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European Medicines Agency's interaction with industry stakeholders

Annual report 2015

Executive Summary

In the spirit of the Framework for EMA interaction with Industry Stakeholders adopted in 2015, EMA has been working to facilitate and streamline its interaction with this stakeholder group. This report provides a high level overview of EMA's engagement with industry stakeholder organisations in 2015 that focused around the following 4 key themes:

- human medicines,

- veterinary medicines,

- operation of the European Medicines Regulatory network,

- global regulatory environment.

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

These included an industry stakeholder consultation on new transparency measures pursuant to the implementation of the EU Clinical Trials Regulation and the Agency's policy on publication of clinical data (policy 0070), a new scheme to reinforce support for human medicines for unmet needs (PRIME), and the development of veterinary vaccines. To provide an opportunity for post-implementation dialogue on recent legislation, policies and initiatives, EMA held regular platform meetings with industry stakeholders focusing on pharmacovigilance, centralised applications and paediatric medicines, with a view to optimising practical operational aspects based on stakeholder experience.

Two surveys targeting industry stakeholders were conducted in 2015: a survey on post –authorisation regulatory procedures (Type I, Type II and PSURs) and a follow-up survey of SMEs on the measures available to support them.

Looking to 2016, the development of guidance to further streamline interaction with industry stakeholders and a survey on centralised applications for marketing authorisation are planned.

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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.

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 2015. 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.

Definition of industry stakeholders and types of interaction

Industry stakeholders, as defined in the framework, are organisations representing the pharmaceutical industry which have an interest in or are impacted by the work of EMA and its partners. This includes amongst other, European industry trade associations representing pharmaceutical companies (e.g. EFPIA, IFAH-Europe, EuropaBio, Medicines for Europe, EGGVP, EUCOPE, AESGP, Europharm SMC) and associations of professionals or service providers operating in or supporting the general interests of industry (e.g. ACRO, EUCROF, EFSPI, PDA, GIRP). See glossary in Annex 1 for list of industry stakeholders registered with EMA as interested parties.

The Agency seeks to establish contacts with European umbrella associations where they exist, and may extend the interaction to international industry organisations where applicable. National or regional associations, and exceptionally individual entities (e.g. non-for-profit entities representing multiple stakeholders), may also be contacted in the absence of an EU organisation.

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 Day);
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).

Eligibility criteria to be fulfilled by industry stakeholder organisations that seek to be consulted and involved directly by the Agency (point 3 above) or to co-operate in specific areas are being developed by the Agency (point 4 above), in line with the approach taken for other EMA stakeholders.

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.

2. Highlights from 2015

This annual report provides a high level overview of areas where the EMA engaged in dialogue with industry stakeholder organisations in 2015 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 and the implementation of new legislation and policies, and, after their implementation, possibilities to optimise existing initiatives and procedures.

Facilitating development of new antibiotics is a strategic priority for the Agency, and in June 2015 the Agency hosted a multi-stakeholder workshop to discuss the use of bacteriophages to treat bacterial infections. With the growing challenge of antimicrobial resistance, the objective was to explore possibilities for promoting the development of this therapeutic approach within the current regulatory framework. Participants, including representatives from academia, industry, policy makers and patient organisations discussed examples of how bacteriophages may be used and the particular regulatory challenges they present (link). In November, a workshop on the use of pharmacokinetics and pharmacodynamics in the development of antibacterial medicinal products was held (link).

In line with EMA's commitment to promote early dialogue to support the development of new medicines, a number of joint meetings with industry associations were held in the course of the year. These included a meeting organised with EuropaBio in October (coinciding with Biotech week), which focused on early regulatory tools to support timely access to new medicines, as well as the development of orphan medicines and advance-therapy medicinal products (ATMPs) (link).

