| **Table S1: List of Included Studies** | | | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study No.** | **Type of Drug** | **FSR Date** | **Data Collection Period** | **Type of RMM\*** | **Timing of aRMMs\*** | **No. of targeted safety concerns\*** | **RMP Categorya** | **Study requested by a regulator** | **Study design** | **No. countries** | | **Type of Survey** | **Target population** | **Sample size** | | **Process indicators with resultse** |
| **N Targetd** | **N Involved** | **N Targetd** | **N Completers (% targeted)** |
| **1**[31] | Antifungal | 17/05/2016 | **6 months:** 02/09/2015 – 29/02/2016 | Patient alert card, HCP Brochure/ Leaflet/ Guide, HCP Checklist | After drug Approval | 3 | Cat 3 | EMA | one-wave | 10 | 10 (FR, DE, UK, IT, NL, HU, DK, IE, ES, AT) | HCP Survey | Specialists with drug experience | 750 | 332 (44.3) | Receipt, use, reading, knowledge, behaviour |
| **2**[32] | Antipsychotic | 10/12/2013 | **3.5 months:** 19/06/2013 -27/09/2013 | HCP Brochure/ Leaflet/ Guide, Patient Brochure/ Leaflet/ Guide | With new safety signal/ precautions | 1 | unknown | Netherlands | one-wave | 8 | 8 (AT, DE, HU, IT, ES, RO, UK, SE) | HCP Survey | GPs, specialists with and w/o drug experience | 800 | 800 (100.0) | Receipt, reading, behaviour |
| **3**[33] | Antithrombotic | 12/02/2016 | **7 months:** 12/02/2015 – 17/09/2015 | Patient alert card, HCP Brochure/ Leaflet/ Guide | At approval extension of indication | 1 | unknown | EMA | one-wave | 9 | 8 (UK, DE, ES, FR, DK, BG, CZ, SK) | HCP Survey | GPs, specialists with drug experience | 400 | 411 (100.0) | Receipt, use, reading, knowledge |
| Patient/ Caregiver Survey | patients/caregivers | 800 | 802 (100.0) | Awareness, receipt, reading, knowledge |
| **4**[34] | Antiandrogen | 20/04/2015 | **11.5 months:** 14/02/2014 – 30/01/2015 | DHPC, HCP Brochure/ Leaflet/ Guide | After new safety signal/ precautions | 2 | Cat 3 | EMA | one-wave | 1 | 1 (DK) | HCP Survey | GPs with drug experience | 25-75b | 32 (100.0) | Knowledge |
| **5**[35] | Antiepileptic | 31/01/2014 | **12.5 months:** 18/09/2012 – 04/10/2013 | HCP Brochure/ Leaflet/ Guide | At product launch | 2 | Cat 3 | No | one-wave | 8 | 8 (UK, DE, DK, ES, CH, SE, NO, SK) | HCP Survey | Specialists with and w/o drug experience | 300 | 294 (98.0) | Reading, knowledge |
| Patient/ Caregiver Survey | patients/caregivers | Not reported due to low recruitment | | |
| **6**[36] | Antiepileptic | 26/08/2015 | **4 months:**  24/09/2014 - 30/01/2015 | Patient alert card | After label changes/ restriction indication/ new safety signal | 2 | Cat 3 | No | one-wave | 7 | 7 (BE, UK, ES, CH, NO, SK and China) | HCP Survey | Specialists with and w/o drug experience | 400 | 414 (100.0) | Receipt, knowledge |
| **7**[37] | Psychostimulant for ADHD and nootropics | 20/11/2014 | **3 months:** 30/06/2014 – 30/09/2014 | HCP Brochure/ Leaflet/ Guide | At extension of indication | 2 | unknown | EMA | one-wave | 5 | 5 (DK, NL, ES, SE, UK) | HCP Survey | Specialists with drug experience | 250 | 250 (100.0) | Use, knowledge, bahaviour |
| **8**[38] | Psychostimulant for ADHD and nootropics | 27/03/2014 | Wave 1  unknown  Wave 2  **2 months:** 16/09/2013 - 22/11/2013 | DHPC, HCP Brochure/ Leaflet/ Guide | After label changes/ new safety signal | 2 | unknown | No | multi-wave | 5 | 5 (DK, NL, ES, SE, UK) | HCP Survey | GPs, specialists with drug experience | Wave 1: 550 | 550 (100.0) | Use, knowledge, bahaviour |
| Wave 2: 750 | unknown |
| **9**[39] | Direct acting antiviral | 16/10/2014 | **2 months:** 13/01/2014 - 18/03/2014 | Routine RMM | NA | 1 | unknown | EMA | one-wave | 9 | 9 (AT, BE, DK, FR, DE, NO, SE, NL, UK) | HCP Survey | GPs, specialists, nurses, pharmacist with drug experience | 289 | 323 (100.0) | Knowledge |
