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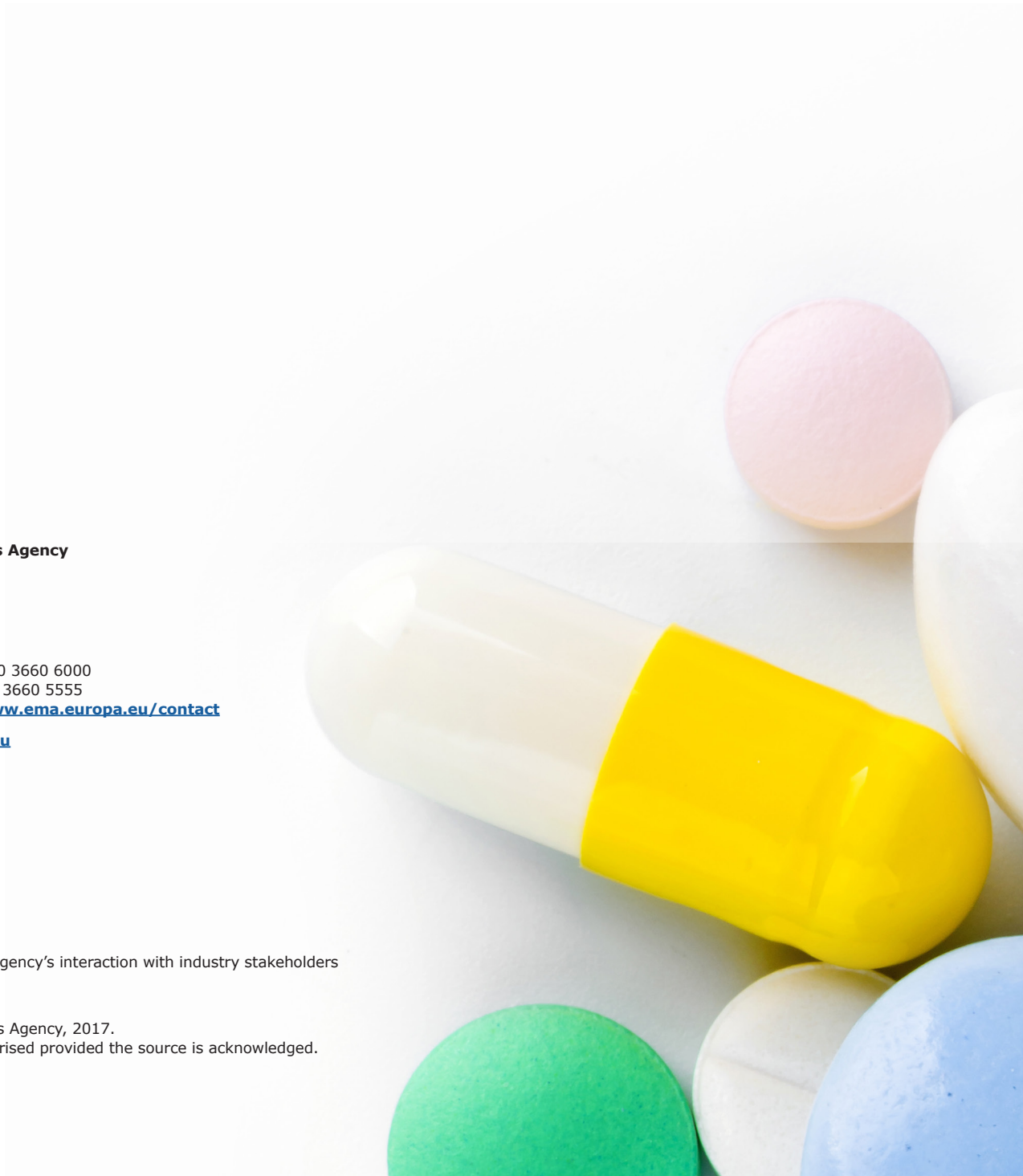

European Medicines Agency's interaction with industry stakeholders
EMA/812253/2016

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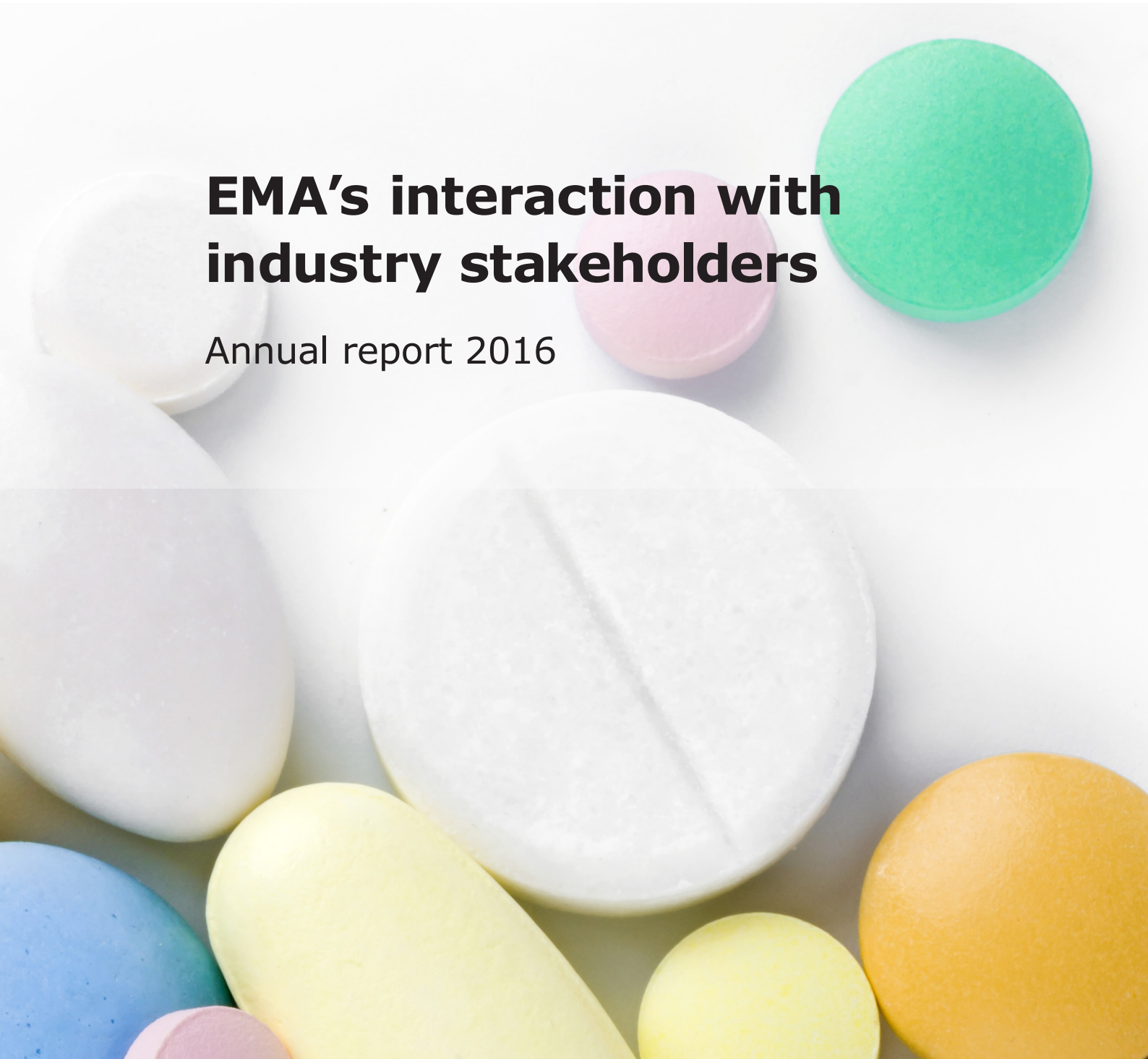


