | Betaine - AMVERSIO (CAP) – EMA/R/0000365548 .....                                                                   | 46 |
| 8.3.2.  | Daridorexant - QUVIVIQ (CAP) – EMA/R/0000365360 .....                                                               | 46 |
| 8.3.3.  | Difelikefalin - KAPRUVIA (CAP) – EMA/R/0000361500 .....                                                             | 47 |
| 8.3.4.  | Leuprorelin - CAMCEVI (CAP) – EMA/R/0000363056 .....                                                                | 47 |
| 8.3.5.  | Lisocabtagene maraleucel - BREYANZI (CAP) – EMA/R/0000355073 .....                                                  | 47 |
| 8.3.6.  | Onasemnogene abeparvovec - ZOLGENSMA (CAP) – EMA/R/0000365386, Orphan .....                                         | 47 |
| 8.3.7.  | Pegfilgrastim - STIMUFEND (CAP) – EMA/R/0000351198 .....                                                            | 47 |
| 8.3.8.  | Relugolix - ORGOVYX (CAP) – EMA/R/0000363768 .....                                                                  | 48 |
| 8.3.9.  | Sitagliptin - SITAGLIPTIN ACCORD (CAP) – EMA/R/0000362632.....                                                      | 48 |
| 8.3.10. | Vildagliptin / Metformin hydrochloride - VILDAGLIPTIN/METFORMIN HYDROCHLORIDE ACCORD (CAP) – EMA/R/0000357008 ..... | 48 |

## **9. Product related pharmacovigilance inspections 48**

### **9.1. List of planned pharmacovigilance inspections..... 48**

### **9.2. Ongoing or concluded pharmacovigilance inspections..... 48**

### **9.3. Others ..... 48**

|               |                                                                                                                                                                       |           |
|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| <b>10.</b>    | <b>Other safety issues for discussion requested by the Member States, CHMP or the EMA</b>                                                                             | <b>49</b> |
| <b>11.</b>    | <b>Scientific advice procedures</b>                                                                                                                                   | <b>49</b> |
| <b>12.</b>    | <b>Organisational, regulatory and methodological matters</b>                                                                                                          | <b>49</b> |
| <b>12.1.</b>  | <b>Mandate and organisation of the PRAC.....</b>                                                                                                                      | <b>49</b> |
| 12.1.1.       | PRAC membership .....                                                                                                                                                 | 49        |
| 12.1.2.       | Nominated proxy .....                                                                                                                                                 | 49        |
| <b>12.2.</b>  | <b>Coordination with EMA Scientific Committees or CMDh-v .....</b>                                                                                                    | <b>49</b> |
| <b>12.3.</b>  | <b>Coordination with EMA Working Parties/Working Groups/Drafting Groups .....</b>                                                                                     | <b>49</b> |
| <b>12.4.</b>  | <b>Cooperation within the EU regulatory network.....</b>                                                                                                              | <b>49</b> |
| 12.4.1.       | Concept paper on guidance on the use of biomarkers of effect in risk assessment - update                                                                              | 49        |
| 12.4.2.       | PRAC strategic review and learning meeting (SRLM) under the Irish presidency of the European Union (EU) Council - Dublin, Ireland, 05-06 November 2026 - update ..... | 49        |
| <b>12.5.</b>  | <b>Cooperation with International Regulators.....</b>                                                                                                                 | <b>50</b> |
| <b>12.6.</b>  | <b>Contacts of the PRAC with external parties and interaction with the Interested Parties to the Committee .....</b>                                                  | <b>50</b> |
| <b>12.7.</b>  | <b>PRAC work plan .....</b>                                                                                                                                           | <b>50</b> |
| <b>12.8.</b>  | <b>Planning and reporting .....</b>                                                                                                                                   | <b>50</b> |
| <b>12.9.</b>  | <b>Pharmacovigilance audits and inspections .....</b>                                                                                                                 | <b>50</b> |
| 12.9.1.       | Pharmacovigilance systems and their quality systems .....                                                                                                             | 50        |
| 12.9.2.       | Pharmacovigilance inspections – 2026 CAP Inspection Programme Revision .....                                                                                          | 50        |
| 12.9.3.       | Pharmacovigilance audits.....                                                                                                                                         | 50        |
| <b>12.10.</b> | <b>Periodic safety update reports (PSURs) &amp; Union reference date (EURD) list .....</b>                                                                            | <b>50</b> |
| 12.10.1.      | Periodic safety update reports .....                                                                                                                                  | 50        |
| 12.10.2.      | PSURs repository .....                                                                                                                                                | 50        |
| 12.10.3.      | Union reference date list – consultation on the draft list .....                                                                                                      | 51        |
| 12.10.4.      | Periodic safety update reports single assessment (PSUSA) – Pilot of completing sections of the assessment report template by MAHs.....                                | 51        |
| <b>12.11.</b> | <b>Signal management.....</b>                                                                                                                                         | <b>51</b> |
| <b>12.12.</b> | <b>Adverse drug reactions reporting and additional reporting .....</b>                                                                                                | <b>51</b> |
| 12.12.1.      | Management and reporting of adverse reactions to medicinal products.....                                                                                              | 51        |
| 12.12.2.      | Additional monitoring .....                                                                                                                                           | 51        |
| 12.12.3.      | List of products under additional monitoring – consultation on the draft list .....                                                                                   | 51        |
| <b>12.13.</b> | <b>EudraVigilance database .....</b>                                                                                                                                  | <b>51</b> |
| 12.13.1.      | Activities related to the confirmation of full functionality.....                                                                                                     | 51        |
| <b>12.14.</b> | <b>Risk management plans and effectiveness of risk minimisations .....</b>                                                                                            | <b>51</b> |
| 12.14.1.      | Risk management systems .....                                                                                                                                         | 51        |
| 12.14.2.      | Tools, educational materials and effectiveness measurement of risk minimisations .....                                                                                | 51        |
| <b>12.15.</b> | <b>Post-authorisation safety studies (PASS) .....</b>                                                                                                                 | <b>52</b> |
| 12.15.1.      | Post-authorisation Safety Studies – imposed PASS .....                                                                                                                | 52        |

|               |                                                                                                                                                        |           |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 12.15.2.      | Post-authorisation Safety Studies – non-imposed PASS .....                                                                                             | 52        |
| <b>12.16.</b> | <b>Community procedures.....</b>                                                                                                                       | <b>52</b> |
| 12.16.1.      | Referral procedures for safety reasons .....                                                                                                           | 52        |
| <b>12.17.</b> | <b>Renewals, conditional renewals, annual reassessments.....</b>                                                                                       | <b>52</b> |
| <b>12.18.</b> | <b>Risk communication and transparency .....</b>                                                                                                       | <b>52</b> |
| 12.18.1.      | Public participation in pharmacovigilance .....                                                                                                        | 52        |
| 12.18.2.      | Safety communication .....                                                                                                                             | 52        |
| <b>12.19.</b> | <b>Continuous pharmacovigilance .....</b>                                                                                                              | <b>52</b> |
| 12.19.1.      | Incident management .....                                                                                                                              | 52        |
| <b>12.20.</b> | <b>Impact of pharmacovigilance activities .....</b>                                                                                                    | <b>52</b> |
| 12.20.1.      | Digital support to risk minimisation measures (RMMs).....                                                                                              | 52        |
| <b>12.21.</b> | <b>Others .....</b>                                                                                                                                    | <b>53</b> |
| 12.21.1.      | Chimeric antigen receptor-T (CAR-T) passport - educational and certification tool for Health Care Professionals (HCP) prescribing CAR-T products ..... | 53        |
| 12.21.2.      | CHMP assessment report (AR) template – Revamp Project - update.....                                                                                    | 53        |
| 12.21.3.      | Guideline on risk assessment of medicinal products on human reproduction and breastfeeding: from data to product information - update .....            | 53        |
| 12.21.4.      | Good pharmacovigilance practice (GVP) – 2027 planning.....                                                                                             | 53        |
| 12.21.5.      | Petition to the European Parliament ‘on the recognition, research and medical support for fluoroquinolone-associated disability (FQAD)’ .....          | 53        |
| 12.21.6.      | Serious cutaneous adverse reactions (SCARs) - PRAC guidance update .....                                                                               | 53        |
| 12.21.7.      | 21 <sup>st</sup> Industry stakeholder platform - operation of European Union (EU) pharmacovigilance - feedback .....                                   | 53        |
| <b>13.</b>    | <b>Any other business</b>                                                                                                                              | <b>53</b> |
| <b>14.</b>    | <b>Explanatory notes</b>                                                                                                                               | <b>53</b> |

## **1. Introduction**

### **1.1. Welcome and declarations of interest of members, alternates and experts**

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PRAC plenary session to be held 26 - 29 October 2026. See November 2026 PRAC minutes (to be published post December 2026 PRAC meeting).

### **1.2. Agenda of the meeting on 26–29 October 2026**

**Action:** For adoption

### **1.3. Minutes of the previous meeting on 28 September–01 October 2026**

**Action:** For adoption

## **2. EU referral procedures for safety reasons: urgent EU procedures**

### **2.1. Newly triggered procedures**

None

### **2.2. Ongoing procedures**

None

### **2.3. Procedures for finalisation**

None

## **3. EU referral procedures for safety reasons: other EU referral procedures**

### **3.1. Newly triggered procedure**

#### **3.1.1. Melitracen hydrochloride, flupentixol hydrochloride (NAP) – EMA/REF/0000382942**

Applicants: various

PRAC Rapporteur: To be appointed; PRAC Co-Rapporteur: To be appointed

Scope: Review of the benefit-risk balance following notification by Belgium of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data.

