EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA's interaction with industry stakeholders

Annual report 2017

Executive summary

With reference to the Framework for EMA interaction with Industry Stakeholders adopted in 2015, this report provides a high level, annual overview of EMA's engagement with industry stakeholder organisations in 2017. It is focused around 4 key themes: human medicines, veterinary medicines, operation of the European Medicines Regulatory network, and global regulatory environment.

"Brexit" was a key feature of 2017. In May 2017, the Agency launched the first phase of its business continuity plan (BCP) to prepare for relocation and the UK's withdrawal from the EU. As a result work in some areas was reprioritised, suspended or postponed to resource Brexit preparedness activities and safeguard core activities. This approach to BCP enabled EMA to maintain an effective level of stakeholder engagement in 2017 and initiate dialogue with industry on the operational changes required as a result of Brexit. Guidance for industry was published by EMA and the European Commission and a series of dedicated meetings for both human and veterinary industry stakeholders were set up towards the latter half of the year to discuss preparedness activities.

As 2017 marked the tenth anniversary of the EU Paediatric Regulation, several meetings were organised on aspects of paediatric medicines development with participation of industry stakeholders. A new type of meeting, the paediatric strategy forum, was piloted to enable industry and other stakeholders to share information in a pre-competitive space to inform the development strategy for paediatric cancer indications.

Platforms meetings on centralised applications and pharmacovigilance continued to provide valuable opportunities to discuss post-implementation experience and optimise practical operational aspects where relevant. This year also saw the extension of the platform meeting in the pre-authorisation phase, to cover all aspects of R&D support for human medicines, including paediatrics, scientific advice, orphan designation and innovation support.

A dedicated stakeholder meeting was held on the PRIority MEdicines (PRIME) scheme to coincide with the first anniversary of its implementation in May 2017. By the end of 2017, a total of 34 medicines were included in this scheme which provides early and enhanced support to developers of products that pose a major therapeutic advantage in addressing patients' unmet medical needs.

In the veterinary field, antimicrobials, containment of antimicrobial resistance and the development of veterinary vaccines were just some of the key topics discussed with stakeholders throughout the year. Specific focus groups were convened to explore the specific challenges faced by industry in performing field trials for veterinary vaccines, and to promote availability of vaccines for Lumpy Skin Disease.

A new and enhanced EudraVigilance system was launched in November 2017 and EMA engaged with industry stakeholders throughout the year to prepare for the launch of the new system.

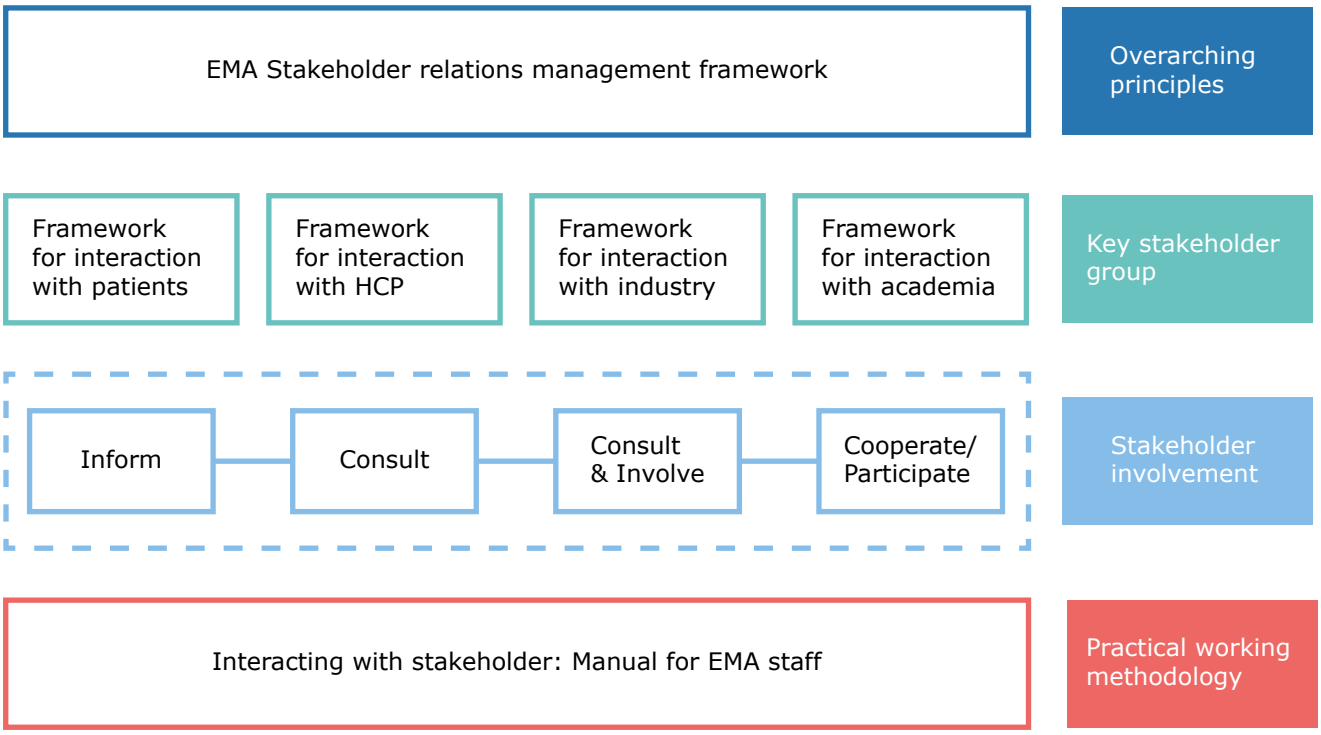
In 2017 a tri-partite survey (Rapporteurs-Industry-EMA) on initial marketing authorisation applications for human use was finalised and the results were communicated at a centralised platform meeting with industry stakeholders. The survey results showed a high level of overall satisfaction in terms of quality and timeliness of the interaction with industry stakeholders, across the three phases of the evaluation procedures (from pre-submission to validation, via the 1st and 2nd phases of the evaluation to adoption of the opinion). It also identified some areas that would benefit from optimisation and an action plan is being implemented to address these.

Looking to 2018, the second phase of EMA's business continuity plan (BCP) will take effect from January onwards to provide the necessary resources to prepare the groundwork for the Agency's relocation to Amsterdam in March 2019.