# EMA's interaction with industry stakeholders

Annual report 2016

# Executive summary

With reference to the Framework for EMA interaction with Industry Stakeholders adopted in 2015, EMA continues to streamline its interaction with this stakeholder group. This report provides a high level overview of EMA's engagement with industry stakeholder organisations in 2016, focused around 4 key themes: human medicines, veterinary medicines, operation of the European Medicines Regulatory network, and global regulatory environment.

The report is not intended to provide a comprehensive overview of all contacts with industry stakeholder organisations, but highlights some of the important topic-driven events, and targeted consultations carried out throughout the year.

2016 saw the launch of the PRIME scheme to reinforce support to medicines developers of human medicines which target unmet needs, and implementation of EMA's flagship policy to proactively publish clinical data submitted by pharmaceutical companies for human medicines within the centralised procedure. Workshops were held, amongst others, to explore next steps in the Adaptive Pathways concept, to promote development of advanced therapies, development of veterinary vaccines and to consider the potential use of 'big data' in medicines development and regulation.

EMA continued to host regular platform meetings with industry stakeholders to provide an opportunity for post-implementation dialogue. In 2016, platform meetings focussed on paediatric medicines, centralised applications and pharmacovigilance, with the aim of optimising practical operational aspects based on stakeholder experience.

A report from a survey on post-authorisation procedures was published and showed a high level of industry stakeholder satisfaction with type IB and type II variations and PSURs in terms of procedural management, level of interaction and overall communication. It also identified some areas for further simplification and guidance development that have subsequently been implemented.

Looking to 2017, EMA will report on the outcome of an industry stakeholder survey on the initial marketing authorisation application launched in September 2016. EMA will be preparing operationally for the withdrawal of UK from EU which will require close co-operation with industry stakeholders to ensure a smooth transition.

# 1. Introduction

A formal 'Framework for interaction between the European Medicines Agency and industry stakeholders' (hereafter referred to as "framework"), describing the objectives and the terms of reference for the Agency's engagement with industry stakeholder organisations, was adopted by the EMA Management Board in October 2015.

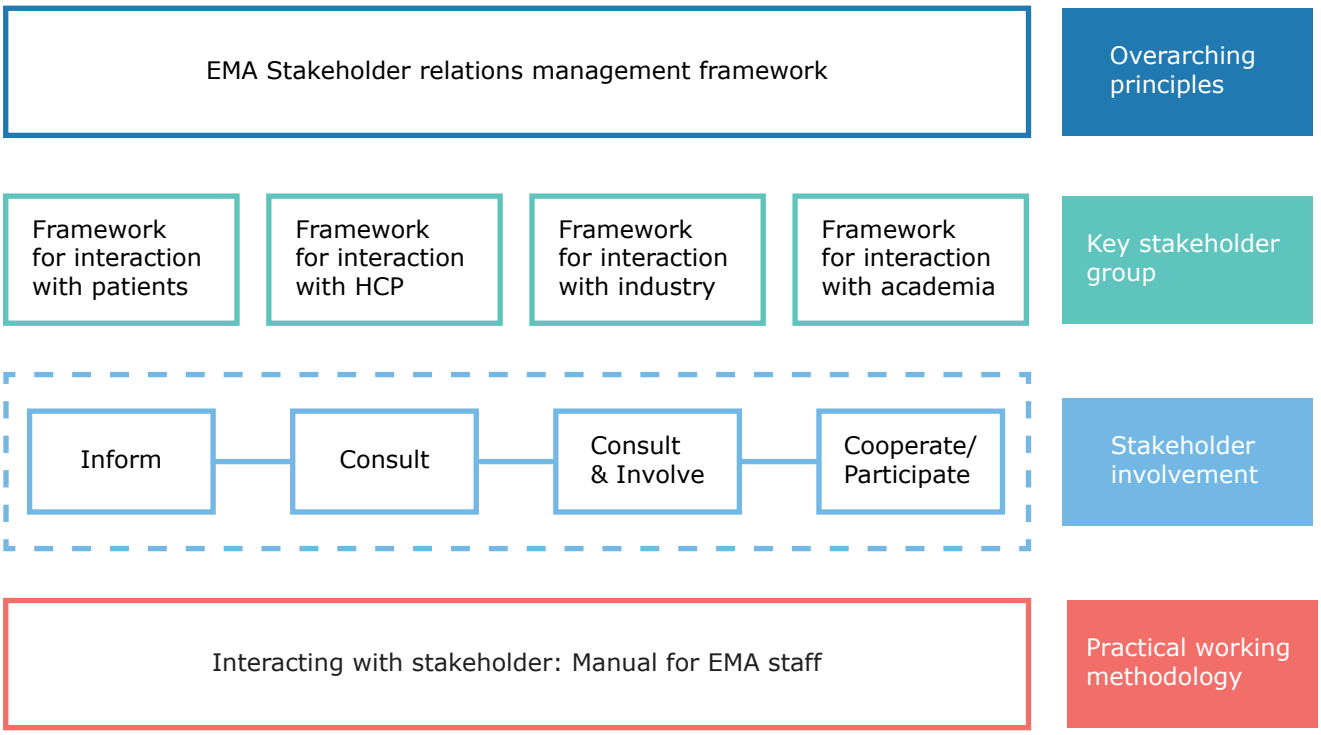
The framework is based on the establishment of regular interactions with industry associations, aiming to facilitate and streamline communications in line with principles of accountability, transparency and broad representation, amongst others.