| **10** | ‎Drug affecting bone structure and mineralisation | 10/09/2015 | Round 1  **5.5 months:** 01/01/2013 - 12/06/2013  Round 2  **8.5 months:** 28/08/2013 - 15/05/2014 | Routine RMM | NA | 1 | unknown | No | multi-wave | 9 | 9 (FI, FR, DE, IT, NO, ES, SE, UK) | HCP Survey | Specialists with drug experience | 420 | 420 (100.0) | Knowledge |
| **11** | Antimalarial | 26/06/2015 | 12-month survey  **7 months:**  09/2013 - 03/2014  24-month survey  **5 months:** 11/2014 - 03/2015 | HCP Brochure/ Leaflet/ Guide | At product launch | 4 | unknown | EMA | multi-wave | 5 | 3 (FR, DE, IT) | HCP Survey | GPs, specialists, pharmacist, with and w/o drug experience | 180 | 77 (42.8) | Receipt, knowledge |
| **12**[40] | Opioid | 16/11/2016 | **6.5 months:**  01/04/2015 - 15/10/2015 | HCP Brochure/ Leaflet/ Guide | At product launch | 5 | unknown | EMA | one-wave | 2 | 2 (FR, NL) | HCP Survey | GPs, specialists with and w/o drug experience | 267 | 310 (100.0) | Receipt, use, knowledge |
| **13** | Antineoplastic agent | 19/11/2015 | **17 months:** 10/04/2014 - 11/09/2015 | HCP Brochure/ Leaflet/ Guide, Patient Brochure/ Leaflet/ Guide | At product launch | 6 | unknown | EMA | one-wave | 13 | 10 (AT, BE, FR, DE, IE, IT, ES, SE, NL, UK) | HCP Survey | Specialists, with drug experience | 105-115c | 94 (89.5) | Awareness, receipt, use, reading, knowledge, behaviour |
| Patient/ Caregiver Survey | patients/caregivers | 28 | 28 (100.0) | Receipt, use, knowledge, behaviour |
| **14** | Antipsychotic | 23/12/2016 | Initial stage  **12 months:** 27/07/2014 - 09/07/2015  Extension  **5.5 months:**  10/07/2015 - 04/01/2016 | HCP Brochure/ Leaflet/ Guide, Patient Brochure/ Leaflet/ Guide | At extension of indication | 4 | Cat 2 | EMA | one-wave | 13 | 13 (AT, DE, DK, IE, IT, ES, SE, NO, UK, PT, SI, EL, CY) | HCP Survey | GPs, specialists, nurses, pharmacist with drug experience | 150 | 118 (78.7) | Awareness, receipt, use, reading, knowledge, behaviour |
| Patient/ Caregiver Survey | patients/caregivers, | 148-158c | 16 (10.8) | Awareness, receipt, reading, knowledge, behaviour |
| **15**[41] | Antiandrogen | 31/05/2016 | **8 months:**  26/06/2015 - 21/02/2016 | Patient alert card, DHPC, HCP Brochure/ Leaflet/ Guide | After label changes/ restriction indication/ new safety signal | 1 | Cat 1 | EMA | one-wave | 5 | 5 (AU, CZ, FR, NL, ES) | HCP Survey | GPs, specialists with drug experience | 500 | 759 (100.0) | Receipt, knowledge |
| **16**[42] | Antineoplastic agent | 07/03/2017 | **24 months:** 30/09/2014 - 30/09/2016 | Patient alert card | At product launch | 12 | Cat 3 | EMA | one-wave | 6 | 10 (AT, BE, DK, FR, DE, IE, IT, NL, SE, UK) | Patient/ Caregiver Survey | Patients/caregivers | 25-40b | 39 (100.0) | Awareness, receipt, use, reading, knowledge |
| **17**[43] | Antineoplastic agent | 07/03/2017 | **24 months:** 30/09/2014 - 30/09/2016 | HCP Brochure/ Leaflet/ Guide | At product launch | 12 | Cat 3 | EMA | one-wave | 6 | 10 (AT, BE, DK, FR, DE, IE, IT, NL, SE, UK) | HCP Survey | Specialists with drug experience | 150 | 98 (65.3) | Awareness, receipt, use, reading, knowledge |
| **18** | Cardiac therapy | 16/09/2015 | **2 months:**  21/11/2014 - 15/01/2015 | DHPC | At restriction of indication | 1 | unknown | EMA | one-wave | 12 | 12 (BG, CZ, EE, FR, HU, LV, LT, PL, PT, RO, SK, ES) | HCP Survey | GPs, specialists with and w/o drug experience | 1320 | 1123 (85.1) | Receipt, knowledge, behaviour |
| **19**[44] | Propulsive | 13/06/2017 | **3 months:**  04/01/2017 - 31/03/2017 | DHPC | At product launch | 1 | Cat 1 | EMA | one-wave | 5 | 5 (FR, DE, UK, BE. ES) | HCP Survey | GPs, specialists with drug experience | 1880 | 1805 (96.0) | Receipt, knowledge |