The Agency will continue to implement its framework for interaction with industry stakeholders albeit at a reduced level. As a result of BCP, the number of stakeholder meetings will be reduced, annual bilateral meetings with industry stakeholders will be temporarily suspended and will resume as soon as EMA reverts to being fully operational. Brexit related meetings and webinars will be considered a priority. A survey of human and veterinary industry stakeholder is planned in Q1 2018 to gather information on regulatory plans, and medicines supply chains impacted by Brexit.

Stakeholder dialogue on key topics areas such as antimicrobial resistance, medicines availability and support to innovation is planned to take place next year, subject to BCP and resource availability.

Figure 1: Illustration of stakeholder relations management framework



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 2017. 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

EMA has defined guiding principles its key stakeholder interactions in its Stakeholder Relations Management Framework. Although the involvement of stakeholders in EMA activities is not a 'one size fits all' methodology, the aim is to streamline engagement across the various stakeholder groups, which include patients and consumers, healthcare professionals, and academia and align working methodologies where possible. EMA reports annually on its interaction with all its key stakeholder groups.

In addition to the stakeholder specific framework documents highlighted in figure 1 above (Patients and consumers, EMA/637573/2014; Healthcare Professionals, EMA/688885/2010; Industry stakeholders, EMA/591272/2014; Academia, EMA/125511/2017), EMA has put in place a working methodology[1] in terms of the level of stakeholder involvement. Four levels of involvement in EMA activities have been identified:

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).

The first 2 levels of stakeholder involvement referred to above are open to all external parties and do not require specific stakeholder eligibility criteria to be applied. Any organisation can register with the EMA as an interested party to receive information and notice of written consultations in selective areas of interest (via StakeholdersDB@ema.europa.eu).

For more direct involvement (i.e. at the latter 2 levels) eligibility criteria are applied to ensure that the organisations, which EMA consults and involves directly or co-operates with, represent the broadest array of relevant stakeholders. Multi-stakeholder dialogue is encouraged wherever possible, with all eligible organisations meeting the relevant criteria for participation. The list of eligible industry organisations is published on the EMA website (link), see also Annex 1.

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.

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 EMA's website (link).

[1] The working methodology is aligned with the European Commission's Better European Regulation package

2. Highlights from 2017

This annual report provides a high level overview of areas where the EMA engaged in dialogue with industry stakeholder organisations in 2017 around 4 key themes:

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

"Brexit" was a key feature of 2017. In May 2017, the Agency launched the first phase of its business continuity plan (BCP) to prepare for relocation and the UK's withdrawal from the EU. As a result work in some areas was reprioritised, suspended or postponed to resource Brexit preparedness activities and safeguard core activities. This approach to BCP enabled EMA to maintain an effective level of stakeholder engagement in 2017 and initiate dialogue with industry on the operational changes required as a result of Brexit. Guidance for industry has been published and a series of dedicated meetings with both human and veterinary industry stakeholders were set up throughout the year to discuss preparedness activities (see page 7).

Human medicines

In the human medicines field, the Agency discussed a broad range of topics with industry stakeholders, 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.

Fostering development of new **antibacterial medicines** continued to be a priority for the Agency in 2017, with a focus on global development. In that context, two further tripartite multi-stakeholder meetings with EMA, US FDA and the Japanese PMDA were held, one in April at EMA (link) and one in Japan in October (link).Building on the work of the 2016 meeting, the aim was to identify further areas for convergence in the regulatory approach to the evaluation of antimicrobials across the regions. Agreement was reached to further align the design of clinical trials for new antibiotics in certain indications, such as uncomplicated gonorrhoea or urinary tract infections and to explore how to better streamline paediatric development of new antibacterial agents. The importance of characterising the pharmacokinetic-pharmacodynamic relationship and monitoring the benefit-risk balance throughout the medicine lifecycle was also discussed. A further meeting is planned in 2018.

In March a targeted stakeholder consultation workshop (link) was held to discuss the revision of guidance on **first in-human clinical trials** with investigational medicines. Multi-stakeholder comments received during the public consultation, including those received from pharmaceutical industry, contract research organisations and academia were discussed with representatives of the European Medicines Regulatory network. The final guideline, which reflected the output of the workshop, was published in July 2017. It emphasises the sponsor's responsibility to define the uncertainty associated with the medicine tested at each step of the development and to describe how the potential risks that might arise from this uncertainty will be addressed by the design and conduct of the trial.

As part of the Agency's **patient registry** initiative, in 2017 EMA defined a vision, strategy and work plan to support a more systematic approach to the contribution of existing disease registries to the benefit-risk evaluation of medicines. Industry stakeholders took part in two multi-stakeholder workshops organised on cystic fibrosis registries (link) and multiple sclerosis registries (link) in June and July respectively. The objectives were to agree on implementable recommendations on the core data elements to be collected in registries, protocols, consents, governance, and registry interoperability and on the actions needed from the stakeholder groups to advance registry use. Further details can be found in the linked reports. In 2017, EMA also initiated the registration of multinational disease registries in the ENCePP resource database. By the

end of the year, the inventory included a total of 66 disease registries.

2017 marked the tenth anniversary of the EU Paediatric Regulation, and during the course of the year several meetings were organised on aspects of **paediatric medicines development** with participation of industry stakeholders. These included:

- A paediatric strategy forum piloted by EMA/ ACCELERATE in January which focussed on anaplastic lymphoma kinase (ALK), an important oncogene and target in several paediatric tumours with unmet therapeutic needs. During the meeting stakeholders shared knowledge and evidence to support planning and discussed regulatory aspects and developmental challenges to address the therapeutic needs of paediatric patients. Stakeholders representing patient organisations, clinicians, academia, pharmaceutical industry and regulators contributed. Pharmaceutical companies presented data for relevant compounds under development. For further details see report (link).

- A joint workshop was organised by EMA/ FDA/Health Canada in June to discuss requirements for the development of medicines in paediatric pulmonary arterial hypertension (PAH). The objectives were to improve the understanding of the challenges in conducting clinical trials, refine endpoints and study design, set priorities for future research on pharmacokinetic and pharmacodynamic parameters and post-marketing tools and to provide medicine developers with more guidance specific to global product development. For further details see published documents (link).

- A second paediatric strategy forum was held in November to share information, in a pre-competitive setting, and discuss the approach to developing medicines for treatment of children with mature B cell malignancies. For further details, please see enclosed (link).