This report describes the outcome and progress of EMA's interaction with industry stakeholders active in the human and veterinary medicine fields during the course of 2016. The focus is on the interaction between the EMA and industry stakeholder organisations rather than contacts with individual companies, which fall outside the scope of the framework.

## Stakeholder relations Management Framework and Eligibility criteria for industry associations adopted

In June 2016, EMA's Management Board adopted a framework for stakeholder relations management (EMA/48651/2016), a high level document which outlines the overarching principles for managing EMA's key stakeholder interactions. The framework builds on the Agency's experience in interacting with stakeholder associations representing patients and consumers, healthcare professionals, the pharmaceutical industry and, more recently, academia (see Figure 1). The aim of this overarching framework is to streamline interaction activities across the various stakeholder groups and align working methodologies where possible.

**Figure 1.** Illustration of stakeholder relations management framework



In addition, stakeholder specific framework documents (Patients and consumers, EMA/637573/2014; Healthcare Professionals, EMA/688885/2010; Industry stakeholders, EMA/591272/2014; Academia, EMA/125511/2017) formalise the interaction with these main stakeholder groups and provide further details on the working methodologies specific to each of them. Further, EMA has put in place a new working methodology in terms of the level of stakeholder involvement. Four levels of involvement in EMA activities have been identified, taking into account the general principles for stakeholder consultation outlined in the European Commission's Better Regulation package:

1. Inform (to enable feedback e.g. news items, Q&As, Information Days)
2. Consult (via written consultation e.g. guidelines development, public consultations)
3. Consult & Involve (based on direct interactions e.g. focus groups, platform meetings) and
4. Co-operate (jointly engaging towards a common technical goal e.g. technical expert groups)

Finally, a manual aims to support the systematic integration and translation of these overarching principles and relevant frameworks for interaction into the Agency's day-to-day operations. Together, these building blocks ensure a consistent approach to stakeholder relations management across a variety of stakeholder groups and interaction types.

The Board also adopted the criteria to be fulfilled by industry stakeholder organisations to be eligible for direct involvement in the Agency's activities (points 3 and 4 above). These eligibility criteria stem from the Agency's framework for interaction between EMA and industry stakeholders came into effect in January 2017. The aim is to ensure participating industry associations represent the broadest array of relevant pharmaceutical industry stakeholders. Where possible dialogue with all eligible organisations meeting criteria for participation will be encouraged to ensure representation of different views where they exist. The list of eligible organisations is published on the EMA website (link), see also Annex 1.

As smaller companies are often not members of industry organisations, interaction with small and medium-sized enterprises is facilitated through the Agency's SME office, which was established in 2005. An overview of the support on offer to SMEs and an annual activity report is published on the EMA website (link).

# 2. Highlights from 2016

This annual report provides a high level overview of areas where the EMA engaged in dialogue with industry stakeholder organisations in 2016 around 4 key themes:

- human medicines
- veterinary medicines
- operation of the European Medicines Regulatory network
- global regulatory environment

## Human medicines

In the human medicines field, the Agency discussed with industry stakeholders a broad range of topics, including scientific and technical matters related to the development of guidance, implementation of new legislation and policies, and post-implementation opportunities to optimise existing initiatives and procedures based on experience.

In line with EMA's strategic priorities and commitment to promote early dialogue to support the development of new medicines, the **PRIME (PRIority MEdicines)** scheme was launched in March 2016 to enhance support for the development of medicines that target an unmet medical need (link). PRIME as a

procedural tool offers pharmaceutical companies and academia early proactive support during development to help pave the way for patients to benefit as early as possible from promising medicines that may significantly improve their quality of life. An earlier entry point into the scheme has been foreseen for SMEs and academia, recognising that a lack of regulatory experience may hamper progress to the later stages of clinical development. EMA will be monitoring implementation closely and a multi-stakeholder workshop, including industry representatives is planned in May 2017 to review the key performance indicators and experience of the first wave of applicants.

On a similar theme, between 2014-2016 EMA has been piloting the **Adaptive Pathways** concept - an approach to medicines approval that aims to improve patients' access to medicines in cases of high unmet medical need. A workshop jointly organised by EMA and EC on 8 December 2016, was attended by representatives of patients' and healthcare professionals' organisations, academia, pharmaceutical companies, HTA bodies, payers, and other stakeholders, to discuss lessons learnt from the pilot (link) and address important questions from stakeholders, see report link. EMA continues to build on the experience gained from the adaptive pathways pilot within the existing mechanism of scientific advice, which provides for early multi-stakeholder dialogue. There will be further opportunities for discussion with stakeholders at various forums, such as the forthcoming 2017 EMA – Industry research and development support platform.