**Action:** For adoption (Appointment of Rapporteurs, Adoption of TT, Adoption of LoQ)

### 3.2. Ongoing procedures

None

### 3.3. Procedures for finalisation

None

### 3.4. Re-examination procedures<sup>1</sup>

None

### 3.5. Others

None

## 4. Signals assessment and prioritisation<sup>2</sup>

### 4.1. New signals detected from EU spontaneous reporting systems and/or other sources

#### 4.1.1. Human normal immunoglobulin - DEQSIGA (CAP); FLEBOGAMMA DIF (CAP); HIZENTRA (CAP); HYQVIA (CAP); KIOVIG (CAP); PRIVIGEN (CAP), NAP

Applicant(s): Baxalta Innovations GmbH (HyQvia), CSL Behring GmbH (Hizentra, Privigen), Instituto Grifols, S.A. (Flebogamma DIF), Takeda Manufacturing Austria AG (Deqsig, Kiovig), various

PRAC Rapporteur: Dirk Mentzer

Scope: Signal of batch-associated hypersensitivity reactions

**Action:** For adoption of PRAC recommendation

EPITT 20318 – New signal

Lead Member State(s): DE

<sup>1</sup> Re-examination of PRAC recommendation under Article 32 of Directive 2001/83/EC

<sup>2</sup> Each signal refers to a substance or therapeutic class. The route of marketing authorisation is indicated in brackets (CAP for Centrally Authorised Products; NAP for Nationally Authorised Products including products authorised via Mutual Recognition Procedures and Decentralised Procedure). Product names are listed for reference Centrally Authorised Products (CAP) only. PRAC recommendations will specify the products concerned in case of any regulatory action required

## 4.2. Signals follow-up and prioritisation

### 4.2.1. Cefpodoxime (NAP)

---

Applicant: various

PRAC Rapporteur: Amelia Cupelli

Scope: Signal of drug interaction between cefpodoxime and proton pump inhibitor (PPIs) resulting in a potentially reduced efficacy of cefpodoxime

**Action:** For adoption

EPITT 20280 – Follow-up to June 2026

### 4.2.2. Lithium (NAP)

---

Applicants: various

PRAC Rapporteur: Dennis Lex

Scope: Signal of drug interaction between lithium and GLP-1 agonists leading to increased lithium levels

**Action:** For adoption

EPITT 20275 – Follow-up to June 2026

### 4.2.3. Oseltamivir – TAMIFLU (CAP) - EMEA/H/C/000402/SDA/107; zanamivir – DECTOVA - EMEA/H/C/004102/SDA/019 (CAP)

---

Applicant(s): Roche Registration GmbH (Tamiflu); GlaxoSmithKline Trading Services Limited (Dectova)

PRAC Rapporteur: Terhi Lehtinen

Scope: Signal of new information on the safety in patients critically ill with influenza

**Action:** For adoption

EPITT 20299 – Follow-up to July 2026

## 4.3. Variation procedure(s) resulting from signal evaluation

None

## 5. Risk management plans (RMPs)

### 5.1. Medicines in the pre-authorisation phase

#### 5.1.1. Bilayer engineered collagen hydrogel containing living autologous keratinocytes and fibroblasts (CAP MAA) - EMEA/H/C/006357, Orphan

---

ATMP

Scope (pre D-120 phase): Treatment of adults and children with partial deep dermal and full-thickness burns

**Action:** For adoption

#### 5.1.2. Deuruxolitinib (CAP MAA) - EMEA/H/C/006812

---

Scope (pre D-180 phase): Treatment of severe alopecia areata in adults

**Action:** For adoption

#### 5.1.3. Enlicitide (CAP MAA) - EMEA/H/C/006815

---

Scope (pre D-180 phase): Indicated in adults with primary hypercholesterolaemia or mixed dyslipidaemia

**Action:** For adoption

#### 5.1.4. Enlicitide (CAP MAA) - EMEA/H/C/007131

---

Scope (pre D-180 phase): Indicated in adults with primary hypercholesterolaemia or mixed dyslipidaemia

**Action:** For adoption

#### 5.1.5. Hexaminolevulinate (CAP MAA) - EMEA/H/C/006878

---

Scope (pre D-180 phase): Treatment of adult patients with histologically confirmed cervical high-grade squamous intraepithelial lesions (HSIL)

**Action:** For adoption

#### 5.1.6. Ianalumab (CAP MAA) - EMEA/H/C/006748

---

Scope (pre D-180 phase): Treatment of Sjögren's disease in adults

**Action:** For adoption

#### 5.1.7. Omalizumab (CAP MAA) - EMEA/H/C/006687

---

Scope (pre D-180 phase): Treatment of asthma in adults and children from 6 years of age,

and treatment of chronic rhinosinusitis with nasal polyps in adults

**Action:** For adoption

#### 5.1.8. Ponatinib (CAP MAA) - EMEA/H/C/006894

---

Scope (pre D-180 phase): Treatment of chronic myeloid leukaemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) in adults

**Action:** For adoption

#### 5.1.9. Regadenoson (CAP MAA) - EMEA/H/C/006848

---

Scope (pre D-180 phase): Pharmacological stress agent for myocardial perfusion imaging (MPI) and measurement of fractional flow reserve (FFR) in adults

**Action:** For adoption

#### 5.1.10. Veligrotug (CAP MAA) - EMEA/H/C/006813

---

Scope (pre D-180 phase): Treatment of moderate to severe thyroid eye disease in adults

**Action:** For adoption

### 5.2. Medicines in the post-authorisation phase – PRAC-led procedures

#### 5.2.1. Canakinumab - ILARIS (CAP) – EMA/VR/0000368030

---

Applicants: Novartis Europharm Limited

PRAC Rapporteur: Dirk Mentzer

Scope: Update of section 4.2 of the SmPC in order to reflect removal of patient cards as additional Risk Minimisation Measures (aRMM) based on the update of the Risk Management Plan (RMP) to version 15; Annex IID and the Package Leaflet are updated accordingly. The RMP version 15 has also been submitted.

**Action:** For adoption

#### 5.2.2. Etanercept - BENEPALI (CAP) – EMA/VR/0000365721

---

Applicants: Samsung Bioepis NL B.V.

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Submission of the final report from study (BADBIR), listed as a category 3 study in the RMP. This is the British Association of Dermatologists Biologic Interventions Register: a nationwide registry which seeks to assess the long-term safety of biologic treatments for psoriasis. An updated RMP version 12.0 has also been submitted.

**Action:** For adoption

### 5.2.3. Ipilimumab - YERVOY (CAP); Nivolumab - OPDIVO (CAP) – EMA/VR/0000362961

---

Applicants: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: C.9.b - to propose and extension of the due date for study CA2098Y8 from '28 February 2027' to '31 December 2027' and to revised the due date of a PAES study CA2098Y8, also listed in Annex II of the Product Information, from 'by 28th February 2027' to 'by 31st December 2027'.

**Action:** For adoption

### 5.2.4. Siponimod - MAYZENT (CAP) – EMA/VR/0000317924

---

Applicants: Novartis Europharm Limited

PRAC Rapporteur: Maria del Pilar Rayon

Scope: A grouped application consisting of:

Type II (C.I.13): Submission of the final report from study CBAF312A2006 listed as a category 3 study in the RMP. This is a survey conducted among healthcare professionals and Multiple Sclerosis patients/caregivers in selected European countries plus Canada to evaluate the knowledge required for the safe use of Mayzent (siponimod). The RMP version 8.0 has also been submitted.

Type IB (C.I.11): Submission of an updated RMP version 8.0 in order to update the siponimod exposure data in accordance with the results of the drug-drug interaction study CBAF312A02101 in alignment with the EMA/VR/0000255116 procedure.

**Action:** For adoption

## 5.3. Medicines in the post-authorisation phase – CHMP-led procedures

### 5.3.1. 5-aminolevulinic acid - GLIOLAN (CAP) – EMA/VR/0000365302

---

Applicants: Photonamic GmbH & Co. KG

PRAC Rapporteur: Carla Torre

Scope: Extension of indication to include visualisation of tumour tissue during surgery for meningioma (WHO Grade I to III) in adults for GLIOLAN, based on the results from the US/EU pivotal Phase 3 clinical study MEN 301; this is a Phase 3 multicenter study of Gleolan (aminolevulinic acid hydrochloride) to enhance visualization of tumor in patients with newly diagnosed or recurrent meningiomas. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) brought the PI in line with the latest QRD template version 10.4, and introduced editorial and administrative changes to the PI including an update to the list of local representatives in the Package Leaflet. As part of the application, the MAH is requesting one year of additional data exclusivity.

**Action:** For adoption

### 5.3.2. Adagrasib - KRAZATI (CAP); NAP – EMA/X/0000358567

---

Applicants: Bristol-Myers Squibb Pharma EEIG, various

PRAC Rapporteur: Kimmo Jaakkola

Scope: Extension application to add two new strengths (300 mg and 400 mg, film-coated tablets in blister). The RMP (version 3.0) is updated in accordance.

The MAH took also the opportunity to correct the product name in the PI from KRAZATI to Krazati.

**Action:** For adoption

### 5.3.3. Alglucosidase alfa - MYOZYME (CAP) – EMA/VR/0000368063

---

Applicants: Sanofi B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Update of sections 4.2 and 4.8 of the SmPC in order to update information regarding use in different special populations, based on safety review following the completion of post-authorisation safety studies. The RMP version 12.0 is submitted to reflect the removal of the missing information topics accordingly. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI.

**Action:** For adoption

### 5.3.4. Asciminib - SCEMBLIX (CAP) – EMA/VR/0000342126

---

Applicants: Novartis Europharm Limited

PRAC Rapporteur: Eva Jirsová

Scope: Update of section 4.4 of the SmPC in order to add a new warning on arterial occlusive events, based on a safety review. The Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted.

**Action:** For adoption

### 5.3.5. Atidarsagene autotemcel - LIBMELDY (CAP) – EMA/VR/0000368167

---

Applicants: Orchard Therapeutics (Netherlands) B.V., ATMP

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of the final report from study 205756, listed as a category 3 study in the RMP. This is a Phase II, single arm, open label, clinical study of cryopreserved autologous CD34+ cells transduced with lentiviral vector containing human ARSA cDNA (OTL-200), for the treatment of early-onset metachromatic leukodystrophy (MLD). The RMP version 4.2 has also been submitted.

**Action:** For adoption

#### 5.3.6. Dengue tetravalent vaccine (live / attenuated) - DENGUE TETRAVALENT VACCINE (LIVE, ATTENUATED) TAKEDA (ART 58); QDENG (CAP) – EMA/VR/0000323434

---

Applicants: Takeda Pharmaceuticals International AG Ireland Branch, various

PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update safety and efficacy information regarding the administration of a booster dose based on the final results of Part 5 from study DEN-301, listed as a category 3 study in the RMP; this is a Phase III, double-blind, randomized, placebo-controlled trial to investigate the efficacy, safety and immunogenicity of a Tetravalent Dengue Vaccine (TDV) administered subcutaneously in healthy children aged 4–16 years old, investigating a TDV booster dose in the booster phase (Parts 4 and 5) of the trial. The RMP version 3.3 has also been submitted. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI and to update the list of local representatives in the Package Leaflet for Qdenga.