Also in the field of oncology, at year end EMA hosted a workshop on new **oncology development methodologies on 14 December**. The meeting provided an opportunity for different stakeholders to discuss situations where a site and histology-independent clinical development might be a viable option and the challenges in terms of development, benefit-risk evaluation and health-technology assessment. For further details, see published documents (link).

In 2017, EMA continued to organise annual bilateral meetings with EU industry trade associations to exchange views and promote dialogue on topics of common interest. Meetings were held with Association of the European Self-Medication Industry - AESGP (link), Medicines for Europe (link), EuropaBio (link) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) (link). In 2017, EMA continued to organise annual bilateral meetings with EU industry trade associations to exchange views and promote dialogue on topics of common interest.

Veterinary medicines

In 2017, the Agency continued to engage in constructive dialogue with its industry stakeholders in the veterinary field on a variety of topics. The **Veterinary Medicines Info Day** held in March to discuss latest developments in the scientific review, regulation and marketing authorisation procedures, saw continued high interest and participation from veterinary pharmaceutical companies and stakeholder associations (link). For the first time, dedicated information points on e-submissions, veterinary application submissions and veterinary medicines innovation were provided in the margins of the meeting.

A stakeholder focus group meeting on availability of **lumpy skin disease** (LSD) vaccines authorised to European Union (EU) standards was organised in January within the scope of the Heads of Medicines Agencies Network Strategy on availability for veterinary vaccines, which aims to increase their availability by ensuring efficient and effective cooperation between all stakeholders. The purpose of the meeting was to review the current scientific knowledge and regulatory environment for the development of LSD vaccines following incursion of the disease in 2015 and to identify regulatory options to facilitate the development and authorisation of vaccines in accordance with EU standards (link).

The annual **European Surveillance of Veterinary Antimicrobial Consumption** (ESVAC) meeting for stakeholders held in March was organised by EMA to inform EU Member States, stakeholders and observers on latest activities related to the collection of data

of veterinary antimicrobials, on the draft guidance on provision of data on antimicrobial use by animal species and also to share information on activities for the containment of antimicrobial resistance (link).

A focus group with invited stakeholders on field efficacy trials in the context of an EU authorisation for **veterinary vaccines** was held in June, to explore the specific challenges faced by industry in performing field trials to support efficacy claims and how these challenges might be overcome whilst still obtaining adequate assurances of the expected efficacy of a vaccine under field conditions. The focus group meeting was organised within the scope of the HMA Network Strategy on availability for veterinary vaccines that aims to increase their availability by ensuring efficient and effective cooperation between all stakeholders (link).

The annual CVMP interested parties meeting held in September covered topics related to antimicrobials resistance (AMR), persistent, bioaccumulative and toxic (PBT) assessments, quality guidelines on veterinary medicines, the Pilot Project on the Harmonisation and Optimisation of Veterinary Antimicrobials (PPHOVA), update on 3Rs (replacement, reduction and refinement) activities and Brexit preparedness.

An Interested Parties meeting was also held with the CVMP Pharmacovigilance Working Party in September, focussed on harmonisation, communication of pharmacovigilance data to the public, challenges for adverse event quality and how to encourage reporting of adverse events.

Bilateral discussions were held once in 2017 with AnimalhealthEurope (formerly International Federation for Animal Health – Europe), and once with EGGVP (European Group for Generic Veterinary Products) to exchange views and discuss topics of mutual interest.

Operation of the European Medicines Regulatory Network

United Kingdom's withdrawal from the European Union ('Brexit') preparedness

Further to the UK's notification to the European Council on 29 March 2017 of its intention to withdraw from the EU, EMA has been making preparations to ensure that it can continue to deliver on its mission to protect public and animal health after the UK leaves the EU on 30 March 2019, the date currently set by the timeframe provided in Article 50 of the Treaty on European Union.

In May 2017, EMA and the European Commission published guidance to help pharmaceutical companies responsible for both human and veterinary medicines prepare for 'Brexit'. The aim is to ensure that companies are ready to take the necessary steps to enable undisrupted supply of their medicines for the benefit of patients and animal health, based on the assumption that the UK will become a third country as of 30 March 2019. The following Brexit related documents were published in 2017 and are kept periodically updated as new information becomes available:

- Notice to MAHs of centrally authorised medicinal products for human and veterinary use (link),which clarifies the requirements and timelines to adapt processes and consider changes to marketing authorisations to ensure continuous validity and exploitation, once UK has left the Union.

- A Questions and Answers document for medicinal products for human and veterinary use within the framework of the Centralised Procedure (link), which provides more detail on requirements (e.g. for establishment location for UK based entities, and generic and hybrid marketing authorisations).

- Practical guidance for procedures related to Brexit for medicinal products for human and veterinary use within the framework of the centralised procedure (link).

To complement the published guidance, regular dialogue with industry stakeholders was initiated in 2017, through a series of EMA meetings, teleconferences and webinars:

- Meeting on Brexit and operation of the centralised procedure for human medicines on 4 October 2017 (link).

- Teleconference on Brexit and operation of the centralised procedure for veterinary medicines on 13 October 2017 (link)

- 3 topic specific "Brexit" related webinars on:

  - MAH transfers" (Human and Veterinary) on 23 November 2017;

  - Pharmacovigilance (Human only) on 24 November 2017;

  - Manufacturing and supply (Human and Veterinary) on 12 December 2017.

These interactions have enabled the Industry to obtain further clarification on the requirements in order to establish "Brexit" preparedness plans in due time, raise any questions and highlight general concerns. Meetings every 2-3 months are planned throughout 2018, with further information available on a dedicated area of EMA's website (link).

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. Involving stakeholders in Telematics activities is crucial as IT systems underpin the work of the European Medicines Regulatory Network with wide-reaching impact on the Agency's stakeholders, including pharmaceutical industry.

Meetings between industry associations and the EU Telematics Management Board provide a forum to update and engage in dialogue on Telematics related activities. The meetings that took place in April 2017, offered industry associations the possibility to share their consolidated views on the implementation of the eCTDv4.0 standard in view of the updated eSubmission roadmap and on the development of the Telematics strategy 2025. In addition, and at the request of the EU TMB, an update from industry associations on their current IT initiatives that are of relevance to the Telematics domain was delivered.