On 30 June 2016, EMA held a workshop on Single Arm Trials in Oncology with the aim of optimising the development of new **cancer treatments** where patients have no treatment option or where the conduct of standard trials with a comparative arm is difficult, such as in rare cancers or selected populations. The views of various stakeholder groups were explored and the need for further regulatory guidance discussed (link). Industry stakeholders contributed to the discussion which focussed on the experience gained so far with marketing authorisation applications based on single-arm trial data, the strengths and weaknesses of different approaches, and opportunities from data sharing initiatives.

Facilitating development of new **tuberculosis (TB) medicines** has also been a priority in 2016 and a workshop was held on 25 November 2016 to consult stakeholders on the revision of EMA's guidance for the development of new treatments for tuberculosis (link). Guidance will be finalised in 2017 as part of the addendum to EMA's guideline on the evaluation of medicines to treat bacterial infections taking into account stakeholders' feedback.

In May 2016, a multi-stakeholder expert meeting (link) was organised to explore possible ways to foster the **development of advanced therapy medicinal products (ATMPs)** in Europe and expand patients' access to these new treatments. Clinical trials investigating ATMPs represent a fast-growing field of interest, underlining the need to better support innovation through a coherent and appropriate regulatory environment. Industry stakeholders played an active role in the discussions together with other stakeholders, particularly regarding proposals to facilitate research and development and optimise regulatory processes for ATMPs (link to the outcome report). Based on the ideas and solutions proposed, EMA and its scientific committees, together with the European Commission and the national competent authorities, have developed a follow-up action plan.

ATMPs were also the focus of a regulatory conference organised later in the year by EMA and European Biopharmaceutical Enterprises (EBE) on 16 December 2016 (link). Amongst the topics discussed with a broad range of public and private stakeholders were: initiatives to improve access by patients to ATMPs, specific requirements for gene-therapy medicinal products, and standards for development and commercialisation. See report link for further details.

Towards the end of 2016, EMA organised a workshop on 14-15 November 2016 to identify the opportunities and challenges associated with the use of **"Big Data"** in medicines development and regulation (link). Rapid developments in technology have led to the generation of vast volumes of data, which have the capability to transform the way the benefit-risk of medicinal products is assessed over their entire life cycle. Regulators convened with a wide range of individuals from the healthcare environment and from technology companies, to discuss advances in the field and opportunities for the multitude of data sources to contribute to medicinal product development, authorisation and post-marketing surveillance. The tools and

data discussed at the workshop will not replace randomised clinical trials, however, further work is required to take full advantage of the value of this type of evidence to improve clinical trials and also complement trial data, supporting decision-making on medicines (Report link). Work in this area is being progressed through a joint HMA and EMA Task force on "Big Data" which was set up at the end of 2016 (link). A report is foreseen for next year.

EMA collaborated with EuropaBio on an Info-day on 22 November 2016 (link). The three main topics discussed were: innovation and development support, international cooperation with Medicines Agencies, and evidence generation during medicinal life-cycle. See report link for further details.

In addition to participation in the above-mentioned multi-stakeholder meetings, EMA organises annual bilateral meetings with EU industry trade associations to exchange views and promote dialogue on topics of common interest. In 2016, bilaterals were held with Medicines for Europe (previously known as the European Generic and Biosimilar Medicines Association – EGA) (link) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) (link).

# Veterinary medicines

In 2016, the Agency continued to foster co-operation with its industry stakeholders in the veterinary field. The jointly organised annual EMA/IFAH-Europe Info Day, a conference to discuss latest developments in the scientific review, regulation and marketing authorisation procedure, saw high interest and participation from veterinary pharmaceutical companies and stakeholder associations.

The annual European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) meeting for stakeholders held in March was organised by the EMA to inform European Union Member States, stakeholders and observers on latest activities related to collection of data of **veterinary antimicrobials** and on the draft ESVAC strategy 2016-2020 and also to share information on activities for the containment of **antimicrobial resistance** (link).

A focus group meeting aiming to facilitate the exchange of views from regulators, industry, research and veterinarians as part of the public consultation process on the revised draft reflection paper on **anthelmintic resistance** was held in June, in preparation for a second consultation period for the reflection paper. In December, a meeting with industry stakeholders was held to discuss the availability of **veterinary vaccines** (as a follow up to the Joint EMA/HMA Workshop on requirements for the authorisation of veterinary vaccines in the EU held in 2015).

The annual CVMP interested parties meeting held in April covered topics related to Minor Use Minor Species (MUMS) and JEG 3R (replacement, reduction and refinement), availability of veterinary medicines antimicrobials resistance and discussion on operational excellence (link). In addition, bilateral discussions were held once in 2016 with IFAH-Europe (International Federation for Animal Health – Europe), and once with EGGVP (European Group for Generic Veterinary Products) to discuss current topics with those stakeholders.

# Operation of the European Medicines Regulatory Network

### EU Telematics

EU Telematics is the collective name for a joint endeavour in the context of the regulation of medicines for human and veterinary use between the European Commission, EMA and NCAs. Guided by a shared vision and strategy for the future of information-technology (IT) services at a pan-European level, EU Telematics aim to put in place and maintain common IT services to implement European pharmaceutical policy and legislation.

As Telematics activities have wide-reaching impact on the Agency's stakeholders, including pharmaceutical industry, meetings between industry associations and the EU Telematics Management Board are scheduled twice a year to update and engage in dialogue on these activities. The meetings that took place in February and November 2016 offered industry associations the possibility to share their consolidated views on the Vision for Telematics strategy to 2025.

## Global regulatory environment

EMA recognises the need for international cooperation on a wide range of issues and continued to actively engage with industry associations on international activities and initiatives in 2016.

The Agency participated in the June and November meetings of the International Council for Harmonization (ICH). As part of the reforms concluded in 2015, industry stakeholder representation in ICH has now been extended to different global industry sectors. New pharmaceutical industry members in 2016 included International Generics and Biosimilars Association (IGBA), World Self-Medication Industry (WSMI) and Biotechnology Innovation Organization (BIO). In addition to a number of new final and draft guidelines, ICH announced a major review of ICH guidelines relating to Good Clinical Practice (GCP) and clinical trials. Further information on the guidance being developed in the international setting through ICH is available on the ICH & VICH websites.