**Action:** For adoption

#### 5.3.7. Denosumab - WYOST (CAP) – EMA/VR/0000363226

---

Applicants: Sandoz GmbH

PRAC Rapporteur: Karin Bolin

Scope: Quality.

**Action:** For adoption

#### 5.3.8. Deutivacaftor / Tezacaftor / Vanzacaftor - ALYFTREK (CAP) – EMA/X/0000358872

---

Applicants: Vertex Pharmaceuticals (Ireland) Limited

PRAC Rapporteur: Dennis Lex

Scope: Extension Application to introduce a new pharmaceutical form (granules) in two dosage strengths (100 mg/32 mg/8 mg and 150 mg/48 mg/12 mg) for a new indication, to support inclusion of patients with Cystic Fibrosis aged 2 to less than 6 years old. The RMP version 1.1 has also been submitted.

**Action:** For adoption

#### 5.3.9. Dolutegravir - TIVICAY (CAP) – EMA/VR/0000351003

---

Applicants: ViiV Healthcare B.V.

PRAC Rapporteur: Dennis Lex

Scope: Extension of indication to include, in combination with other anti-retroviral medicinal products, the treatment of Human Immunodeficiency Virus (HIV) infected neonates from birth to less than 4 weeks and weighing at least 2 kg for TIVICAY, based on safety, tolerability, and PK data from the study 212161 (IMPAACT 2023) conducted in term (gestational age  $\geq 37$  weeks) neonates exposed to HIV-1 weighing at least 2 kg and enrolled within 5 days of birth who received dolutegravir (DTG) in addition to standard of

care prophylaxis. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 23.0 of the RMP has also been submitted. In addition, the MAH is taking the opportunity to introduce minor amendments to the PI.

**Action:** For adoption

#### 5.3.10. [Dolutegravir / Lamivudine - DOVATO \(CAP\) – EMA/X/0000335457](#)

---

Applicants: ViiV Healthcare B.V.

PRAC Rapporteur: David Olsen

Scope: Extension application to introduce a new pharmaceutical form (dispersible tablet) associated with a new strength (5 mg/30 mg) grouped with an extension of indication type II variation (C.6.a) to include treatment of children weighing at least 20 kg for Dovato based on results from Study 207742 and Study 205861. Study 207742 is a randomised non-inferiority trial with nested PK to assess DTG/3TC fixed dose formulations for the maintenance of virological suppression in children with HIV infection aged 2 to <15 years old: Intensive PK Substudy; and study 205861 is a Phase 3b, open label, single arm study in Antiretroviral Therapy (ART)-naïve adolescents. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 7.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes and to update the PI in accordance with the latest EMA excipients guideline.

**Action:** For adoption

#### 5.3.11. [Eravacycline - XERAVA \(CAP\) – EMA/VR/0000343900](#)

---

Applicants: Paion Pharma GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Update of section 5.1 of the SmPC in order to update the list of pathogens susceptible to eravacycline, based on the final results from study NC-IHMA-2018-01, listed as a category 3 study in the RMP; this is a surveillance study of the activity of eravacycline against bacteria collected from hospitals in Asia / Pacific, Europe and the USA from 2018 to 2022. The RMP version 4.2 has also been submitted.

**Action:** For adoption

#### 5.3.12. [Furosemide - BOPEDIAT \(CAP\) – EMA/X/0000358405](#)

---

Applicants: Proveca Pharma Limited

PRAC Rapporteur: Carla Torre

Scope: Extension application to introduce a new strength (1 mg orodispersible tablets). The application is grouped with a type IB variation (Q.II.f.1.b.5) to extend the shelf-life of the finished product 5 mg orodispersible tablets (EU/1/26/2027/001-004) as packaged for sale from 1 to 2 years when stored at the following storage conditions: "Do not store above 25°C,

Store in the original package in order to protect from light”, in accordance with ICH guidelines. The RMP has been updated (version 1.1).

**Action:** For adoption

#### **5.3.13. Givinostat - DUVYZAT (CAP) – EMA/VR/0000343703**

---

Applicants: Italfarmaco S.p.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Update of section 5.3 of the SmPC based on results from carcinogenicity studies in mice and rat. The RMP version 1.1 has also been submitted.

**Action:** For adoption

#### **5.3.14. Givinostat - DUVYZAT (CAP) – EMA/VR/0000343737**

---

Applicants: Italfarmaco S.p.A., various

PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.2 and 5.2 of the SmPC based on final results from study ITF/2357/60. This is a Phase I, open-label, non-randomized study to evaluate the pharmacokinetic, safety and tolerability of ITF2357 given as an oral single 50 mg dose in participants with chronic hepatic impairment relative to matched participants with normal hepatic function. The RMP version 1.1 has also been submitted.

**Action:** For adoption

#### **5.3.15. Glofitamab - COLUMVI (CAP) – EMA/VR/0000348695**

---

Applicants: Roche Registration GmbH

PRAC Rapporteur: Veronika Macurova

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to add 'Progressive multifocal leukoencephalopathy (PML)' to the list of adverse drug reactions (ADRs) with frequency 'not known' based on post-marketing data and literature. The Package Leaflet is updated accordingly. The RMP version 7 has also been submitted.

**Action:** For adoption

#### **5.3.16. Ipilimumab - YERVOY (CAP); Nivolumab - OPDIVO (CAP) – EMA/VR/0000350392**

---

Applicants: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Dirk Mentzer

Scope: Extension of indication to include nivolumab (OPDIVO) in combination with ipilimumab (YERVOY) for the neoadjuvant treatment of resectable stage III melanoma in adults and adolescents 12 years of age and older, based on results of the NADINA study (CA2096FR; NCT04949113): this is a multicenter, international, open-label, 2-arm, randomised, Phase 3 trial including 423 subjects with Stage III ( $\leq 3$  resectable in-transit

metastases allowed) cutaneous or unknown primary melanoma. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflets are updated in accordance. Version 54.0 of the RMP for OPDIVO and version 47.0 of the RMP for YERVOY have also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI for OPDIVO and YERVOY.

**Action:** For adoption

#### **5.3.17. Lebrikizumab - EBGLYSS (CAP) – EMA/X/0000358474**

---

Applicants: Almirall S.A.

PRAC Rapporteur: Liana Martirosyan

Scope: Extension application to introduce a new strength (125 mg solution for injection in pre-filled syringe) grouped with an Extension of Indication to extend existing treatment of moderate-to-severe atopic dermatitis to the paediatric patients of 6 months and older for EBGLYSS based on interim results from clinical studies J2T-MC-KGBI (ADorable-1) and J2T-MC-KGBJ (ADorable-2). As part of the application, the MAH is requesting a 1-year extension of the market protection. The RMP version 2.0 has also been submitted.

**Action:** For adoption

#### **5.3.18. Mavacamten - CAMZYOS (CAP) – EMA/VR/0000343906**

---

Applicants: Bristol-Myers Squibb Pharma EEIG, various

PRAC Rapporteur: Kimmo Jaakkola

Scope: Submission of the final report from study CV0271148, listed as a category 3 study in the RMP. This is a meta-analysis to assess cardiovascular safety of mavacamten. RMP version 8.0 has also been submitted.

**Action:** For adoption

#### **5.3.19. Methylphenidate hydrochloride - TUZULBY (CAP) – EMA/X/0000327555**

---

Applicants: Neuraxpharm Pharmaceuticals S.L.

PRAC Rapporteur: Dennis Lex

Scope: Extension application to introduce a new pharmaceutical form associated with new strength (5 mg/ml powder for prolonged-release oral suspension).

The RMP version 1.1 is updated in accordance.

**Action:** For adoption

#### **5.3.20. Osilodrostat - ISTURISA (CAP) – EMA/VR/0000315678, Orphan**

---

Applicants: Recordati Rare Diseases

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Extension of indication to include the treatment of endogenous Cushing's syndrome in adolescents and children aged 6 years and older for ISTURISA, based on results from study CLCI699C2203; this is a Phase II, multicenter, open-label, non-comparative study to evaluate the pharmacokinetics, pharmacodynamics, and tolerability of osilodrostat in children and adolescent patients with Cushing's disease. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted.

**Action:** For adoption

#### 5.3.21. Repotrectinib - AUGTYRO (CAP) – EMA/X/0000357212

---

Applicants: Bristol-Myers Squibb Pharma EEIG

PRAC Rapporteur: Marina Lesičar

Scope: Extension application to introduce a new pharmaceutical form (oral suspension) associated with a new strength (32mg/ml), grouped with an Extension of Indication to extend existing indication to paediatric patients (age  $\geq 1$  month to  $< 18$  years) with advanced solid tumours expressing an NTRK gene fusion for AUGTYRO based on interim results from pivotal study CA1271029 (CARE). The RMP version 2.0 has also been submitted.

**Action:** For adoption

#### 5.3.22. Rezafungin - REZZAYO (CAP) – EMA/VR/0000363537

---

Applicants: Mundipharma GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Extension of indication to include prophylaxis of invasive fungal disease in adults undergoing allogeneic haematopoietic stem cell transplantation or with haematological malignancies who are expected to have severe neutropenia for  $\geq 10$  days for REZZAYO, based on new clinical study results including from the pivotal ReSPECT Phase 3 study (CD101.IV.3.08); this is a Phase 3, multicenter, randomised, double-blind study of the efficacy and safety of rezafungin for injection versus the standard antimicrobial regimen to prevent invasive fungal diseases in adults undergoing allogeneic blood and marrow transplantation. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

**Action:** For adoption

#### 5.3.23. Risankizumab - SKYRIZI (CAP) – EMA/VR/0000360512

---

Applicants: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Update of section 4.4 of the SmPC in order to amend an existing warning on infections and tuberculosis, based on clinical trial, postmarketing, and real-world evidence,

together with mechanistic insights regarding selective IL-23 inhibition; the Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted.