New and enhanced EudraVigilance system

In accordance with the EudraVigilance Auditable Requirements project plan, the new and enhanced EudraVigilance system was launched on 22 November 2017.

As part of its change management strategy in 2017, EMA has engaged with industry stakeholders in preparation of the launch of the new system. This included the following activities in liaison with the EudraVigilance Expert Working Group, where industry is also represented:

- Regular meetings with pharmaceutical industry, which provided a platform to discuss project progress and to address/clarify technical and procedural issues. These meetings included EudraVigilance Info Days, industry stakeholder platform meetings and other information events.

- Monthly webinars to address questions from users.

- eLearning offerings for users to familiarise themselves with the new system components, the ICH ICSR reporting standard as well as procedural aspects related to adverse reaction reporting and signal management.

- Face to face training offerings based on the new system functionalities and reporting standard at the premises of the EMA and in Member States.

- Quarterly updates based on the QPPV Pharmacovigilance Newsletter.

- Testing with marketing authorisation holders (MAHs) on the basis of the EudraVigilance checklist and technical support plan for MAHs and Sponsors of Clinical Trials in the EEA.

- Instructions for MAHs on the EudraVigilance go-live strategy.

- Publication of Questions and Answers on the launch of the EudraVigilance system received from stakeholders.

EudraVigilance now provides enhanced functionalities to National Competent Authorities, and MAHs for effective reporting and an extensive data set for monitoring of adverse drug reaction data and detection of risks related to the safety of medicines, thus contributing to the protection and promotion of public health. EudraVigilance is used by more than 5,519 companies (with 18,688 users). With regard to the new signal management responsibilities of MAHs, registrations for the EudraVigilance Data Analysis System at present include 2,043 MAHs (6,198 users).

SPOR

EMA is currently implementing the standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP). The ISO IDMP standards provide data elements, formats and terminologies to unambiguously identify medicines and exchange information about them. Following a phased implementation process, pharmaceutical companies will be required to submit data to EMA in accordance with the new formats and terminologies.

To facilitate the implementation of these ISO IDMP standards, EMA is delivering a set of master data management services for the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential (attributes such as pharmaceutical form and route) data. These four domains or areas are known collectively as SPOR.

EMA-Industry Change Liaisons have been appointed to facilitate close interaction with industry stakeholders on SPOR. The first two services, the Referentials management service (RMS) and Organisations management service (OMS) were launched in June 2017 and webinars were held in November 2017 (link) and December 2017 (link) to update industry stakeholders on the use in electronic application forms.

EMA is also exploring the broader potential uses of SPOR to support different regulatory procedures (e.g. simplification of Type IA variations) and a Joint SPOR/ Regulatory Optimisation Group (ROG) meeting was held in June to consult stakeholders.

Use of Cloud Services

The Agency is proceeding with the use of cloud services in an incremental and controlled manner and has set up a Cloud Security Consultative Group to inform and consult stakeholders on the information that will be stored in the Cloud including the necessary controls ensuring that information stored is secure. This group is a body that brings together representation from pharmaceutical industry, civil society and healthcare professionals groups to discuss the use of cloud services by the Agency. Given the regulatory remit of EMA and the range of data including public and commercially confidential that it currently maintains, the group plays an important role in providing views and promoting dialogue on use of cloud services, supporting the secure and progressive adoption of cloud services by EMA and reporting developments and any relevant information to the respective affiliated nominated associations.

Integrated regulatory and scientific Information Management (IRIS)

In 2017 EMA launched the integrated regulatory and scientific Information Management (IRIS, formerly known as 'S-REPS'), a pilot project aiming to implement a comprehensive procedural and scientific support platform for Orphan Designation (OD) and allied operational procedures. This is a first step in the EMA's wider digital transformation strategy, and if successful the pilot may be extended to other scientific regulatory processes.

The project envisages aligning the scientific and regulatory end-to-end process, which is currently supported by multiple tools. The guiding principles of the pilot project include limited customisations and use of 'Out of the Box' functionalities to support end-to-end processes. Key benefits for Industry Stakeholders include a single portal with a user friendly and time saving interface, better visibility and usability and data quality. S-REPS will be a Cloud based platform accessible on multiple devices (laptop, tablet, and phone) through a single web portal to access OD procedure data. There will be real-time access to EMA/COMP outputs, with possibility to get alerts. The platform will be fully integrated with EMA Master Data Management Services (SPOR) to ensure consistency.

Stakeholders will be involved in a User Acceptance Testing (UAT) prior to 'go-live' which is currently

expected in mid-June 2018, followed by a 3-month transition period, prior to mandatory use of the web portal.

Global regulatory environment

EMA continued to engage with a range of stakeholders, including industry and academia, on a wide range of issues in the area of international cooperation during 2017.

The Agency participated in the June and November 2017 meetings of the International Council for Harmonization (ICH), which saw proposals for involvement of unrepresented national pharmaceutical industry associations through the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Although there were no new industry members in 2017, as a sign of the widening stakeholder footprint of ICH, the Bill & Melinda Gates Foundation joined as official Observers. A number of new final and draft guidelines were agreed in 2017, including agreement on new guidance for multi-national clinical trials, work on paediatric medicines, and the beginning of work on revision of the GCP guidelines. Further information on the guidance being developed in the international setting through ICH is available on the ICH & VICH websites.

Important developments in the global regulatory setting included activities of the International Coalition of Medicines Regulatory Authorities (ICMRA), which merged with the international summit of medicines regulatory authorities, and key projects such as supply-chain integrity and work on the role of regulators to promote innovation.

A new initiative in 2017 was the organisation of International Awareness Sessions at the Agency, with the first event held in September. The session was primarily aimed at international regulators and non-governmental organisations, but was also web-streamed live to provide access to other interested stakeholders. It is planned to make these regular events and to gradually open up to other stakeholders, including academia.

Another major development in 2017 was the successful conclusion of the EU-US mutual recognition agreement (MRA) on inspections of medicines manufacturers, which entered into force on 1 November 2017. Further information on the transitional arrangements and progress is available on EMA's website (link). The MRA is expected to have significant benefit both for European and US regulators, and pharmaceutical industry.