During the course of the EU-China Regulatory Dialogue held in Beijing, 8 to 11 March 2016, a workshop involving the China Food and Drug Administration (CFDA) and local and international industry was held. Joint FDA-EMA GMP and GCP training workshops were organised for industry in China in October and November 2016 with the assistance of the CPAPE trade association.

A delegation from the Indian Council for Research on International Economic Relations (ICRIER), a policy research institution in New Delhi which cooperates with the Indian government in enhancing pharmaceutical policies and connecting the country with the world economy, visited the Agency on 24 June. Topics discussed included harmonisation of drug registration procedures, and challenges and prospects for clinical trials in India. During the EU-India Joint Working Group on Pharmaceuticals, Biotechnology and Medical Devices held in Brussels, 5 - 6 July 2016, a meeting was also convened with EU industry trade associations.

The 17th International Conference of Drug Regulatory Authorities (ICDRA), organised by World Health Organisation (WHO) in Cape Town on 27 November to 2 December 2016, was preceded by a 2-day Pre-ICDRA conference including industry and Non-Governmental Organisations (NGOs).

# 3. Consultation with industry stakeholders

EMA organises a number of dedicated stakeholder and multi-stakeholder events each year to disseminate information and elicit feedback from its key stakeholder groups, including industry organisations. An overview of the number of stakeholder events involving industry associations is provided below.

These events include a number of regular meetings with industry stakeholders that are organised throughout the year (e.g. Implementation Working Groups, Platform Meetings, - list in Annex 2) as well as topic driven events (list in Annex 3). Further information is available on the events area of EMA's website.

## Stakeholder events involving industry associations

In 2016, EMA hosted a total of 97 stakeholder events. An event, in this context refers to any formal, mainly verbal, interaction (training, focus groups, expert groups, workshops, conferences, platform meetings, info-days and public hearings) convened by the Agency, or hosted at the Agency, involving one or more external stakeholder groups (Patient and Healthcare Professionals (HCP), Academia and Industry as well as other interested parties) to discuss one or more topics with a common goal.

In 2016, 56% of events organised were multi-stakeholder events. On average, EMA events with multiple stakeholder groups were attended more or less equally by all stakeholder types, with healthcare professionals being involved slightly more than the

other three stakeholder groups. 75% of all multi-stakeholder events were attended by Industry (see figure 2).

**Figure 2.** Overview of participation in multi-stakeholder events in 2016

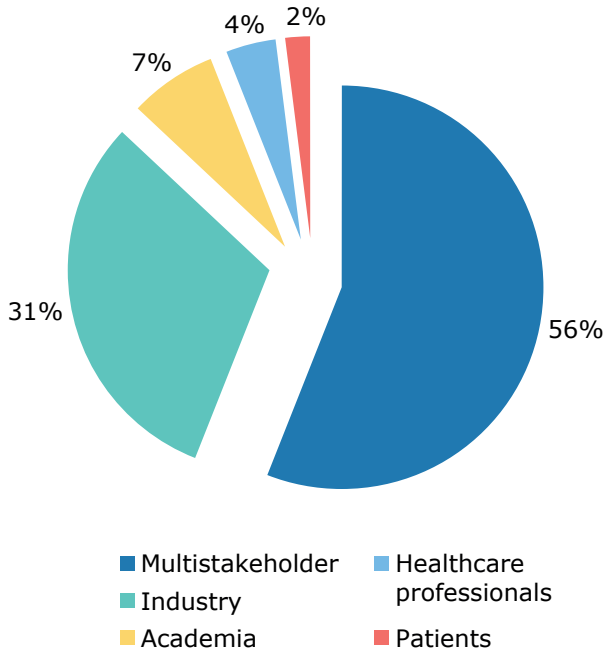
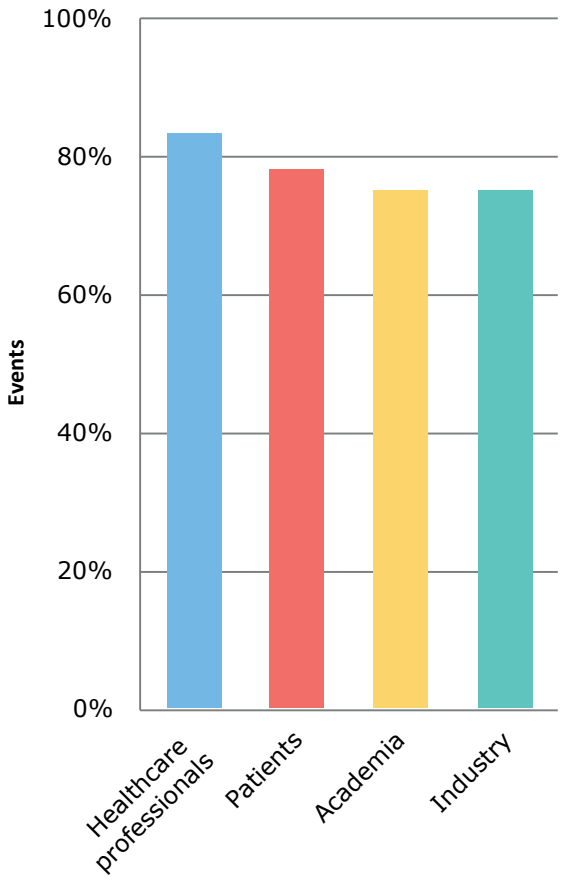



**Figure 3.** Breakdown of stakeholder events in 2016




44% of EMA events in 2016 (excluding routine activity events) were dedicated stakeholder events with one stakeholder group only. 31% of all events were industry focused single stakeholder events (see figure 3).

Two broad areas of topic-based discussions with industry stakeholders are highlighted below: consultation prior to the implementation of new legislation, policies and initiatives; and dialogue in the post-implementation setting.