**Action:** For adoption

#### 5.3.24. [Risankizumab - SKYRIZI \(CAP\) – EMA/VR/0000370015](#)

---

Applicants: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Liana Martirosyan

Scope: Update of sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to introduce a new posology regimen of an alternative sub-cutaneous induction dosing scheme for Crohn's Disease using 360 mg solution for injection in cartridge based on interim results from Phase 3 study M23-784 and final results from Phase 1 studies M24-460 and M25-814. Study M23-784 is a randomized, placebo-controlled, double-blind study to evaluate the efficacy and safety of risankizumab subcutaneous induction treatment in subjects with moderately to severely active Crohn's Disease; the Package Leaflet is updated accordingly. The RMP version 9.0 has also been submitted.

**Action:** For adoption

#### 5.3.25. [Teplizumab - TEIZEILD \(CAP\) – EMA/VR/0000363763](#)

---

Applicants: Sanofi Winthrop Industrie

PRAC Rapporteur: Terhi Lehtinen

Scope: Extension of indication to include paediatric patients 1 to <8 years of age to the approved indication to delay the onset of Stage 3 type 1 diabetes (T1D) in adult and paediatric patients 8 years of age and older with Stage 2 T1D for TEIZEILD, based on interim results from study PRV-031-005; PRV-031-005 (PETITE-T1D) is a Phase 4, Single arm, open-label study to assess the safety and pharmacokinetics of a 14-day regimen of teplizumab in paediatric Stage 2 Type 1 Diabetes (participants <8 years of age with at least two autoantibodies and dysglycemia). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. As part of the application, the MAH is requesting a 1-year extension of the market protection.

**Action:** For adoption

#### 5.3.26. [Teprotumumab - TEPEZZA \(CAP\) – EMA/VR/0000370302](#)

---

Applicants: Amgen Europe B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Update of sections 4.2, 4.4 and 5.1 of the SmPC to introduce retreatment recommendations, amend the existing warning and monitoring guidance on hearing impairment and include new clinical efficacy/safety information, based on final results from study HZNP-TEP-402, listed as a category 3 study in the RMP. This is a Phase 3b/4, double-masked, randomised, international, parallel-assignment, multicentre interventional study in adult patients with thyroid eye disease, designed to evaluate the safety and tolerability of

different teprotumumab dosing durations and the need for retreatment. The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted. In addition, the MAH took the opportunity to introduce editorial and formatting changes to the PI.

**Action:** For adoption

#### 5.3.27. Ustekinumab - STELARA (CAP) – EMA/VR/0000363450

---

Applicants: Janssen Cilag International

PRAC Rapporteur: Rhea Fitzgerald

Scope: Extension of indication to include treatment of active juvenile psoriatic arthritis in patients 5 years and older for STELARA, based on results from study CNTO1275JPA3001. This is a Phase 3 Multicenter, Open-label Study to Evaluate the Efficacy, Pharmacokinetics, Safety, and Immunogenicity of Subcutaneously Administered Ustekinumab or Guselkumab in Pediatric Participants With Active Juvenile Psoriatic Arthritis (PSUMMIT-Jr). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet has been updated in accordance. Version 34.1 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes and to align the PI with the latest QRD template version 10.4.

**Action:** For adoption

#### 5.3.28. Vosoritide - VOXZOGO (CAP) – EMA/VR/0000343152

---

Applicants: Biomarin International Limited, various

PRAC Rapporteur: Zane Neikena

Scope: Update of section 4.8 of the SmPC in order to add 'femur fracture' to the list of adverse drug reactions (ADRs) with frequency 'common' based on post-marketing data. The Package Leaflet is updated in accordance. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to update the PI in accordance with the latest EMA excipients guideline.

**Action:** For adoption

## 6. Periodic safety update reports (PSURs)

### 6.1. PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) only

#### 6.1.1. Albendazole / Ivermectin - IVERMECTIN/ALBENDAZOLE CAP (ART 58) – EMA/PSUR/0000350272

---

Applicants: Laboratorios Liconsa S.A.

PRAC Rapporteur: Jo Robays

Scope: Evaluation of a PSUSA procedure (PSUV Ivermectin/Albendazole)

**Action:** For adoption

#### **6.1.2.     Atogepant - AQUIPTA (CAP) – EMA/PSUR/0000358983**

---

Applicants: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Rugile Pilvinienė

Scope: Evaluation of a PSUSA procedure (PSUSA/00000100/202603)

**Action:** For adoption

#### **6.1.3.     Avelumab - BAVENCIO (CAP) – EMA/PSUR/0000359018**

---

Applicants: Merck Europe B.V.

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00010635/202603)

**Action:** For adoption

#### **6.1.4.     Belantamab mafodotin - BLENREP (CAP) – EMA/PSUR/0000359028**

---

Applicants: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00010869/202604)

**Action:** For adoption

#### **6.1.5.     Betaine - AMVERSIO (CAP); CYSTADANE (CAP) – EMA/PSUR/0000358994**

---

Applicants: Recordati Rare Diseases

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00000390/202602)

**Action:** For adoption

#### **6.1.6.     Certolizumab pegol - CIMZIA (CAP) – EMA/PSUR/0000358998**

---

Applicants: UCB Pharma

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00000624/202603)

**Action:** For adoption

#### **6.1.7.     Clascoterone - WINLEVI (CAP) – EMA/PSUR/0000359039**

---

Applicants: Cassiopea S.p.A.

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00011162/202604)

**Action:** For adoption

---

#### 6.1.8. [Concizumab - ALHEMO \(CAP\) – EMA/PSUR/0000359010](#)

---

Applicants: Novo Nordisk A/S

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011105/202603)

**Action:** For adoption

---

#### 6.1.9. [COVID-19 vaccine \(recombinant / adjuvanted\) - BIMERVAX \(CAP\) – EMA/PSUR/0000359030](#)

---

Applicants: Hipra Human Health S.L.

PRAC Rapporteur: Zane Neikena

Scope: Evaluation of a PSUSA procedure (PSUSA/00011045/202603)

**Action:** For adoption

---

#### 6.1.10. [Dabigatran etexilate - PRADAXA \(CAP\) – EMA/PSUR/0000358991](#)

---

Applicants: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00000918/202603)

**Action:** For adoption

---

#### 6.1.11. [Deutetrabenazine - AUSTEDO \(CAP\) – EMA/PSUR/0000359045](#)

---

Applicants: TEVA GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011177/202603)

**Action:** For adoption

---

#### 6.1.12. [Dupilumab - DUPIXENT \(CAP\) – EMA/PSUR/0000359022](#)

---

Applicants: Sanofi Winthrop Industrie

PRAC Rapporteur: Kimmo Jaakkola

Scope: Evaluation of a PSUSA procedure (PSUSA/00010645/202603)

**Action:** For adoption

#### **6.1.13. Eftrenonacog alfa - ALPROLIX (CAP) – EMA/PSUR/0000359006, Orphan**

---

Applicants: Swedish Orphan Biovitrum AB (publ)

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00010499/202603)

**Action:** For adoption

#### **6.1.14. Emtricitabine / Rilpivirine / Tenofovir alafenamide - ODEFSEY (CAP) – EMA/PSUR/0000359014**

---

Applicants: Gilead Sciences Ireland Unlimited Company

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Evaluation of a PSUSA procedure (PSUSA/00010514/202602)

**Action:** For adoption

#### **6.1.15. Enalapril maleate - AQUMELDI (CAP) – EMA/PSUR/0000358992**

---

Applicants: Proveca Pharma Limited

PRAC Rapporteur: Karin Bolin

Scope: Evaluation of a PSUSA procedure (PSUSA/00000201/202603)

**Action:** For adoption

#### **6.1.16. Enfuvirtide - FUZEON (CAP) – EMA/PSUR/0000359005**

---

Applicants: Roche Registration GmbH

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00001217/202603)

**Action:** For adoption

#### **6.1.17. Epcoritamab - TEPKINLY (CAP) – EMA/PSUR/0000358986**

---

Applicants: Abbvie Deutschland GmbH & Co. KG

PRAC Rapporteur: Maria Martinez Gonzalez

Scope: Evaluation of a PSUSA procedure (PSUSA/00000107/202603)

**Action:** For adoption

#### **6.1.18. Erdafitinib - BALVERSA (CAP) – EMA/PSUR/0000359040**

---

Applicants: Janssen Cilag International

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011072/202604)

**Action:** For adoption

#### **6.1.19. Futibatinib - LYTGOBI (CAP) – EMA/PSUR/0000358985**

---

Applicants: Taiho Pharma Netherlands B.V.

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00000068/202603)

**Action:** For adoption

#### **6.1.20. Glofitamab - COLUMVI (CAP) – EMA/PSUR/0000358982**

---

Applicants: Roche Registration GmbH

PRAC Rapporteur: Veronika Macurova

Scope: Evaluation of a PSUSA procedure (PSUSA/00000067/202603)

**Action:** For adoption

#### **6.1.21. Idecabtagene vicleucel - ABECMA (CAP) – EMA/PSUR/0000359025**

---

Applicants: Bristol-Myers Squibb Pharma EEIG, ATMP

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00010954/202603)

**Action:** For adoption

#### **6.1.22. Imlunestrant - INLURIYO (CAP) – EMA/PSUR/0000359013**

---

Applicants: Eli Lilly Nederland B.V.

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00011175/202603)

**Action:** For adoption

#### **6.1.23. Inavolisib - ITOVEBI (CAP) – EMA/PSUR/0000359036**

---

Applicants: Roche Registration GmbH

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011164/202604)

**Action:** For adoption

#### 6.1.24. Levacetylleucine - AQNEURSA (CAP) – EMA/PSUR/0000359011

Applicants: Intrabio Ireland Limited

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00011174/202603)

**Action:** For adoption

#### 6.1.25. Lutetium (<sup>177</sup>Lu) vipivotide tetraxetan - PLUVICTO (CAP) – EMA/PSUR/0000359032

Applicants: Novartis Europharm Limited

PRAC Rapporteur: John Joseph Borg

Scope: Evaluation of a PSUSA procedure (PSUSA/00011031/202603)

**Action:** For adoption

#### 6.1.26. Maralixibat - LIVMARLI (CAP) – EMA/PSUR/0000359029

Applicants: Mirum Pharmaceuticals International B.V.