A dedicated meeting on emerging therapies / ATMPs was jointly organised with European biopharmaceutical enterprises (EBE) in December (link). A number of ATMPs were authorised in 2015, including the first stem cell therapy and the first oncolytic virus therapy, and this meeting brought together a diverse mix of public and private stakeholders to discuss under the theme of "Emerging Medicinal Products – from laboratory to patient use". The importance of ensuring that regulatory science keeps pace with ATMP development through regular horizon scanning was highlighted as well as some of the challenges: involvement of patients in development to define meaningful outcomes, the need for new clinical endpoints and new models for reimbursement.

A multi-stakeholder workshop on Orphan Medicines was hosted by EMA at year end. Here, discussion focussed on existing methodologies for comparative efficacy and effectiveness and for major contribution to patient care, including patient preferences, and how these could be applied in demonstrating significant benefit at time of marketing authorisation. The impact of significant benefit on health-technology-assessment (HTA) evaluation, pricing decisions and patient access were also addressed (link).

In collaboration with Medicines for Europe (formerly known as EGA), EMA organised a meeting on the Bioequivalence Guideline for Modified Release Products that took place in April. This was followed in September by a workshop on GCP compliance and oversight for bioequivalence studies, with input from Medicines for Europe and the Association of the European Self-Medication Industry (AESGP). In

addition, a second multi stakeholder meeting to reflect on possible further actions to proactively manage medicines shortages was convened in October with an inter-industry association taskforce reporting on possible solutions to address shortages due to manufacturing and quality problems (link).

EMA also held bilateral meetings with AESGP and GIRP (link) to discuss topics of interest for the self-medication industry and pharmaceutical full-line wholesalers respectively. Further bilaterals with stakeholders representing other sectors of the industry (Medicines for Europe and EFPIA) are planned in 2016.

Veterinary medicines

In 2015, 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 again an increased interest and participation from veterinary pharmaceutical companies and stakeholder associations.

A joint EMA/HMA workshop held in March on requirements for the authorisation of veterinary vaccines in the European Union, brought together experts from national competent authorities (medicines regulatory authorities in Member States/NCAs) and industry to debate how to improve the availability of veterinary vaccines, a topic of high priority for EMA and NCAs for many years. In particular, the workshop covered the requirements for marketing authorisation of vaccines in the EU, their impact on availability and the challenges faced by the industry, including SMEs. The objective was to consider whether the current requirements and the way they are interpreted remains proportionate to the risks and benefits associated with this class of products (link).

The annual CVMP interested parties meeting held in April covered topics related to pharmacovigilance, environmental risk assessment, SPC harmonisation and measures taken to promote the 3Rs (replacement, reduction and refinement). In addition, bilateral discussions were held twice in 2015 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 Medicines Agency Network Strategy to 2020

With the rapid evolution in the regulatory landscape over recent years, the degree of integration of the European medicines regulatory network has increased. During the course of 2015, EMA and the Heads of Medicines Agencies (HMA) worked together to finalise their first common strategy to 2020, which outlines joint key priorities and a high-level roadmap to achieve them.

It addresses the need for a coordinated approach to respond to the multiple challenges and opportunities the network is facing, and it also presents pivotal themes around the network's contribution to human and animal health, the optimisation of the operation of the network and global and collaborative action.

The EU Medicines Agencies Network Strategy to 2020 was released for consultation in April 2015. As feedback from stakeholders, including industry stakeholders was deemed key to the network strategy's success, EMA in collaboration with HMA hosted a meeting in June 2015 to present the document to industry stakeholder associations, to listen to their comments and respond to their questions. The revised strategy was adopted in October 2015 by HMA and in December by the Management Board.

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. Yearly meetings between industry associations and the EU Telematics Management Board provide a forum to update and engage in dialogue on Telematics related activities. The first meeting of that sort took place in January 2015, offering industry associations the possibility to share their consolidated views on the EU Telematics Strategy 2014-2016.

In April, the Agency invited representatives of NCAs and industry associations to a Common European Submission Portal workshop to brainstorm on portal functionalities and requirements. This was followed by another workshop in December.

In May 2015, the draft EU Telematics strategy and implementation roadmap 2015-2017 was released to industry associations for consultation. In June 2015, the strategy was adopted by the EU Telematics Management Board and endorsed by HMA and the EMA Management Board in the summer of 2015 (link).