## Consultation prior to the implementation of new legislation, policies and initiatives

### Implementation of Clinical Trials Legislation

During the course of 2016, the Agency continued to collaborate closely with its partners and stakeholders to implement the new Clinical Trial Regulation, adopted in April 2014. EMA has three main projects under its responsibility: the EU Portal and Database, Clinical Trial Safety Reporting (SUSAR and Annual Safety Reports) and EudraCT legacy.

Within the governance structure for the Clinical Trials programme, industry stakeholders take part in CT portal and Database stakeholder meetings (3 meetings took place in 2016) and provide specialised input through topic specific sub-groups. During the meetings a regular update on the progress of the project was provided as well as discussions on specific topics such as User Management.

Development of the EU Portal and Database progressed during 2016. Industry stakeholders are involved in the User Acceptance Testing (UAT), together with representative experts from Member States, and associations representing users of public information – in particular patient and consumer and healthcare professional associations. UAT takes place after each iteration of the system is released. In 2016 four UAT cycles took place with a large and active participation from industry stakeholders.

**Publication of clinical data (Policy 0070)**

In October 2016, EMA initiated the proactive publication of clinical data submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure. This is based on the Agency's flagship policy, to promote increased transparency and help avoid duplication of clinical trials; build public trust and confidence in EMA's scientific and decision-making processes; and enable academics and researchers to re-assess clinical data.

To prepare for implementation and facilitate compliance, EMA consulted industry stakeholders on procedural aspects and principles for redaction of commercially confidential information and anonymisation of personal data. Guidance for industry was published in March 2016 (link).

A webinar with industry associations was held on 9 December 2016 to update on initial experience with implementation and explain the proposed changes to the external guidance. Quarterly webinars with industry stakeholders will be held in 2017 to update on experience.

**Use of Cloud Services**

Since the establishment of EMA in 1995, information management has grown to become an integral part of the Agency's mission to promote and protect public and animal health. This is driven by the increasing importance of interconnected systems for managing and sharing information on medicines, the growing range of EMA customers with different information requirements and the overall digital transformation of society and regulation. EMA is continually refreshing its information technology approach with the goal of establishing a more efficient portfolio of information services and advancing its digital transformation to better connect people, processes, information and technology.

EMA believes that the use of cloud services will be an important factor in delivering on this goal and has been consulting with its key user groups of IT services, one of which is the pharmaceutical industry. To that end, EMA has undertaken a consultation of the pharmaceutical industry via industry stakeholder organisations on the potential use of cloud services, particularly where these would process information submitted by the industry. This was discussed at the joint EU Telematics Management Board (EU-TMB) and Industry meeting on 24 November 2016.

# Dialogue in the post-implementation setting

**EMA - Industry Platform Meetings**

Platform meetings provide industry stakeholders with an opportunity for both a general update on a specific topic area as well as more in-depth discussion of specific processes or issues, fostering constructive feedback and dialogue to support continuous improvement based on experience.

In 2016, EMA held a series of platform meetings in the areas of paediatrics, centralised procedures, and pharmacovigilance. Platform meeting highlights are published on the EMA website in the events calendar (link).

- Paediatric medicines

EMA hosted its second EMA-Industry Stakeholders Platform meeting on paediatric medicines in April 2016 (link). This meeting provided an opportunity to discuss amongst other topics the experience so far with standard paediatric-investigation plans (PIPs), the pilot on early interaction on paediatric development and changes to the summary report and electronic submission.

- Centralised Procedure

In 2016 EMA held one industry stakeholder platform meeting on the operation of the centralised procedure in April 2016 (link). The meeting addressed management of accelerated assessment, pre-submission dialogue, improvements in the post-authorisation management as well as first experience with requests for PRIME.

- Pharmacovigilance

Three platform meetings with industry stakeholder associations on the implementation and operation of the European Pharmacovigilance Legislation took place in April (link), July (link), and September (link) of 2016. Topics addressed, included a roadmap for periodic safety update reports (PSURs), scientific advice for post-authorisation studies and signal management, risk management plan guidance and templates, the Eudravigilance system and medical literature monitoring, good pharmacovigilance practices (GVPs), public hearings and pharmacovigilance impact.

# 4. Surveys

## European Medicines Agency (EMA) survey on centralised post-authorisation procedures

The objective of this EMA-Industry survey on centralised post-authorisation procedures, launched in April 2015, was to receive detailed performance related feedback from both industry stakeholders and EMA on certain post-authorisation procedures, namely type IB variations, type II variations and PSUR procedures (centrally authorised medicinal products only). The survey was initiated further to EMA's reorganisation and re-design and optimisation of the management of procedures during 2014. The aim was to set a baseline for these procedures and monitor their practical implementation from both perspectives, to enhance mutual understanding of issues arising, to elicit direct and on-going feedback from Marketing Authorisation Holders (MAHs), to increase further the transparency on the interactions between EMA and its Industry stakeholders and, ultimately, to enable continuous improvement of processes and guidance development and/or updates.

The results showed a high level of overall satisfaction from both respondents (EMA staff and MAHs) across the three procedures in terms of procedural management, level of interaction and overall communication for the updated procedures. It also identified some areas for further improvement such as proposals for additional simplification and aspects of EMA guidance that necessitated further development. The full report summarises the outcome of the survey (link).

## EMA survey on initial marketing authorisation application 2016

In 2016, an EMA-industry survey was launched on the centralised evaluation procedure, to gather feedback on procedural phases and specific elements (including EMA guidance, committee reports and the level of interaction).

Feedback from marketing authorisation applicants is being sought in the following three phases of the centralised evaluation procedure:

- pre-submission to validation
- primary assessment phase
- opinion finalisation

In parallel, and to enable feedback from both the applicants' and regulators' perspective, EMA staff and rapporteurs involved in these procedures will also participate in a similar survey.

Once the survey is finalised and the responses analysed, the findings will be discussed with industry stakeholder associations in the stakeholder platform on the operation of the centralised procedure in the second quarter of 2017. A report summarising the findings will also be published on the EMA website.