EMA participated to several conference and capacity-building activities outside the EU, particularly in China and India, mostly focused on GMP and GCP compliance. This included workshops in China organised by the China Pharmaceutical Association of Plant Engineering (CPAPE) in Taizhou and Jinan, and the USFDA–EMA–CDSCO-DIA multicentre GCP workshop in Mumbai. The Agency took advantage of the July 2017 meeting of the EU-India Joint Working Group on Pharmaceuticals to participate at the DIA-EFPIA-OPPI (Organisation of Pharmaceutical Producers of India) with a focus on biosimilars and international collaboration, which took place at the offices of the Federation of Indian Chambers of Commerce & Industry (FICCI).

3. Consultation with industry stakeholders

EMA organises dedicated stakeholder and multi-stakeholder events each year to disseminate information and elicit feedback from its key stakeholder groups, including industry organisations, and a number of such events are highlighted in this report. An overview of the total 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 2017, EMA hosted a total of 121 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 (Patients, HealthCare Professionals (HCPs), Academia and Industry as well as other interested parties) to discuss one or more topics with a common goal.

Thirty-nine percent (39%) of all topic driven stakeholder events (excluding routine activity events) had multi-stakeholder participation. This was a slightly lower proportion than 2016 (56%). Figure 2 provides the breakdown down by stakeholder type, with participation by both academia (88%) and industry (83%) at higher levels than last year (75% participation for both groups in 2016).

Sixty-one percent (61%) of EMA events in 2017 (excluding routine activity events) were dedicated stakeholder events with one stakeholder group only. 51% of all stakeholder events were industry focused single stakeholder events.

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.

Figure 2. Overview of participation in multi-stakeholder events in 2017

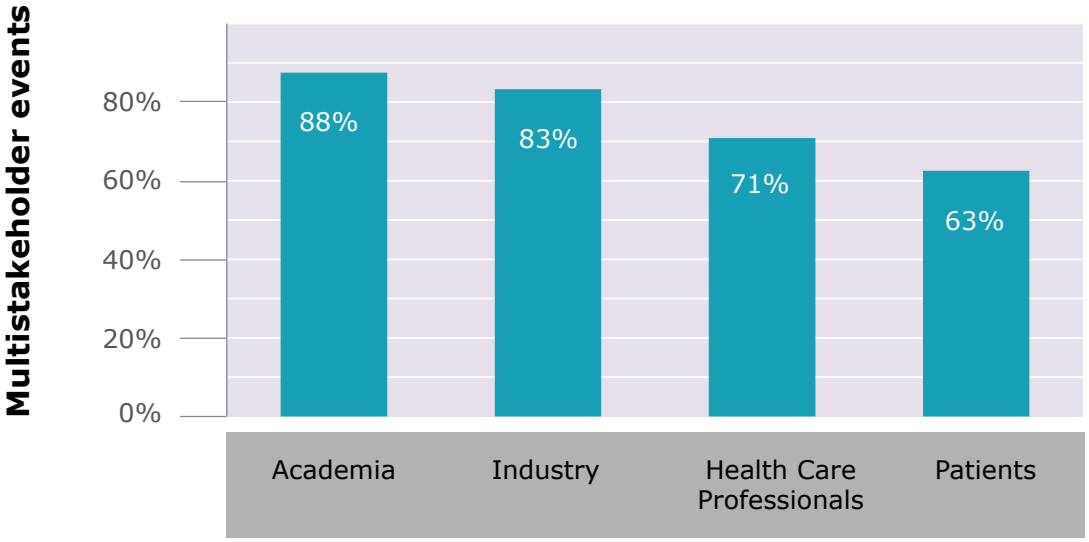
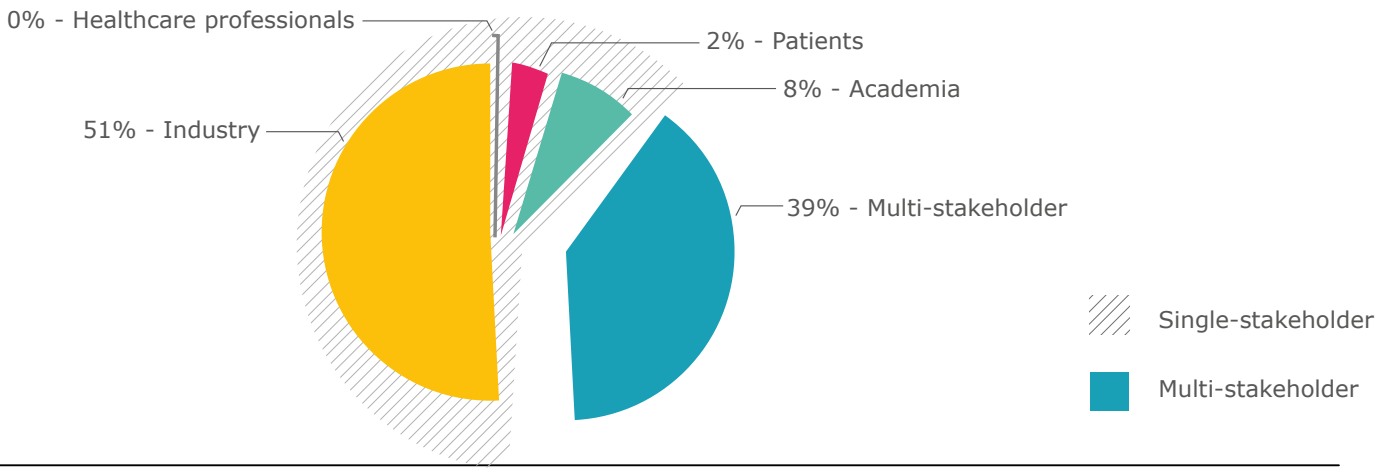


Figure 3. Breakdown of stakeholder events in 2017



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

Implementation of Clinical Trials Legislation

In 2017, 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. The EU portal and Database is designed to support a large and very complex system with multiple stakeholders, including industry.

Within the governance structure for the Clinical Trials programme, industry stakeholders take part in CT stakeholder meetings (2 face to face meetings and additional teleconferences took place in 2017) 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.

In 2017, Industry stakeholders continued to be involved in the User Acceptance Testing (UAT), together with representative experts from Member States. In 2017 two UAT cycles took place with a large and active participation from industry stakeholders. The extensive feedback from UAT was consolidated and analysed. Bugs which were identified and are being fixed and requests for improvement of the system are being prioritised in close cooperation with MS and stakeholders.