Global regulatory environment

International cooperation is a key area of work for the Agency, in an increasingly globalised pharmaceutical market. The Agency worked as part of the European Commission delegation to achieve the reforms of the International Council for Harmonization (ICH, formerly the International Conference on Harmonization) that were concluded in 2015 with the inaugural meeting of the 'new' ICH in October. The reforms included a better balance of the roles of regulators and pharmaceutical industry associations, and the possibility to include wider membership of different global industry sectors affected by ICH harmonisation. These changes do not impact on the work of the Veterinary International Conference on Harmonization (VICH).

Further information on the guidance being developed in the international setting through ICH is available on the ICH & VICH websites. In relation to the ICH quality topic on life-cycle management (ICH Q12), EMA hosted a joint BWP/QWP/GMDP IWG - Industry workshop for human and veterinary stakeholders in October 2015 (link).

EMA presented on international activities and initiatives at a number of industry association annual meetings in 2015, including the International Generic Pharmaceutical Alliance (IGPA, renamed as the International Generic and Biosimilar Medicines Association IGBA) in September 2015, and the International Society for Pharmaceutical Engineering (ISPE) in November 2015.

The Agency received visits from the Indian Council for Research on International Economic Relations (ICRIER) in January 2015 to look at the EU model, and the Japan Health Sciences Foundation (JHSF) in November 2015 that focused on regenerative medicines. The Agency also engaged with industry associations in third countries, including in India (also with the Indian Export Council, Pharmexcil) in April 2015.

Finally, two pilots under international programmes supported by industry stakeholders were launched: the WHO collaborative registration procedure and the International Generic Drug Regulators Programme (IGDRP) information sharing pilot.

3. Targeted consultation with industry stakeholders

Each year, a number of regular meetings with industry stakeholders are organised throughout the year (list in Annex 2). These are complemented by topic driven events, a full listing of which is available on events area of the EMA website. Two broad areas of topic-based discussions with industry stakeholders are highlighted here: 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

Work is ongoing to implement the new Clinical Trial Regulation, adopted in April 2014, and the Agency has been working closely with its partners and stakeholders, including representatives of industry associations, as it progresses with 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 DB stakeholder meetings which take place four times per year and provide specialised input through topic specific sub-groups.

In January 2015, a draft proposal on transparency was released for consultation, as an addendum to the "Functional specifications for the EU portal and EU database". As concerns were raised around the timing for publication of results, particularly for early Phase 1 trials, targeted consultation meetings with industry stakeholders and academia were held in June 2015 to discuss the comments received.

Publication of clinical data (Policy 0070)

The EMA policy on publication of clinical data, adopted in October 2014, will lead to increased transparency through proactive publication of clinical data submitted for the marketing authorisation process. As preparation of the clinical reports for publications will present a number of challenges, including considerable workload for marketing authorisation holders, there has been extensive dialogue with industry stakeholders to prepare for implementation. An information webinar was released and a number of consultative meetings with stakeholders, including representatives of industry associations, were held in 2015.

In October, the EMA consulted with industry on draft guidance under preparation, which includes procedural guidance for industry as well as guidance on commercially confidential information and anonymization of personal data. A teleconference was held to provide an update on the outcome of the consultation exercise, prior to its finalisation in quarter 1 of 2016.

Priority Medicines Initiative (PRIME)

In October 2015, EMA hosted a meeting with industry stakeholders to discuss its proposed Priority Medicines (PRIME) scheme to enhance support for the development of medicines that target an unmet

medical need. The scheme was finalised taking into account comments received from all stakeholders, further to a public consultation held between October and December 2015.

Launched in March 2016, PRIME, offers early and proactive support to medicine developers to optimise the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of medicines applications. PRIME builds on the existing regulatory framework and tools already available such as scientific advice and accelerated assessment. Further information on the PRIME scheme, including a report from the meeting with industry stakeholders, and an overview of comments received through consultation, is available on the EMA website (link).