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00011032/202603)

**Action:** For adoption

#### 6.1.27. Marstacimab - HYMPAVZI (CAP) – EMA/PSUR/0000359043

Applicants: Pfizer Europe MA EEIG

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00011101/202604)

**Action:** For adoption

#### 6.1.28. Mirikizumab - OMVOH (CAP) – EMA/PSUR/0000358984

Applicants: Eli Lilly Nederland B.V.

PRAC Rapporteur: Sonja Radowan

Scope: Evaluation of a PSUSA procedure (PSUSA/00000049/202603)

**Action:** For adoption

#### 6.1.29. Naldemedine - RIZMOIC (CAP) – EMA/PSUR/0000359023

Applicants: Shionogi B.V.

PRAC Rapporteur: Eamon O Murchu

Scope: Evaluation of a PSUSA procedure (PSUSA/00010753/202603)

**Action:** For adoption

#### **6.1.30. Nintedanib - OFEV (CAP) – EMA/PSUR/0000359009**

---

Applicants: Boehringer Ingelheim International GmbH

PRAC Rapporteur: Marina Lesičar

Scope: Evaluation of a PSUSA procedure (PSUSA/00010319/202604)

**Action:** For adoption

#### **6.1.31. Niraparib - ZEJULA (CAP) – EMA/PSUR/0000359021**

---

Applicants: Glaxosmithkline Trading Services Limited

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00010655/202603)

**Action:** For adoption

#### **6.1.32. Olipudase alfa - XENPOZYME (CAP) – EMA/PSUR/0000359026**

---

Applicants: Sanofi B.V.

PRAC Rapporteur: Dennis Lex

Scope: Evaluation of a PSUSA procedure (PSUSA/00011003/202603)

**Action:** For adoption

#### **6.1.33. Pemigatinib - PEMAZYRE (CAP) – EMA/PSUR/0000359031, Orphan**

---

Applicants: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010923/202604)

**Action:** For adoption

#### **6.1.34. Pertussis vaccine (recombinant / acellular / component / adsorbed) - VACPERTAGEN (CAP) – EMA/PSUR/0000359017**

---

Applicants: BioNet Europe

PRAC Rapporteur: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00011176/202603)

**Action:** For adoption

#### 6.1.35. Retifanlimab - ZYNYZ (CAP) – EMA/PSUR/0000359042

Applicants: Incyte Biosciences Distribution B.V.

PRAC Rapporteur: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011059/202603)

**Action:** For adoption

#### 6.1.36. Rezafungin - REZZAYO (CAP) – EMA/PSUR/0000358987

Applicants: Mundipharma GmbH

PRAC Rapporteur: Adam Przybylkowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000221/202603)

**Action:** For adoption

#### 6.1.37. Selumetinib - KOSELUGO (CAP) – EMA/PSUR/0000359038

Applicants: AstraZeneca AB

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00010936/202604)

**Action:** For adoption

#### 6.1.38. Serplulimab - HETRONIFLY (CAP) – EMA/PSUR/0000359033

Applicants: Accord Healthcare S.L.U.

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011112/202603)

**Action:** For adoption

#### 6.1.39. Sotatercept - WINREVAIR (CAP) – EMA/PSUR/0000359035

Applicants: Merck Sharp & Dohme B.V.

PRAC Rapporteur: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00011076/202603)

**Action:** For adoption

#### 6.1.40. Tepotinib - TEPMETKO (CAP) – EMA/PSUR/0000359027

Applicants: Merck Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00010979/202603)

**Action:** For adoption

#### **6.1.41. Tipiracil / Trifluridine - LONSURF (CAP) – EMA/PSUR/0000359015**

---

Applicants: Les Laboratoires Servier

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Evaluation of a PSUSA procedure (PSUSA/00010517/202603)

**Action:** For adoption

#### **6.1.42. Tucatinib - TUKYSA (CAP) – EMA/PSUR/0000359024**

---

Applicants: Pfizer Europe MA EEIG

PRAC Rapporteur: Jean-Michel Dogné

Scope: Evaluation of a PSUSA procedure (PSUSA/00010918/202604)

**Action:** For adoption

#### **6.1.43. Vibegron - OBGEMSA (CAP) – EMA/PSUR/0000359037**

---

Applicants: Pierre Fabre Medicament

PRAC Rapporteur: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00011068/202603)

**Action:** For adoption

#### **6.1.44. Vilobelimab - GOHIBIC (CAP) – EMA/PSUR/0000359044**

---

Applicants: InflaRx GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Evaluation of a PSUSA procedure (PSUSA/00011103/202604)

**Action:** For adoption

#### **6.1.45. Zolbetuximab - VYLOY (CAP) – EMA/PSUR/0000359034**

---

Applicants: Astellas Pharma Europe B.V.

PRAC Rapporteur: Bianca Mulder

Scope: Evaluation of a PSUSA procedure (PSUSA/00011095/202603)

**Action:** For adoption

## **6.2. PSUR single assessment (PSUSA) procedures including centrally authorised products (CAPs) and nationally authorised products (NAPs)**

### **6.2.1. Bimatoprost – LUMIGAN (CAP), NAP – EMA/PSUR/0000359007**

---

Applicants: Abbvie Deutschland GmbH & Co. KG, various

PRAC Rapporteur: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00000413/202603)

**Action:** For adoption

### **6.2.2. Gozetotide - LOCAMETZ (CAP), NAP – EMA/PSUR/0000359041**

---

Applicants: Novartis Europharm Limited, various

PRAC Rapporteur: John Joseph Borg

Scope: Evaluation of a PSUSA procedure (PSUSA/00011030/202603)

**Action:** For adoption

## **6.3. PSUR single assessment (PSUSA) procedures including nationally authorised products (NAPs) only**

### **6.3.1. Aprotinin – EMA/PSUR/0000358989**

---

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00000230/202602)

**Action:** For adoption

### **6.3.2. Bicalutamide – EMA/PSUR/0000358990**

---

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00000407/202602)

**Action:** For adoption

### **6.3.3. Butoconazole – EMA/PSUR/0000358999**

---

Applicants: various

PRAC Lead: Melinda Palfi

Scope: Evaluation of a PSUSA procedure (PSUSA/00000471/202602)

**Action:** For adoption

#### **6.3.4.      Cyproterone acetate / estradiol valerate – EMA/PSUR/0000358995**

---

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00000907/202603)

**Action:** For adoption

#### **6.3.5.      Cystine / pyridoxine hydrochloride – EMA/PSUR/0000358969**

---

Applicants: various

PRAC Lead: Adam Przybyłowski

Scope: Evaluation of a PSUSA procedure (PSUSA/00000910/202603)

**Action:** For adoption

#### **6.3.6.      Diclofenac sodium / orphenadrine citrate – EMA/PSUR/0000358996**

---

Applicants: various

PRAC Lead: Roxana Stefania Udrescu

Scope: Evaluation of a PSUSA procedure (PSUSA/00001045/202603)

**Action:** For adoption

#### **6.3.7.      Diethylamine-salicylate / escin – EMA/PSUR/0000359012**

---

Applicants: various

PRAC Lead: Eva Jirsová

Scope: Evaluation of a PSUSA procedure (PSUSA/00009144/202603)

**Action:** For adoption

#### **6.3.8.      Dimeticone / guaiazulene – EMA/PSUR/0000358993**

---

Applicants: various

PRAC Lead: Zoubida Amimour

Scope: Evaluation of a PSUSA procedure (PSUSA/00001099/202603)

**Action:** For adoption

#### **6.3.9.      Ethinylestradiol / gestodene – EMA/PSUR/0000359001**

---

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001308/202603)

**Action:** For adoption

#### **6.3.10. Ethosuximide – EMA/PSUR/0000359002**

---

Applicants: various

PRAC Lead: Karin Erneholm

Scope: Evaluation of a PSUSA procedure (PSUSA/00001316/202603)

**Action:** For adoption

#### **6.3.11. Fluconazole – EMA/PSUR/0000359008**

---

Applicants: various

PRAC Lead: Marie Louise Schougaard Christiansen

Scope: Evaluation of a PSUSA procedure (PSUSA/00001404/202603)

**Action:** For adoption

#### **6.3.12. Furazidine – EMA/PSUR/0000359046**

---

Applicants: various

PRAC Lead: Polona Golmajer

Scope: Evaluation of a PSUSA procedure (PSUSA/00011098/202602)

**Action:** For adoption

#### **6.3.13. Gliclazide – EMA/PSUR/0000359000**

---

Applicants: various

PRAC Lead: Guðrún Stefánsdóttir

Scope: Evaluation of a PSUSA procedure (PSUSA/00001532/202602)

**Action:** For adoption

#### **6.3.14. Human plasma (pooled and treated for virus inactivation) – EMA/PSUR/0000359003**

---

Applicants: various

PRAC Lead: Dirk Mentzer

Scope: Evaluation of a PSUSA procedure (PSUSA/00001635/202602)

**Action:** For adoption

#### 6.3.15. Nicorandil – EMA/PSUR/0000359019

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00002152/202602)

**Action:** For adoption

#### 6.3.16. Nitrofurantoin, nitrofurantoin / pyridoxine hydrochloride – EMA/PSUR/0000358997

Applicants: various

PRAC Lead: Rugile Pilviniene

Scope: Evaluation of a PSUSA procedure (PSUSA/00002174/202602)

**Action:** For adoption

#### 6.3.17. Perchlorates – EMA/PSUR/0000359020

Applicants: various

PRAC Lead: Jan Neuhauser

Scope: Evaluation of a PSUSA procedure (PSUSA/00002486/202603)

**Action:** For adoption

#### 6.3.18. Piperacillin – EMA/PSUR/0000359004

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00002424/202603)

**Action:** For adoption

#### 6.3.19. Rabies vaccine – EMA/PSUR/0000358988

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00009277/202603)

**Action:** For adoption

#### 6.3.20. Tenoxicam – EMA/PSUR/0000359016

Applicants: various

PRAC Lead: Amelia Cupelli

Scope: Evaluation of a PSUSA procedure (PSUSA/00002893/202602)

**Action:** For adoption

## 6.4. Follow-up to PSUR/PSUSA procedures

### 6.4.1. Baloxavir marboxil - XOFLUZA (CAP) – EMA/PAM/0000365599

---

Applicants: various

PRAC Rapporteur: Sonja Radowan

Scope: Submission of the 2025 (1138929 and 1140188) and 2026 (1153856) resistance reports for Xofluza, to ensure continued compliance with the annual reporting obligation.