## SME office survey on the implementation of the SME regulation - Commission Regulation (EC) No 2049/2005

In August 2015, the Agency launched a survey aimed at SMEs and SME stakeholders to receive detailed feedback on the SME initiative, 10 years following its implementation. It also aimed to identify current and future challenges faced by SMEs in the pharmaceutical sector and areas for further development of the Agency's SME programme. The full report, published in May 2016, summarises the outcome of the survey (link).

EMA has been developing an action plan to better address the needs of SMEs which takes into account the feedback received and the areas of improvement identified. This action plan was published in early 2017 (link).

# 5. Plans for 2017

In 2017, EMA will continue to implement its framework for interaction with industry organisations and streamline its interaction with other key stakeholders including academia. A survey of industry stakeholders is planned to gather feedback on the level of interaction and communication since the framework was adopted in 2015.

The outcome of the survey of industry stakeholders on centralised applications for marketing authorisation will be discussed at the centralised platform meeting in Q2 2017, with a view to identifying areas for further operational improvement.

Following the UK's notification on 29 March 2017 of its intention to withdraw from the European Union, EMA has initiated discussions with the national competent authorities on how the work on the evaluation and monitoring of medicines will be shared between Member States. In 2017, EMA will be working in close cooperation with industry stakeholders to ensure a smooth transition.

# Annex 1

**List of eligible industry stakeholder organisations (as of 27 January 2017)**

With reference to the Criteria to be fulfilled by industry stakeholder organisations involved in EMA activities, (EMA/323235/2016), the following organisations have been deemed eligible to be consulted and involved directly or to co-operate with the Agency in specific areas. All of the organisations in this list are also included in the EC Transparency Register, which provides further detailed information (link).

| Name of organisation | Acronym | Website |
|---|---|---|
| Active Pharmaceutical Ingredients Committee | APIC | www.apic.cefic.org |
| Association of Clinical Research Organizations | ACRO | www.acrohealth.org |
| Association of the European Self-Medication Industry | AESGP | www.aesgp.eu |
| Association of Veterinary Consultants | AVC | www.avc.at |
| European Association for Bioindustries | EuropaBio | www.europabio.org |
| European Association for Logistics and Transportation in Healthcare | EALTH | www.ealth.org |
| European Association of Euro-Pharmaceutical Companies | EAEPC | www.eaepc.org |
| European Biopharmaceutical Enterprises | EBE | www.ebe-biopharma.eu |
| European Coalition on Homeopathic & Anthroposophic Medicinal Products | ECHAMP | www.echamp.eu |
| European Confederation of Pharmaceutical Entrepreneurs | EUCOPE | www.eucope.org |
| European Contract Research Organization Federation | EUCROF | www.eucrof.eu |
| European Federation of Pharmaceutical Industries and Associations | EFPIA | www.efpia.eu |

| Name of organisation | Acronym | Website |
|---|---|---|
| European Federation of Statisticians in the Pharmaceutical Industry | EFSPI | www.efspi.org |
| European Group for Generic Veterinary Products | EGGVP | www.eggvp.org |
| European Healthcare Distribution Association | GIRP | www.girp.eu |
| European Industrial Pharmacists Group | EIPG | www.eipg.eu |
| Europharm SMC | Europharm SMC | www.europharmsmc.org |
| Eye-Care Industries European Economic Interest Grouping | ECI-EEIG | www.eci-eeig.org |
| IFAH-Europe | IFAH-Europe | www.ifaheurope.org |
| Medicines for Europe | N/A | www.medicinesforeurope.com |
| Plasma Protein Therapeutics Association | PPTA | www.pptaglobal.org |
| Vaccines Europe | VE | www.vaccineseurope.eu |

# Annex 2

Regular stakeholder meetings with industry representation held each year

| Event name | Topic | Participants | Frequency |
|---|---|---|---|
| Bilateral Meetings with Key Industry Associations | Policy/Strategy | Individual Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate | Annually<br>▸ MfE 27 Jan 2016 link<br>▸ EFPIA 16 Sep 2016 link |
| Industry Platform meeting on Centralised Procedure | Centralised Procedure | Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate | 1-2 times/year<br>▸ 21 Apr 2016 link |

| Event name | Topic | Participants | Frequency |
|---|---|---|---|
| Industry Platform meeting on Paediatrics | Paediatrics | Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate | Annually<br>▸ 15 Apr 2016 link |
| Industry Platform meeting on the operation of EU Pharmacovigilance legislation | Pharmacovigilance | Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate | 3-4 times/year<br>▸ 4 Apr 2016 link<br>▸ 1 Jul 2016 link<br>▸ 21 Sep 2016 link |
| Stakeholders forum on the implementation of the Pharmacovigilance legislation | Pharmacovigilance | Multistakeholders, including Industry Stakeholder Associations, patients, consumers, healthcare professionals. EMA, Committee and Member States Regulators as appropriate | Annually<br>▸ 21 Sep 2016 link |
| EudraVigilance Expert Working Group (EV-EWG) | Pharmacovigilance | Industry Stakeholder Associations, EMA, Member States Regulators as appropriate, Non-commercial sponsors (EORTC) | 3 times/year<br>▸ 18 Jan 2016<br>▸ 19 May 2016<br>▸ 29 Sep 2016 |
| ENCePP Steering Group | Pharmaco-epidemiology | Industry Stakeholder Associations (EFPIA), EMA, Committee and Member States Regulators as appropriate, learned societies and ENCePP centres (academics and CROs) | 2 times/year<br>▸ 20 Jun 2016 link<br>▸ 11 Oct 2016 link |
| EU Clinical Trial & Union Portal DB meeting with stakeholders | Clinical Trials/IT | Multi-stakeholders, including Industry Stakeholder Associations, patients, consumers, healthcare professionals, EMA and European Commission | 3 times/year<br>▸ 24 Feb 2016<br>▸ 21 Sep 2016<br>▸ 28 Nov 2016 |

| Event name | Topic | Participants | Frequency |
|---|---|---|---|
| EU Telematics Management Board | Information Technology | Industry Stakeholder Associations, EU-TMB, EMA | 2 times/year<br>▸ 2 Feb 2016<br>▸ 24 Nov 2016 |
| ISO - IDMP IWG | IT/Data Management Standards | Industry Stakeholder Associations, Software Vendors, EMA, Member States Regulators as appropriate | 4 times/year + additional virtual meetings on ad hoc basis<br>▸ 19 Feb 2016 link<br>▸ 30 June 2016<br>▸ 21 Sept 2016<br>▸ 13 Dec 2016 link |
| Certain EMA Scientific Committees-Interested Parties meetings (CAT/ CMDh/IP) | Committee specific topics | | Annually or Biannually |
| Certain EMA Working Parties-Interested Parties meetings (QWP, SWP/IP) | WP specific topics | | Annually or Biannually |