Dialogue in the post-implementation setting

Roundtable to discuss 10 years of SME office

2015 was the year that marked the 10-year anniversary since the establishment of the SME Office. Over these 10 years, the SME Office has been in regular contact with stakeholders, to ensure that the practical implementation of the EU SME regulation addresses the needs of SMEs and to gain feedback for further improvements. A roundtable meeting with stakeholders took place in November 2015 (link). The European Commission, National Innovation Offices, the investment community, representatives of micro, small and medium sized enterprises (SMEs), and industry stakeholder organisations participated in the event and presented on achievements, challenges and opportunities. The SME office provided an overview of 10 years of experience and achievements. The main themes resulting from the 2015 SME Survey were also presented (see section 4 below). A tour de table with stakeholders provided an opportunity to voice concerns, and to suggest areas where SMEs might require further assistance.

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 2015, EMA continued the opportunity for interactive dialogue in the area of pharmacovigilance through the organisation of a series of platform meetings, and introduced two additional platforms focussing on centralised procedures and paediatrics. Platform meeting highlights are published on the EMA website (link).

- Pharmacovigilance

Industry feedback on the implementation of the pharmacovigilance legislation (July 2012), indicated a need to establish a platform for regular dialogue to provide general updates and discuss specific processes and issues. The first EMA-Industry stakeholder platform meeting on the operation of the pharmacovigilance legislation and system was held on 16 September 2014, followed by five platform meetings in 2015 (list in Annex 2).

Experience with risk-management plans (RMP), post-authorisation safety studies (PASS) and post-authorisation efficacy studies (PAES), updates on pharmacovigilance information systems and services (including Article 57 product database, EudraVigilance, medical literature monitoring and the periodic safety report (PSUR) repository), and pharmacovigilance fees, were amongst the topics discussed with industry stakeholder organisations. A review of experience with PSUR and referrals procedures,

updates on GVP Module P-II and biological medicinal products and medication errors, were also addressed.

- Centralised Procedure

The first EMA-Industry stakeholder platform meeting on the operation of the centralised procedure was held in April 2015 (link). The objective was to engage in dialogue in view of recent legislative changes, intra-committee interactions, EMA organisational changes, and in the spirit of the Agency's goal to continuously improve the centralised procedure. Particular focus was placed on the interface between applicants of the centralised procedure, marketing authorisation holders and EMA staff, as well as the management of variations. A performance indicator survey was run between 1 April 2015 and 30 September 2015 (see section 4), and the results were presented at the second EMA-Industry stakeholder platform meeting held in November 2015 (link). Discussions during this second platform focussed on actions to be taken and recommendations for improvement. Industry stakeholders provided feedback on challenges encountered with management of variation procedures and draft guidelines on Accelerated Assessment and Conditional Marketing Authorisation which were released for consultation.

- Paediatric medicines

The inaugural meeting of this type in the area of paediatrics was held on 11 May 2015 (link). It aimed to provide an update on the current operations, achievements to date, and planned improvements. Particular focus was placed on the class waiver list review, the possibility for early interaction with regulators, public summaries and paediatric investigation plan (PIP) compliance check during validation. Based on the positive feedback received during the meeting, the organisation of annual paediatric platform meetings was proposed, with a follow-up meeting scheduled for April 2016.

4. Surveys

Survey on post-authorisation procedures

In 2015 an EMA-Industry survey was launched on post-marketing authorisation procedures for human medicines, covering Type IB/II variations and PSURs (for centrally authorised products), to gather feedback on procedural phases (pre-submission, evaluation) and specific elements (including EMA guidance, committee reports, requests for supplementary information). The survey results were presented at the centralised industry platform meeting held in November (link). Overall, both EMA staff and MAHs were satisfied with the quality of submissions, procedural management and communication across the 3 post-MA procedures. Areas identified for further improvement included, visibility of alerts when guidance is updated, timeliness of the pre-submission query service, proactive communication in case of delays in the assessment report/product information and opinions/notifications circulation, and optimisation of the PSUR process. Industry stakeholders welcomed the survey and ongoing dialogue, and EMA's commitment to continuous improvement.