**Action:** For adoption

### 6.4.2. Semaglutide – OZEMPIC (CAP) – EMA/PAM/0000338018

---

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Karin Bolin

Scope: To assess the potential association between semaglutide exposure and cardioembolic stroke as part of a post-authorisation measure (LEG) - EMEA/H/C/PSUSA/00010671/202505

**Action:** For adoption

### 6.4.3. Semaglutide – RYBELSUS (CAP) – EMA/PAM/0000337900

---

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Karin Bolin

Scope: To assess the potential association between semaglutide exposure and cardioembolic stroke as part of a post-authorisation measure (LEG) - EMEA/H/C/PSUSA/00010671/202505

**Action:** For adoption

### 6.4.4. Semaglutide – WEGOVY (CAP) – EMA/PAM/0000337800

---

Applicant: Novo Nordisk A/S

PRAC Rapporteur: Karin Bolin

Scope: To assess the potential association between semaglutide exposure and cardioembolic stroke as part of a post-authorisation measure (LEG) - EMEA/H/C/PSUSA/00010671/202505

**Action:** For adoption

## 6.5. Variation procedure(s) resulting from PSUSA evaluation

### 6.5.1. Levofloxacin - QUINSAIR (CAP) – EMA/VR/0000365289

---

Applicants: Chiesi Farmaceutici S.p.A., various

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Update of sections 4.4 and 4.8 of the SmPC in order to delete the adverse drug reaction (ADR) table entitled "Tabulated list of additional adverse reactions reported following systemic administration of levofloxacin" based on a cumulative review of the adverse reactions, following the outcome of the PSUR procedure PSUSA/00010429/202505. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.

**Action:** For adoption

### 6.5.2. Rotavirus vaccine, live - ROTARIX (CAP) – EMA/VR/0000368203

---

Applicants: GlaxoSmithKline Biologicals, various

PRAC Rapporteur: Jean-Michel Dogné

Scope: Update of section 4.8 of the SmPC in order to add vomiting, gastroenteritis, and Immune Thrombocytopenic Purpura to the list of adverse drug reactions (ADRs) following EMA/PAM/0000343686; the Package Leaflet is updated accordingly. In addition, the MAH took opportunity to update the frequency of anaphylactic reaction in section 4.8.

**Action:** For adoption

## 6.6. Expedited summary safety reviews<sup>3</sup>

None

## 7. Post-authorisation safety studies (PASS)

### 7.1. Protocols of PASS imposed in the marketing authorisation(s)<sup>4</sup>

#### 7.1.1. Beremagene geperpavec - VYJUVEK (CAP) – EMA/PASS/0000287685

---

Applicants: Krystal Biotech Netherlands B.V., ATMP

PRAC Rapporteur: Liana Martirosyan

---

<sup>3</sup> Submission of expedited summary safety reports for review in addition to the requirements for submission of PSUR(s) falling within the pandemic period and requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC

<sup>4</sup> In accordance with Article 107n of Directive 2001/83/EC

Scope: PASS protocol [107n]: A prospective, non-interventional, multi-country study to confirm the long-term safety profile, including in paediatric patients less than 6 months of age, of B-VEC for the treatment of DEB wounds in a real-life clinical setting.

**Action:** For adoption

---

#### 7.1.2. Ciltacabtagene autoleucel - CARVYKTI (CAP) – EMA/PASS/0000372428

---

Applicants: Janssen Cilag International, ATMP

PRAC Rapporteur: Jo Robays

Scope: PASS amendment [107o]: An Observational PASS to evaluate the safety of multiple myeloma patients treated with ciltacabtagene autoleucel

**Action:** For adoption

---

#### 7.1.3. Donanemab - KISUNLA (CAP) – EMA/PASS/0000339391

---

Applicants: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: PASS protocol [107n]: Secondary database study to characterise safety, drug utilisation and effectiveness of risk minimisation activities in donanemab treated patients in the EU (Protocol IST-MC-B017)

**Action:** For adoption

---

#### 7.1.4. Donanemab - KISUNLA (CAP) – EMA/PASS/0000339404

---

Applicants: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: PASS protocol [107n]: A registry-based observational study to characterise ARIA within a cohort of donanemab-treated patients in the EU (Protocol IST-MC-B015)

**Action:** For adoption

---

#### 7.1.5. Doxecitine / Doxribtimine - KYGEVVI (CAP) – EMA/PASS/0000372539

---

Applicants: UCB Pharma

PRAC Rapporteur: Marina Lesičar

Scope: PASS protocol [107n]: TK0109 A non-interventional PASS to describe safety and clinical outcomes of doxecitine and doxribtimine treatment in patients with genetically confirmed thymidine kinase 2 deficiency (TK2d) with age of symptom onset on or before 12 years

**Action:** For adoption

## 7.2. Protocols of PASS non-imposed in the marketing authorisation(s)<sup>5</sup>

### 7.2.1. Aficamten - MYQORZO (CAP) – EMA/PAM/0000368228

---

Applicants: Cytokinetics (Ireland) Limited, various

PRAC Rapporteur: Eva Jirsová

Scope: Submission of protocol for Post-Authorisation Safety Study CY 6042 required as an additional Category 3 pharmacovigilance activity in the RMP. Study CY 6042 is an observational safety study of aficamten in patients with obstructive hypertrophic cardiomyopathy using existing registries and hospital data.

**Action:** For adoption

### 7.2.2. Bimekizumab - BIMZELX (CAP) – EMA/PAM/0000365441

---

Applicants: UCB Pharma

PRAC Rapporteur: Liana Martirosyan

Scope: Protocol PS0036 is a Bimekizumab Pregnancy Exposure and Outcome Registry: An OTIS Autoimmune Diseases in Pregnancy Study. The objective of this study is to assess maternal, foetal and infant outcomes among people who become pregnant while exposed to bimekizumab relative to the outcomes in 2 matched comparator populations.

Following FDA request for amendment, the MAH has submitted a revised protocol (version 3.0, amendment #3), that contains the changes requested by the FDA for assessment.

**Action:** For adoption

### 7.2.3. Brensocatib - BRINSUPRI (CAP) – EMA/PAM/0000368428

---

Applicants: Insmmed Netherlands B.V., various

PRAC Rapporteur: Zane Neikena

Scope: Draft protocol for a Category 3 Non-Interventional Post-Authorisation Safety Study (NI PASS) (MEA post-authorisation commitment) MEA 0321

**Action:** For adoption

### 7.2.4. Bupropion hydrochloride / Naltrexone hydrochloride - MYSIMBA (CAP) – EMA/PAM/0000363244

---

Applicants: Orexigen Therapeutics Ireland Limited

PRAC Rapporteur: Dennis Lex

Scope: Submission of an updated protocol for study NB-451: Drug Utilisation and Safety Study of Mysimba/Contrave in Europe and the United States

---

<sup>5</sup> In accordance with Article 107m of Directive 2001/83/EC, supervised by PRAC in accordance with Article 61a (6) of Regulation (EC) No 726/2004

**Action:** For adoption

#### **7.2.5. Chikungunya vaccine (live) - IXCHIQ (CAP) – EMA/PAM/0000341603**

---

Applicants: Valneva Austria GmbH, various

PRAC Rapporteur: Dirk Mentzer

Scope: Submission of the protocols for the post-authorisation safety studies VLA1553-403 (version 6.0) and VLA1553-406 (version 6.0) which are category 3 studies in the RMP. VLA1553-403 is an observational study to evaluate the safety of VLA1553 in pregnant women exposed to the vaccine in Brazil. VLA1553-406 is a prospective safety cohort study.

**Action:** For adoption

#### **7.2.6. Donanemab - KISUNLA (CAP) – EMA/PAM/0000338752**

---

Applicants: Eli Lilly Nederland B.V.

PRAC Rapporteur: Amelia Cupelli

Scope: Protocol for a category 3 study in the RMP: Healthcare provider survey to assess the effectiveness of the donanemab additional risk minimisation activities in the EU

**Action:** For adoption

#### **7.2.7. Nipocalimab - IMAAVY (CAP) – EMA/PAM/0000358660**

---

Applicants: Janssen Cilag International, various

PRAC Rapporteur: Dirk Mentzer

Scope: Protocol for RMP category 3 study PCSIMMA0302: A Non-Interventional, Post-Authorization Safety Study (PASS) of Patients Treated with Nipocalimab for Generalized Myasthenia Gravis (gMG) in Routine Clinical Practice in France

**Action:** For adoption

#### **7.2.8. Setmelanotide - IMCIVREE (CAP) – EMA/PAM/0000368955**

---

Applicants: Rhythm Pharmaceuticals Netherlands B.V.

PRAC Rapporteur: Miroslava Gocova

Scope: Protocol amendments for non-imposed PASS study RM-IMC-901, a registry of patients with Biallelic Pro-Opiomelanocortin (POMC), Proprotein Convertase Subtilisin/Kexin Type 1 (PCSK1), or Leptin Receptor (LEPR) Deficiency Obesity, Bardet-Biedl Syndrome (BBS), or Acquired Hypothalamic Obesity (aHO) Treated with Setmelanotide., following CHMP conclusions on procedure EMA/VR/0000288021,

**Action:** For adoption

### 7.3. Results of PASS imposed in the marketing authorisation(s)<sup>6</sup>

None

### 7.4. Results of PASS imposed and non-imposed in the marketing authorisation(s)<sup>7</sup>

#### 7.4.1. Imiglucerase - CEREZYME (CAP) – EMA/VR/0000362491

---

Applicants: Sanofi B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: Update of section 4.6 of the SmPC in order to update information on pregnancy and include the amended 10th Gaucher Pregnancy and Lactation Sub-Registry Report, following the post-authorization measure (PAM) procedure (EMA/H/C/000157/MEA/040.12).

**Action:** For adoption

#### 7.4.2. Infliximab - FLIXABI (CAP) – EMA/VR/0000358948

---

Applicants: Samsung Bioepis NL B.V.