# Annex 3

Overview of stakeholder events involving industry stakeholders in 2016

| Meeting Date | Meeting title | Type of stakeholder | EMA Website |
|---|---|---|---|
| 25 January 2016 | Veterinary stakeholder meeting | Industry | n/a |
| 04 February 2016 | Challenges for the Approval of Anti-Cancer Immunotherapeutic Drugs | Multi-stakeholder | link |
| 05 February 2016 | SME Workshop on Biostatistics | Industry | link |
| 02 March 2016 | The annual European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) stakeholders annual meeting 2016 | Multi-stakeholder | link |

| Meeting Date | Meeting title | Type of stakeholder | EMA Website |
|---|---|---|---|
| 04 March 2016 | Workshop on the implementation of ISO standard for individual case safety reports (ICSRs) | Industry | link |
| 07-09 March 2016 | EudraVigilance training | Multi-stakeholder | link |
| 05 April 2016 | EU Workshop on ICH Q3D from a Quality perspective | Multi-stakeholder | link |
| 11 April 2016 | IDMP SPOR Programme - Industry Change Liaison | Industry | n/a |
| 18 April 2016 | EudraVigilance training | Multi-stakeholder | link |
| 21 April 2016 | Workshop on adherence to time-tables | Industry | n/a |
| 21 April 2016 | eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD )face-to-face training XEVMPD | Industry | link |
| 26 April 2016 | DIA/EMA Individual case safety report (ICSR) information day | Multi-stakeholder | link |
| 17 May 2016 | European Medicines Agency public workshop on extrapolation of efficacy and safety in medicine | Multi-stakeholder | link |
| 25 May 2016 | ENCePP Special Interest Group on Impact | Multi-stakeholder | n/a |
| 27 May 2016 | Multi-stakeholder advanced therapy medicinal products (ATMPs) expert meeting: exploring solutions to foster ATMPs' development and patient access in Europe | Multi-stakeholder | link |
| 01-02 June 2016 | IMI ADAPT SMART, IMI GetReal and MIT NEW Drug Development ParadIGmS (NEWDIGS) "Adaptive Design Laboratory" workshop | Multi-stakeholder | link |
| 02-03 June 2016 | 2016 annual workshop of the European network of paediatric research (Enpr-EMA) at the European Medicines Agency | Multi-stakeholder | link |

| Meeting Date | Meeting title | Type of stakeholder | EMA Website |
|---|---|---|---|
| 07 June 2016 | Targeted consultation on the guideline for development of new medicinal products for the treatment of rheumatoid arthritis | Multi-stakeholder | link |
| 21 June 2016 | DIA/EMA EudraVigilance Information Day | Multi-stakeholder | link |
| 27 June 2016 | Falsified medicines | Multi-stakeholder | n/a |
| 30 June 2016 | Workshop on Single Arm Trials in oncology products | Multi-stakeholder | link |
| 04 August 2016 | Introduction to SPOR data services | Industry | link |
| 22 August 2016 | ISO IDMP Workshop | Multi-stakeholder | n/a |
| 26 August 2016 | Shortage of critical medicines and vaccines | Multi-stakeholder | n/a |
| 12-13 September 2016 | Second annual scientific workshop at EMA: Applying regulatory science to neonates | Multi-stakeholder | link |
| 13 September 2016 | EMA/Industry MLM scope workshop | Industry | link |
| 3 October 2016 | Workshops for micro, small and medium-sized enterprises: focus on non-clinical aspects | Industry | link |
| 10 October 2016 | Joint DIA/EFGCP/EMA better medicines for children conference 2016 on optimisation of drug development for the benefit of children | Multi-stakeholder | link |
| 19 October 2016 | Innovative Medicines Initiative WEB-RADR workshop: mobile technologies and social media as new tools in pharmacovigilance | Multi-stakeholder | link |
| 20 October 2016 | DIA Information day on medication errors | Multi-stakeholder | link |
| 28 October 2016 | PSUR information day | Multi-stakeholder | link |
| 28 October 2016 | Patient registries workshop | Multi-stakeholder | link |

| Meeting Date | Meeting title | Type of stakeholder | EMA Website |
|---|---|---|---|
| 11 November 2016 | Spinal muscular atrophy workshop | Multi-stakeholder | link |
| 14 November 2016 | Workshop on identifying opportunities for 'big data' in medicines development and regulatory science | Multi-stakeholder | link |
| 21 November 2016 | Workshop on qualification and reporting of physiologically-based pharmacokinetic (PBPK) modelling and simulation | Multi-stakeholder | link |
| 22 November 2016 | European Medicines Agency-EuropaBio information day | Industry | link |
| 25 November 2016 | Workshop on the development of new medicines to treat tuberculosis | Multi-stakeholder | link |
| 05 December 2016 | Workshop on measuring the impact of pharmacovigilance activities | Multi-stakeholder | link |
| 08 December 2016 | Adaptive pathways workshop | Multi-stakeholder | link |
| 09 December 2016 | Update on the implementation of EMA policy on publication of clinical data (Policy 0070) and draft revisions to the guidance to industry – industry associations webinar | Industry | link |
| 16 December 2016 | European Medicines Agency (EMA) / European Biopharmaceutical Enterprises (EBE) fifth annual regulatory conference on optimising the development of advanced therapies to meet patient needs | Industry | link |