As agreed by Management Board in December 2017, further information on timelines, including for the system go-live, will be communicated after the audit of the system (link).

Preparation for the implementation of Medical Device and In-Vitro Diagnostic Legislation

In advance of the Implementation of the new Medical Device Regulation (Regulation (EU) 2017/745) and the "In Vitro Diagnostic Regulation" (Regulation (EU) 2017/746), where certain responsibilities lie with EMA, dialogue was initiated with industry stakeholders as part the Research and Development platform meeting organised in April 2017 (see below), in the context of the discussion on personalised medicines. A number of issues and challenges were highlighted by industry stakeholders, particularly on the future procedural interactions between the different stakeholders during development and marketing authorisation of both companion diagnostics and medicinal products.

An internal EMA Task Force has been set up to prepare for implementation and further exchanges with stakeholders are expected in 2018.

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 2017, a new Research and Development support platform was launched to replace the paediatric platform and extend its scope (see below). This complements the existing platforms for centralised procedures and pharmacovigilance, and provides an opportunity for dialogue on processes throughout a medicines' lifecycle. Highlights from the platform meetings are published on the EMA website in the events calendar (link).

- **Research and Development support**

EMA hosted two EMA-Industry Stakeholders Platform meetings on Research and Development Support in April 2017 (link) and November 2017 (link). These meetings provide an opportunity to address all areas of product development support, from scientific advice, over specifics for paediatric and orphan medicines, to innovation support. Topics covered included: experience with parallel HTA/regulatory scientific advice, advances in the co-development process for personalised medicines, the use of Real World Evidence within development programmes, guidance for orphan medicinal products, opportunities for early dialogue on paediatric development plans, parallel EMA/FDA scientific advice, learnings on PRIME, and opportunities for integrated R&D product support with the example

of the "Scientific and Regulatory Evaluation Procedure Support (S-REPS)".

In a post-meeting survey participants' feedback confirmed the relevance of the scope of this new platform. Despite the implementation of a Business Continuity Plan and ongoing work to prepare for EMA's relocation, the Agency committed to maintain two of these platforms in 2018 to continue the dialogue and foster innovation in Europe.

- **Centralised Procedure**

In 2017 EMA held one industry stakeholder platform meeting on the operation of the centralised procedure in July 2017 (link). The main topic discussed was the outcome of the tri-partite survey (Rapporteurs-Industry-EMA) on initial Marketing Authorisation Applications. Industry stakeholders reported an overall high level of satisfaction with the centralised procedure and discussed with regulators areas for further improvement (see page 15 and link).

Other topics addressed at the meeting included: work ongoing to strengthen EMA support to its committees and the network, the accelerated assessment process, the report on the conditional marketing authorisation, the established Benefit Risk assessment framework and the use of the Effects Table as a communication tool, and the linguistic review process for initial MAAs.

A second platform meeting which had been tentatively scheduled to take place Q4 2017 was replaced by an Industry Stakeholder meeting on Brexit preparedness. In 2018, much of the focus of Industry stakeholder interactions will shift to cover Brexit preparedness with meetings tentatively foreseen every two to three months (see page 7).

- **Pharmacovigilance**

Three platform meetings with industry stakeholders on the implementation and operation of the European Pharmacovigilance Legislation took place in February (link), June (link), and November (link) of 2017. Topics addressed, included post-authorisation safety & efficacy studies, registries, MAHs' compliance with PRAC signal recommendations, the roadmap for periodic safety update reports (PSURs), signal management, the Eudravigilance system, good pharmacovigilance practices (GVPs) and Brexit.

Experience with the PRIME scheme

In 2017, EMA celebrated the first anniversary of its PRIority MEdicines (PRIME) scheme, launched in March 2016 to provide early and enhanced support to medicines that can potentially address patients' unmet medical needs. Between its launch in 2016 and December 2017, EMA received a total of 154 applications for PRIME, 77 of which were from SMEs. A total of 34 medicines were accepted into the scheme. The most represented therapeutic area was cancer, with a total of 12 medicines accepted.

During 2017, the Agency provided support for PRIME products through 30 scientific advice procedures and 17 multidisciplinary kick-off meetings. In addition, three marketing authorisation applications for products accepted into the scheme were submitted.

In May 2017, the Agency organised a meeting with industry stakeholders and academia to review the experience gained after the first year of its implementation. The meeting was an opportunity to discuss how the criteria for eligibility have been applied and what types of support applicants have received so far. It also allowed review of some practical examples that illustrate the benefits of PRIME and how the scheme makes optimal use of existing tools supporting regulatory and scientific advice.

Overall, stakeholders gave positive feedback on the scheme's performance after the first year of implementation (link). Further discussion will take place in industry R&D platform meetings that the Agency organises regularly with stakeholders.

Webinars on Clinical Data publication

2017 was also the first full year of operation of the Agency's flagship policy on the publication of clinical data. This policy aims to increase transparency and to help to avoid the duplication of clinical trials. In addition, it is intended to build public trust and confidence in EMA's scientific evaluation and decision-making processes. Finally it should enable academics and researchers to re-assess the clinical data.

EMA held webinars with industry associations on 23 March 2017 and 29 June 2017. The webinars provided updates regarding the experience gained during the

practical implementation of this policy. They also provided opportunities to explain upcoming changes to the EMA external guidance on the implementation of this policy and allowed to obtain feedback from industry. The EMA external guidance was updated (and a summary of changes prepared) after each of these webinars. The agenda and documents discussed at the industry webinars were published in the EMA events calendar on the EMA website.

In addition, to gauge how the initiative to publish clinical data is meeting its intended aims and to gather information on user experience, the EMA carried out a survey of users in mid-2017. Preliminary feedback from users of the website showed an increase in trust in EMA's regulatory activities and highlighted the importance of this policy to facilitate third-party reassessment of the published clinical data.

4. Surveys

EMA survey on initial marketing authorisation application

A tri-partite survey (Rapporteurs-Industry- EMA) on initial Marketing Authorisation Applications was launched in 2016, to gather feedback on the following three phases of the centralised evaluation procedure and other specific elements (including EMA guidance, committee reports and the level of interaction):

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

In 2017 the survey was finalised and the findings were discussed with industry stakeholder associations in the stakeholder platform on the operation of the centralised procedure in April 2017 (see presentation).