| **20**[45] | Antidiabetic agent | 29/03/2017 | **6.5 months:** 16/05/2016 - 01/12/2016 | DHPC, Patient Brochure/ Leaflet/ Guide | At new strength | 1 | Cat 3 | No | one-wave | 3 | 3 (FR, DE, SE) | HCP Survey | GPs, specialists, nurses, pharmacist with and w/o drug experience | 280 | 146 (52.1) | Awareness, receipt, use, reading, knowledge, behaviour |
| Patient/ Caregiver Survey | patients/carers, | 280 | 7 (2.5) | Not reported due to low recruitment |
| **21** | Antiviral | 14/08/2017 | **3.5 months:** 25/11/2016 - 07/03/2017 | DHPC | After new safety signal / label changes | 1 | Cat 3 | No | one-wave | 8 | 7 (BU, DK, FR, DE, HU, ES, UK) | HCP Survey | GPs, specialists, pharmacist with and w/o drug experience | 200 | 301 (100.0) | Knowledge, behaviour |
| **22** | ‎Immunosuppressant | 29/09/2017 | **6 months:** 11/2016 - 04/2017 | Patient alert card | At product launch | 6 | Cat 3 | EMA | one-wave | 5 | 5 (FR, DE, ES, SE, UK) | HCP Survey | specialists, nurses with drug experience | 80 | 79 (98.8) | Awareness, receipt, use, reading, knowledge, behaviour |
| Patient/Caregiver Survey | patients/carers, | 400 | 190 (47.5) | Awareness, receipt, use, reading, knowledge, behaviour |
| **23** | Antithrombotic agent | 24/05/2017 | **18 months:** 26/08/2015 - 26/02/2017 | Patient alert card, HCP Brochure/ Leaflet/ Guide | At product launch | 3 | Cat 3 | EMA | one-wave | 10 | 10 (AU, BE, DK, FR, DE, IT, NO, ES, SE, UK) | HCP Survey | GPs, specialists, nurses, pharmacists | 384 | 370 (96.4) | Receipt, use, reading, knowledge, behaviour |
| Patient/ Caregiver Survey | Patients/carers | 192 | 125 (65.1) | Awareness, receipt, use, reading, knowledge, behaviour |
| **24** | Antimycotic for systemic use | 30/05/2017 | Wave 2 only  **11 months:** 14/03/2016 - 13/02/2017 | HCP Brochure/ Leaflet/ Guide | At product launch | 5 | unknown | EMA | multi-wave | 8 | 8 (CZ, FR, DE, EL, IT, PL, ES, UK) | HCP Survey | Specialists with drug experience | 340 | 246 (100.0) | Receipt, use, knowledge |

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| **NOTE:** Only references for studies with FSRs available in the EU PAS Register are provided. The remaining are kept on file as they were provided by MAHs or by EMA via freedom of information requests.  a-RMP Study Categories (GVP V[40]):   * Category 1: imposed as an obligation in accordance with REG Art 9(4)(cb) and Art 10a(1)(a) and with DIR Art 21a(b) and Art 22a(1)(a) (category 1 of studies in GVP Module V); * Category 2: imposed as a specific obligation in the framework of a marketing authorisation granted under exceptional circumstances * Category 3: required in the risk management plan (RMP) to investigate a safety concern or to evaluate the effectiveness of risk minimisation activities * Other: conducted voluntarily by a marketing authorisation holder   b-the upper extreme of the interval was used to calculate the percentage  c-the lower extreme of the interval was used to calculate the percentage  d-Data extracted from Study Protocol  e-Given the variability of terms used across FSRs to name endpoints, the categories presented here relate to what is asked in the question and not the term used in the study documents. We have created 5 survey dimensions (receipt, use, reading, knowledge, behaviour) and assigned process indicators/questions to these.  \*if these data were not available from FSRs or protocols, the product Summary of Products Characteristics and the EPAR were searched and used as additional sources of information.  ADHD: attention deficit hyperactivity disorder; aRMM: additional risk minimisation measure; DHPC: dear healthcare professional communication; FSR: final study report; GP: general practitioner; HCP: healthcare professional; PASS: post-authorisation safety study; RMM: risk minimisation measure; RMP: risk management plan |