PRAC Rapporteur: Karin Bolin

Scope: A grouped application to submit the final reports from the non-interventional post-authorisation safety studies ARTIS (Anti-Rheumatic Therapies In Sweden) and RABBIT-RA (German Biologics Register - Rheumatoid Arthritis), listed as category 3 studies in the RMP, as well as to request for waiver of the final study report submission requirement for study BSRBR-RA (The British Society for Rheumatology Biologics Register - Rheumatoid Arthritis), listed as a category 3 study in the RMP. The RMP version 15.0 has also been submitted.

**Action:** For adoption

#### 7.4.3. Mexiletine - NAMUSCLA (CAP) – EMA/VR/0000365999

---

Applicants: Lupin Europe GmbH

PRAC Rapporteur: Eva Jirsová

Scope: Submission of the final clinical study report for the non-interventional post-authorisation safety study (PASS) 'LUP-MEX-2018-00', a category 3 study in the RMP. This is an observational study to describe the long-term safety and effectiveness of NaMuscla in the symptomatic management of myotonia in adult patients with non-dystrophic myotonic disorders.

**Action:** For adoption

---

<sup>6</sup> In accordance with Article 107p-q of Directive 2001/83/EC

<sup>7</sup> In accordance with Article 61a (6) of Regulation (EC) No 726/2004, in line with the revised variations regulation for any submission as of 4 August 2013

#### 7.4.4. Sonidegib - ODOMZO (CAP) – EMA/VR/0000357142

---

Applicants: Sun Pharmaceutical Industries (Europe) B.V.

PRAC Rapporteur: Petar Mas

Scope: Submission of the final report from study NISSO (CLDE225A2404) listed as a category 3 study in the RMP. This is a non-imposed, non-interventional, multi-national, multi-center post-authorization safety study) to assess the long-term safety and tolerability of Odomzo (sonidegib) administered in patients with locally advanced basal cell carcinoma (laBCC). The RMP version 9.2 has also been submitted.

**Action:** For adoption

#### 7.4.5. Tofacitinib - XELJANZ (CAP) – EMA/VR/0000368202

---

Applicants: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of the final reports from the non-interventional PASS studies A3921312, A3921314, A3921316 and A3921317, listed as category 3 studies in the RMP. These are from the rheumatoid arthritis (RA) registries of the UK (BSRBR-RA), Sweden (ARTIS), Spain (BIOBADASER) and Germany (RABBIT).

**Action:** For adoption

### 7.5. Interim results and other post-authorisation measures for imposed and non-imposed studies

#### 7.5.1. COVID-19 mRNA vaccine - COMIRNATY (CAP) – EMA/PAM/0000359120

---

Applicants: BioNTech Manufacturing GmbH

PRAC Rapporteur: Liana Martirosyan

Scope: Submission of interim CSR of study C4591036; this is a low interventional cohort study aimed to characterize the clinical course, risk factors, long-term sequelae, and quality of life in children and young adults <21 years with acute post-vaccine myocarditis.

**Action:** For adoption

#### 7.5.2. Idecabtagene vicleucel - ABECMA (CAP) – EMA/PAM/0000365985

---

Applicants: Bristol-Myers Squibb Pharma EEIG, ATMP

PRAC Rapporteur: Jenny-Maria Jönsson

Scope: Transgene assay service testing of secondary malignancies with insertion site analysis as applicable. The objective of this study is tumour tissue sample testing from patients that develop a secondary malignancy of T cell origin.

**\*\*First Interim report - 5 year report\*\***

**Action:** For adoption

#### 7.5.3. Lecanemab - LEQEMBI (CAP) – EMA/PAM/0000339581

---

Applicants: Eisai GmbH

PRAC Rapporteur: Eva Jirsová

Scope: Cat 3 PASS BAN2401-G000-301 OLE

Evaluate the long-term safety and tolerability of LEC10-BW in subjects with early Alzheimer's disease in the Extension Phase.

**Action:** For adoption

#### 7.5.4. Naldemedine - RIZMOIC (CAP) – EMA/PAM/0000320323

---

Applicants: Shionogi B.V.

PRAC Rapporteur: Eamon O Murchu

Scope: 4th Annual Progress Report with interim report with study results for Naldemedine: An Observational Post-Authorisation Safety Study (PASS) of Patients with Chronic Opioid Use for Non-Cancer Pain and Cancer Pain who have Opioid-Induced Constipation (OIC)

**Action:** For adoption

#### 7.5.5. Solriamfetol - SUNOSI (CAP) – EMA/PAM/0000349991

---

Applicants: Atnahs Pharma Netherlands B.V.

PRAC Rapporteur: Julia Pallos

Scope: Progress Report #7 for the solriamfetol post authorisation safety study (PASS) number JZP865-401 entitled "A post-authorisation safety study (PASS) to evaluate cardiovascular events in adult patients with obstructive sleep apnoea (OSA) treated with solriamfetol".

**Action:** For adoption

#### 7.5.6. Tofacitinib - XELJANZ (CAP) – EMA/PAM/0000334570

---

Applicants: Pfizer Europe MA EEIG

PRAC Rapporteur: Liana Martirosyan

Scope: Next interim study report for Study A3921352 is an active surveillance, post-authorization study to characterize the safety of tofacitinib in patients with moderately to severely active ulcerative colitis in the real-world setting using data from the United Registries for Clinical Assessment and Research (UR-CARE) in the European Union (EU), as requested in MEA/01034/1 (EMA/PAM/0000247897).

**Action:** For adoption

#### 7.5.7. Velaglucerase alfa - VPRIV (CAP) – EMA/PAM/0000357579

---

Applicants: Takeda Pharmaceuticals International AG Ireland Branch

PRAC Rapporteur: Dennis Lex

Scope: Submission of 15th annual report of Gaucher Disease Outcome Survey (GOS): An Observational, International, Multicenter, Long-term Registry of Patients with Gaucher Disease. Interim results with data cut off of 30 January 2026.

**Action:** For adoption

#### 7.5.8. Zilucoplan - ZILBRYSQ (CAP) – EMA/PAM/0000369248

---

Applicants: UCB Pharma

PRAC Rapporteur: Karin Erneholm

Scope: PASS cat. 3 study (MG0026): A Multi-National Cohort Study to Assess the Implementation of the Risk Minimization Measures to Prevent Meningococcal Infection in Patients with Generalized Myasthenia Gravis Initiating Zilucoplan, and Zilucoplan Safety in Real-World Settings.

**Action:** For adoption

## 8. Renewals of the marketing authorisation, conditional renewal and annual reassessments

### 8.1. Annual reassessments of the marketing authorisation

#### 8.1.1. Amino acids - MAAPLIV (CAP) – EMA/S/0000362071

---

Applicants: Recordati Rare Diseases

PRAC Rapporteur: Amelia Cupelli

Scope: Annual reassessment of the marketing authorisation

**Action:** For adoption

#### 8.1.2. Evinacumab - EVKEEZA (CAP) – EMA/S/0000351184

---

Applicants: Ultragenyx Germany GmbH

PRAC Rapporteur: Karin Bolin

Scope: Annual reassessment of the marketing authorisation

**Action:** For adoption

#### 8.1.3. Lonafernib - ZOKINVY (CAP) – EMA/S/0000362361

---

Applicants: Integral Pharma Solutions EU Limited

PRAC Rapporteur: Adam Przybylowski

Scope: Annual reassessment of the marketing authorisation

**Action:** For adoption

#### 8.1.4. Mecasermin - INCRELEX (CAP) – EMA/S/0000365495

---

Applicants: Esteve Pharmaceuticals S.A.

PRAC Rapporteur: Terhi Lehtinen

Scope: Annual reassessment of the marketing authorisation

**Action:** For adoption

#### 8.1.5. Nelarabine - ATRIANCE (CAP) – EMA/S/0000360566

---

Applicants: Sandoz Pharmaceuticals d.d.

PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Annual reassessment of the marketing authorisation

**Action:** For adoption

#### 8.1.6. Odevixibat - BYLVAY (CAP) – EMA/S/0000362582

---

Applicants: Ipsen Pharma

PRAC Rapporteur: Adam Przybylowski

Scope: Annual reassessment of the marketing authorisation

**Action:** For adoption

#### 8.1.7. rADAMTS13 - ADZYNMA (CAP) – EMA/S/0000363431

---

Applicants: Takeda Manufacturing Austria AG

PRAC Rapporteur: Maia Uusküla

Scope: Annual reassessment of the marketing authorisation

**Action:** For adoption

#### 8.1.8. Smallpox and monkeypox vaccine (live modified vaccinia virus Ankara) - IMVANEX (CAP) – EMA/S/0000363676

---

Applicants: Bavarian Nordic A/S

PRAC Rapporteur: Dirk Mentzer

Scope: Annual reassessment of the marketing authorisation

**Action:** For adoption

#### 8.1.9. [Tofersen - QALSODY \(CAP\) – EMA/S/0000349866](#)

---

Applicants: Biogen Netherlands B.V.

PRAC Rapporteur: Kimmo Jaakkola

Scope: Annual reassessment of the marketing authorisation

**Action:** For adoption

#### 8.1.10. [Vestronidase alfa - MEPSEVII \(CAP\) – EMA/S/0000363212](#)

---

Applicants: Ultragenyx Germany GmbH

PRAC Rapporteur: Maria del Pilar Rayon

Scope: Annual reassessment of the marketing authorisation

**Action:** For adoption

### 8.2. **Conditional renewals of the marketing authorisation**

#### 8.2.1. [Exagamglogene autotemcel - CASGEVY \(CAP\) – EMA/R/0000365884](#)

---

Applicants: Vertex Pharmaceuticals (Ireland) Limited, ATMP

PRAC Rapporteur: Bianca Mulder

Scope: Conditional renewal of the marketing authorisation

**Action:** For adoption

### 8.3. **Renewals of the marketing authorisation**

#### 8.3.1. [Betaine - AMVERSIO \(CAP\) – EMA/R/0000365548](#)

---

Applicants: Serb

PRAC Rapporteur: Dennis Lex

Scope: 5-year renewal of the marketing authorisation

**Action:** For adoption

#### 8.3.2. [Daridorexant - QUVIVIQ \(CAP\) – EMA/R/0000365360](#)

---

Applicants: Idorsia Pharmaceuticals Deutschland GmbH

PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: 5-year renewal of the marketing authorisation

**Action:** For adoption

#### **8.3.3.      [Difelikefalin - KAPRUVIA \(CAP\) – EMA/R/0000361500](#)**

---

Applicants: Vifor Fresenius Medical Care Renal Pharma France

PRAC Rapporteur: Karin Bolin

Scope: 5-year renewal of the marketing authorisation

**Action:** For adoption

#### **8.3.4.      [Leuprorelin - CAMCEVI \(CAP\) – EMA/R/0000363056](#)**

---

Applicants: Accord Healthcare S.L.U.