Across the three phases of the evaluation, the survey results showed a high level of overall satisfaction from all three categories of respondents in terms of quality and timeliness of the interaction. Generally there was a high level of interaction during pre-submission phase, essentially through pre-submission meetings, which were positively rated by the respondents.

The survey also identified areas that would benefit from optimisation. These included the need to improve: applicants' understanding of the validation process and reduce administrative comments, circulation timelines for assessment reports and final opinion and the communication of any delays, presentation of the application in general, and the need for mature dossiers and responses during the evaluation.

A report summarising the findings and the actions planned to address the areas identified for improvement has been published on EMA's website (link).

This survey was the second to be undertaken by EMA with Industry stakeholders since the reorganisation of EMA in 2014 when work was carried out to redesign and optimise its procedures. It sets a baseline for future surveys. The scope and frequency of further surveys will be determined based on feedback received from stakeholders, changes introduced and EMA's strategic priorities.

Communication perception survey

In May 2017, EMA ran a Communication Perception Survey to gather feedback from partners and stakeholders, including the pharmaceutical industry, on EMA's communication to the public. The survey covered use, awareness, and quality of EMA communications, as well as perceptions of transparency and engagement. It was disseminated via the website and through targeted contact with partner and stakeholder organisations. Members of the pharmaceutical industry contributed significantly to the survey making up around a quarter of the responses. Outcomes and conclusions from analysis of the survey results will help EMA identify opportunities to focus on communication activities that meet stakeholders' and partners' needs.

5. Plans for 2018

Looking to 2018, the second phase of EMA's business continuity plan (BCP) will take effect from January onwards to provide the necessary resources to prepare the groundwork for the Agency's relocation to Amsterdam in March 2019.

The Agency will continue to implement its framework for interaction with industry stakeholders albeit at a reduced level. As a result of BCP, the number of stakeholder meetings will be reduced, annual bilateral meetings with industry stakeholders will be temporarily suspended and the industry stakeholder survey originally planned for 2017 will remain on hold. These activities will resume once EMA has relocated and BCP has been inactivated.

Brexit will continue to be high on the agenda, as EMA and the European Commission continue to engage closely with stakeholders to prepare for UK leaving the EU and becoming a third country. A survey of human and veterinary industry stakeholder is planned in Q1 2018 to gather information on regulatory plans, and flag up any potential concerns for disruption in medicines supply. Regular meetings and webinars will be held to clarify any questions and provide information on any developments.

Stakeholder dialogue on key topics areas such as antimicrobial resistance, medicines availability and support to innovation are planned to take place next year, subject to BCP and resource availability. Support to early development will be maintained in 2018, with a report planned to coincide with 2 years of experience with the PRIME scheme.

The outcome of the communication perception survey carried out in 2017 will be discussed with stakeholder groups with a view to defining areas where communication and stakeholder outreach could be further enriched in the future, once EMA reverts to being fully operational again.

Annex 1

List of eligible industry stakeholder organisations (as of 16 May 2018)

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
AnimalhealthEurope (previously known as IFAH-Europe)	N/A	www.animalhealtheurope.eu
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

Name of organisation	Acronym	Website
European Federation of Pharmaceutical Industries and Associations	EFPIA	www.efpia.eu
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
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 ‣ AESGP 11 Jan 2017 link ‣ Medicines for Europe 24 Jan 2017 link ‣ EuropaBio 09 Jun 2017 link ‣ EFPIA 10 Jul 2017 link
Industry Platform meeting on Centralised Procedure	Centralised Procedure	Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate	1-2 times/year ‣ 3 Jul 2017 link
Industry Platform meeting on research and development supports	Research and Development	Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate	1-2 times/year ‣ 25 Apr 2017 link ‣ 15 Nov 2017 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 ‣ 3 Feb 2017 link ‣ 2 Jun 2017 link ‣ 24 Nov 2017 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 ‣ 21 Sep 2017 link
Webinars on the implementation of EMA policy on publication of clinical data (Policy 0070) and guidance to industry	Clinical data publication	Industry Stakeholder Associations, EMA	2-4 times/year ‣ 23 Mar 2017 link ‣ 29 Jun 2017 link

Event name	Topic	Participants	Frequency
EudraVigilance Expert Working Group (EV-EWG)	Pharmacovigilance	Industry Stakeholder Associations, EMA, Member States Regulators as appropriate, Non-commercial sponsors (EORTC)	3 times/year ‣ 23-24 Feb 2017 ‣ 22-23 Jun 2017 ‣ 28-29 Sep 2017
EudraVigilance training	Pharmacovigilance	Users of EudraVigilance, including Industry Stakeholder Associations, EMA and Member States Regulators	Over 30 trainings/year
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)	2-6 times/year ‣ 02 Feb 2017 link ‣ 19 Apr 2017 link ‣ 12 May 2017 link ‣ 11 Jul 2017 link ‣ 4 Sep 2017 link ‣ 13 Oct 2017 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	2-3 times/year ‣ 14 Mar 2017 ‣ 03 Oct 2017
EU Telematics Management Board	Information Technology	Industry Stakeholder Associations, EU-TMB, EMA	1-2 times/year ‣ 26 Apr 2017
European Union International Organization for Standardization (ISO) for the identification of medicinal products (IDMP) / Substance, Product, Organisation and Referential data (SPOR) task force meeting	IT/Data Management Standards	Industry Stakeholder Associations, Software Vendors, EMA, Member States Regulators as appropriate	2-4 times/year + additional virtual meetings on ad hoc basis ‣ 10 Mar 2017 link ‣ 20 Oct 2017 link

Event name	Topic	Participants	Frequency
Certain EMA Scientific Committees-Interested Parties meetings (CMDh/ DMDv)	Committee specific topics	EMA, Member States Regulators as appropriate, Industry	Annually or Biannually
Certain EMA Working Parties-Interested Parties meetings (BWP/ BMWP/SWP/IWG)	WP specific topics	EMA, Member States Regulators as appropriate, Industry	Annually or Biannually
European network of paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meetings	Paediatrics	Multi-stakeholders, including Industry Stakeholder Associations, patients, consumers, healthcare professionals, EMA	3 times/year ‣ 20 Jan 2017 link ‣ 17 May 2017 link ‣ 25 Oct 2017 link
Workshop of the European network of paediatric research at the European Medicines Agency (Enpr-EMA)	Paediatrics	Multi-stakeholders, including Industry Stakeholder Associations, patients, consumers, healthcare professionals, EMA	Annually ‣ 16 May 2017 link
Industry stakeholder meetings on Brexit	Brexit	Industry Stakeholder Associations, EMA	Periodic updates (4-6 times per year) ‣ 04 Oct 2017 (human) link ‣ 13 Oct 2017 (vet) link ‣ 23 Nov 2017 webinar on “MAH Transfers” (human &vet) ‣ 12 Dec 2017 webinar on “manufacturing and supply” (human &vet)

Annex 3

Overview of stakeholder events involving industry stakeholders in 2017

Meeting Date	Meeting title	Type of stakeholder	EMA Website
18 January 2017	ADAPT SMART SC meeting	Multi-stakeholder	n/a
20 January 2017	SPC Harmonisation of Established Veterinary Antibiotics	Industry	n/a
30 January 2017	Multi-stakeholder paediatric oncology strategy workshop (cancers with anaplastic lymphoma kinase aberrations)	Multi-stakeholder	link
31 January 2017	Stakeholder focus group meeting on availability of lumpy skin disease (LSD) vaccines authorised to European Union (EU) standards	Multi-stakeholder	link
02 February 2017	EMA-IPFA-PPTA Staff meeting 2017	Multi-stakeholder	n/a
22 February 2017	CESSP Workshop	Industry	n/a
02 March 2017	ESVAC annual network meeting 2017	Industry	n/a
08-09 March 2017	Product and Substance Management Service workshop	Industry	n/a
16 March 2017	European Medicines Agency veterinary medicines info day	Multi-stakeholder	link
20 March 2017	SME info day on the new clinical trial regulation	Industry	link
23 March 2017	ADVANCE Workshop	Multi-stakeholder	n/a
28 March 2017	Workshop on revising the guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicines	Multi-stakeholder	link
29 March 2017	Seventh Framework Programme (FP7) small-population research methods projects and regulatory application workshop	Multi-stakeholder	link

Meeting Date	Meeting title	Type of stakeholder	EMA Website
10 May 2017	Workshop: Long-term effects of medicines taken before, during pregnancy and breastfeeding	Multi-stakeholder	n/a
19 May 2017	First anniversary of PRIME: experience so far	Multi-stakeholder	link
7 June 2017	EudraVigilance information day	Multi-stakeholder	link
12 June 2017	EMA/FDA/Health Canada joint workshop addressing unmet needs of children with pulmonary arterial hypertension	Multi-stakeholder	link
12-13 June 2017	Product and Substance Management Service workshop	Industry	n/a
13 June 2017	Joint SPOR/ROG meeting	Industry	n/a
14 June 2017	Cystic fibrosis workshop – Registries initiative	Multi-stakeholder	link
15 June 2017	WEB-RADR WP1-WP4 joint meeting	Industry	n/a
20 June 2017	Stakeholder guidance workshop on shared facilities joint with SWP	Multi-stakeholder	n/a
20 June 2017	Workshop on generation and use of Health Based Exposure Limits (HBEL)	Multi-stakeholder	link
21 June 2017	Workshop on higher tier testing of VMPs in dung fauna	Multi-stakeholder	n/a
22-23 June 2017	Focus group with invited stakeholders on field efficacy trials in the context of an EU authorisation for veterinary vaccines	Multi-stakeholder	link
27 June 2017	HMA/EMA Joint Task Force on Big Data	Multi-stakeholder	n/a
07 July 2017	Multiple sclerosis workshop – Registries initiative	Multi-stakeholder	link
19 September 2017	EudraVigilance information day	Multi-stakeholder	link

Meeting Date	Meeting title	Type of stakeholder	EMA Website
18-19 September 2017	Introduction to the European Union regulatory system and European Medicines Agency for international regulators and non-governmental organisations	Multi-stakeholder	link
21 September 2017	Eleventh stakeholder forum on the pharmacovigilance legislation	Multi-stakeholder	link
22 September 2017	PSUR roadmap: joint training	Multi-stakeholder	link
26 September 2017	Pharmacovigilance Risk Assessment Committee (PRAC)-Public Hearing: Valproate	Multi-stakeholder	link
05 October 2017	First EMA workshop on non-animal approaches in support of medicinal product development: challenges and opportunities for use of micro-physiological systems	Multi-stakeholder	link
16 October 2017	Joint Drug Information Association (DIA) / European Forum for Good Clinical Practice (EFGCP) /European Medicines Agency (EMA) conference on how to optimise children's access to innovative medicines	Multi-stakeholder	link
24 October 2017	Third tripartite meeting held between EMA, PMDA and FDA to discuss regulatory approaches for the evaluation of antibacterial agents	Multi-stakeholder	link
27 October 2017	European Medicines Agency (EMA) / Drug Information Association (DIA) signal management information day	Multi-stakeholder	link
14 November 2017	European Medicines Agency information day on measuring the impact of pharmacovigilance activities	Multi-stakeholder	link
13-14 November 2017	Second paediatric strategy forum on medicine development for mature B cell malignancies in children	Multi-stakeholder	link

Meeting Date	Meeting title	Type of stakeholder	EMA Website
17 November 2017	Info day for micro, small and medium-sized enterprises: supporting innovative medicines' development and early access	Industry	link
23 November 2017	BWP-QWP Workshop with stakeholders in relation to prior knowledge	Industry	n/a
28 November 2017	Using Organisations Management Services (OMS) and Referentials Management Service (RMS) data in electronic application forms (eAF): SPOR webinar	Industry	link
29 November 2017	TAG on anonymisation	Multi-stakeholder	n/a
30 November – 01 December 2017	Data anonymization workshop	Multi-stakeholder	link
01 December 2017	European Medicines Agency (EMA) / Drug Information Association (DIA) statistics forum: The role of observational data in assessing the benefits and risks of medicines	Multi-stakeholder	link
07 December 2017	SPOR data services: questions and answers webinar with industry	Industry	link
11 December 2017	A common data model in Europe? – Why? Which? How?	Multi-stakeholder	link
14 December 2017	Workshop on site and histology – Independent indications in oncology	Multi-stakeholder	link
15 December 2017	EudraVigilance information day	Multi-stakeholder	link
19 December 2017	European Medicines Agency information day on risk management planning: implementation of GVP V and RMP template rev. 2 guidance	Multi-stakeholder	link

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