PRAC Rapporteur: Amelia Cupelli

Scope: 5-year renewal of the marketing authorisation

**Action:** For adoption

#### **8.3.5.      [Lisocabtagene maraleucel - BREYANZI \(CAP\) – EMA/R/0000355073](#)**

---

Applicants: Bristol-Myers Squibb Pharma EEIGATMP

PRAC Rapporteur: Dirk Mentzer

Scope: 5-year renewal of the marketing authorisation

**Action:** For adoption

#### **8.3.6.      [Onasemnogene abeparvovec - ZOLGENSMA \(CAP\) – EMA/R/0000365386, Orphan](#)**

---

Applicants: Novartis Europharm Limited ATMP

PRAC Rapporteur: Karin Bolin

Scope: 5-year renewal of the marketing authorisation

**Action:** For adoption

#### **8.3.7.      [Pegfilgrastim - STIMUFEND \(CAP\) – EMA/R/0000351198](#)**

---

Applicants: Fresenius Kabi Deutschland GmbH

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

**Action:** For adoption

#### 8.3.8. Relugolix - ORGOVYX (CAP) – EMA/R/0000363768

---

Applicants: Accord Healthcare S.L.U.

PRAC Rapporteur: Karin Erneholm

Scope: 5-year renewal of the marketing authorisation

**Action:** For adoption

#### 8.3.9. Sitagliptin - SITAGLIPTIN ACCORD (CAP) – EMA/R/0000362632

---

Applicants: Accord Healthcare S.L.U.

PRAC Rapporteur: Bianca Mulder

Scope: 5-year renewal of the marketing authorisation

**Action:** For adoption

#### 8.3.10. Vildagliptin / Metformin hydrochloride - VILDAGLIPTIN/METFORMIN HYDROCHLORIDE ACCORD (CAP) – EMA/R/0000357008

---

Applicants: Accord Healthcare S.L.U.

PRAC Rapporteur: Karin Bolin

Scope: 5-year renewal of the marketing authorisation

**Action:** For adoption

## 9. Product related pharmacovigilance inspections

### 9.1. List of planned pharmacovigilance inspections

None

### 9.2. Ongoing or concluded pharmacovigilance inspections

Disclosure of information on results of pharmacovigilance inspections could undermine the protection of the purpose of these inspections, investigations and audits. Therefore such information is not reported in the agenda.

### 9.3. Others

None

## 10. Other safety issues for discussion requested by the Member States, CHMP or the EMA

None

## 11. Scientific advice procedures

Information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

## 12. Organisational, regulatory and methodological matters

### 12.1. Mandate and organisation of the PRAC

#### 12.1.1. PRAC membership

---

**Action:** For information

#### 12.1.2. Nominated proxy

---

**Action:** For information

### 12.2. Coordination with EMA Scientific Committees or CMDh-v

None

### 12.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

None

### 12.4. Cooperation within the EU regulatory network

#### 12.4.1. Concept paper on guidance on the use of biomarkers of effect in risk assessment - update

---

PRAC lead: Anette Kirstine Stark

**Action:** For adoption

#### 12.4.2. PRAC strategic review and learning meeting (SRLM) under the Irish presidency of the European Union (EU) Council - Dublin, Ireland, 05-06 November 2026 - update

---

PRAC lead: Rhea Fitzgerald, Eamon O Murchu

**Action:** For discussion

## **12.5. Cooperation with International Regulators**

None

## **12.6. Contacts of the PRAC with external parties and interaction with the Interested Parties to the Committee**

None

## **12.7. PRAC work plan**

None

## **12.8. Planning and reporting**

None

## **12.9. Pharmacovigilance audits and inspections**

### **12.9.1. Pharmacovigilance systems and their quality systems**

---

None

### **12.9.2. Pharmacovigilance inspections – 2026 CAP Inspection Programme Revision**

---

Action: For adoption

### **12.9.3. Pharmacovigilance audits**

---

None

## **12.10. Periodic safety update reports (PSURs) & Union reference date (EURD) list**

### **12.10.1. Periodic safety update reports**

---

None

### **12.10.2. PSURs repository**

---

None

---

12.10.3. Union reference date list – consultation on the draft list

---

**Action:** For adoption

12.10.4. Periodic safety update reports single assessment (PSUSA) – Pilot of completing sections of the assessment report template by MAHs

---

**Action:** For discussion

**12.11. Signal management**

None

**12.12. Adverse drug reactions reporting and additional reporting**

12.12.1. Management and reporting of adverse reactions to medicinal products

---

None

12.12.2. Additional monitoring

---

None

12.12.3. List of products under additional monitoring – consultation on the draft list

---

**Action:** For adoption

**12.13. EudraVigilance database**

12.13.1. Activities related to the confirmation of full functionality

---

None

**12.14. Risk management plans and effectiveness of risk minimisations**

12.14.1. Risk management systems

---

None

12.14.2. Tools, educational materials and effectiveness measurement of risk minimisations

---

None

## **12.15. Post-authorisation safety studies (PASS)**

### **12.15.1. Post-authorisation Safety Studies – imposed PASS**

---

None

### **12.15.2. Post-authorisation Safety Studies – non-imposed PASS**

---

None

## **12.16. Community procedures**

### **12.16.1. Referral procedures for safety reasons**

---

None

## **12.17. Renewals, conditional renewals, annual reassessments**

None

## **12.18. Risk communication and transparency**

### **12.18.1. Public participation in pharmacovigilance**

---

None

### **12.18.2. Safety communication**

---

None

## **12.19. Continuous pharmacovigilance**

### **12.19.1. Incident management**

---

None

## **12.20. Impact of pharmacovigilance activities**

### **12.20.1. Digital support to risk minimisation measures (RMMs)**

---

PRAC lead: Liana Martirosyan

**Action:** For discussion

## 12.21. Others

- 12.21.1. Chimeric antigen receptor-T (CAR-T) passport - educational and certification tool for Health Care Professionals (HCP) prescribing CAR-T products
- 

**Action:** For information

- 12.21.2. CHMP assessment report (AR) template – Revamp Project - update
- 

**Action:** For discussion

- 12.21.3. Guideline on risk assessment of medicinal products on human reproduction and breastfeeding: from data to product information - update
- 

PRAC lead: Ulla Wändel Liminga

**Action:** For discussion

- 12.21.4. Good pharmacovigilance practice (GVP) – 2027 planning
- 

PRAC lead: Ulla Wändel Liminga

**Action:** For discussion

- 12.21.5. Petition to the European Parliament 'on the recognition, research and medical support for fluoroquinolone-associated disability (FQAD)'
- 

**Action:** For information

- 12.21.6. Serious cutaneous adverse reactions (SCARs) - PRAC guidance update
- 

PRAC Lead(s): Ulla Wändel Liminga, Zane Neikena

**Action:** For adoption

- 12.21.7. 21<sup>st</sup> Industry stakeholder platform - operation of European Union (EU) pharmacovigilance - feedback
- 

PRAC Lead(s): Liana Martirosyan

**Action:** For discussion

## 13. Any other business

None

## 14. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the

---

agenda.

## **List of acronyms and abbreviations**

For a list of acronyms and abbreviations used in the PRAC agenda, see:

[List of abbreviations used in EMA human medicines scientific committees and CMDh documents, and in relation to EMA's regulatory activities](#)

## **EU Referral procedures for safety reasons: Urgent EU procedures and Other EU referral procedures**

(Items 2 and 3 of the PRAC agenda)

A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the European Union (EU). For further detailed information on safety related referrals please see: [Referral procedures: human medicines | European Medicines Agency \(europa.eu\)](#)

## **Signals assessment and prioritisation**

(Item 4 of the PRAC agenda)

A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. The evaluation of safety signals is a routine part of pharmacovigilance and is essential to ensuring that regulatory authorities have a comprehensive knowledge of a medicine's benefits and risks.

The presence of a safety signal does not mean that a medicine has caused the reported adverse event. The adverse event could be a symptom of another illness or caused by another medicine taken by the patient. The evaluation of safety signals is required to establish whether or not there is a causal relationship between the medicine and the reported adverse event.

The evaluation of safety signals may not necessarily conclude that the medicine caused the adverse event in question. In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary and this usually takes the form of an update of the summary of product characteristics and the package leaflet.

## **Risk Management Plans (RMPs)**

(Item 5 of the PRAC agenda)

The RMP describes what is known and not known about the side effects of a medicine and states how these risks will be prevented or minimised in patients. It also includes plans for studies and other activities to gain more knowledge about the safety of the medicine and risk factors for developing side effects.

RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available.

## **Assessment of Periodic Safety Update Reports (PSURs)**

(Item 6 of the PRAC agenda)

A PSUR is a report providing an evaluation of the benefit-risk balance of a medicine, which is submitted by marketing authorisation holders at defined time points following a medicine's authorisation.

PSURs summarises data on the benefits and risks of a medicine and includes the results of all studies carried out with this medicine (in the authorised and unauthorised indications).

## **Post-authorisation Safety Studies (PASS)**

(Item 7 of the PRAC agenda)

A PASS is a study of an authorised medicinal product carried out to obtain further information on its safety, or to measure the effectiveness of risk management measures. The results of a PASS help regulatory agencies to evaluate the safety and benefit-risk profile of a medicine.

## **Product related pharmacovigilance inspections**

(Item 9 of the PRAC agenda)

Inspections carried out by regulatory agencies to ensure that marketing authorisation holders comply with their pharmacovigilance obligations.

More detailed information on the above terms can be found on the EMA website: [www.ema.europa.eu/](http://www.ema.europa.eu/)

## **Article 58 procedures (Art 58)**

Article 58 of Regulation (EC) No 726/2004 allows the Committee for Medicinal Products for Human Use

(CHMP) to give opinions, in co-operation with the World Health Organisation (WHO) on medicinal products for human use that are intended exclusively for markets outside of the European Union (EU)