SME Survey

The objective of a survey launched by the SME office in August 2015 was to receive detailed feedback from SMEs and SME stakeholders 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 feedback was representative of the results of the previous SME survey conducted in 2015, confirming that the incentives on offer are considered very relevant or relevant for the large majority of registered SMEs, which have benefited from the scheme. In terms of scope of the SME programme, regulatory assistance and financial incentives were the areas where increased support was deemed to be needed. This was equally highlighted in the most frequent challenges identified by SMEs, which relate to regulatory requirements, the administrative burden and cost of regulatory procedures. Market access and recruitment, education and training also emerged as challenges for SMEs (link).

5. Plans for 2016

In 2016 work will continue to streamline the Agency's interaction with all of its key stakeholders including industry organisations. An overarching Stakeholder Relations Management Framework will be developed with guidance on engagement methodology and best practice.

EMA stakeholder eligibility criteria for industry associations will be finalised and a list of eligible organisations will be published on the EMA website. A survey of industry stakeholders on centralised applications for marketing authorisation is planned in the second half of 2016.

Annex 1 - Glossary of industry associations and service providers to the pharmaceutical industry[1]

Name of organisation	Acronym
European Federation of Pharmaceutical Industries and Associations	EFPIA
Vaccines Europe	n/a
European Biopharmaceutical Enterprises	EBE
The European Association for Bioindustries	EuropaBio
Medicines for Europe (previously EGA)	n/a
Association of the European Self-Medication Industry	AESGP
European Confederation of Pharmaceutical Entrepreneurs	EUCOPE
Europharm SMC	n/a
European Animal Health Industry	IFAH-Europe
European Group for Generic Veterinary Products	EGGVP
Association of Veterinary Consultants	AVC
Plasma Protein Therapeutics Association	PPTA
Alliance for Regenerative Medicine	ARM
Animal Cell Technology Industrial Platform	ACTIP
Eye-Care Industries European Economic Interest Grouping	ECI-EEIG
Medical technology industry in Europe	Eucomed
European Diagnostic Manufacturers Association	EDMA
European CRO Federation	EUCROF
European Federation for Exploratory Medicines Development	EUFEMED
Association of Clinical Research Organisations	ACRO
Parenteral Drug Association	PDA
Active Pharmaceutical Ingredients Committee	APIC
European Chemical Industry Council	CEFIC

[1] Non-exhaustive list of EU and International associations registered with EMA as interested parties.
Eligibility criteria to be fulfilled by industry stakeholder organisations are under development by the EMA and a list of eligible organisations according to those criteria will be made public (see section 1).

Name of organisation	Acronym
European Quality Assurance Confederation	EQAC
European Healthcare Distribution Association	GIRP
European Association For Logistics And Transport In Healthcare	EALTH
European Association of Euro-Pharmaceutical Companies	EAEPC
European Federation of Statisticians in the Pharmaceutical Industry	EFSPI
Association Programming Pharmaceutical Users Software Exchange	PhUSE
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry	COCIR
European Coalition on Homeopathic and Anthroposophic Medicinal Products	ECHAMP
Health Food Manufacturers' Association	HFMA

Annex 2 - Regular industry stakeholder meetings

Event name	Topic	Participants	Frequency
Industry Stakeholder Roundtable	Policy/Strategy	Industry Stakeholder Associations, EMA	Annually
Bilateral Meetings with Key Industry Associations	Policy/Strategy	Individual Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate	Annually
Industry Platform meeting on Centralised Procedure	Centralised Procedure	Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate	Twice a year
Industry Platform meeting on Paediatrics	Paediatrics	Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate	Annually
Industry Platform meeting on the operation of EU Pharmacovigilance legislation	Pharmacovigilance	Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate	4 times/year
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
EudraVigilance Expert Working Group (EV-EWG)	Pharmacovigilance	Industry Stakeholder Associations, EMA, Member States Regulators as appropriate, Non-commercial sponsors (EORTC)	3 times/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)	4 times a year
Art57(2) Joint Implementation Working Group (Art.57-IWG)	Pharmacovigilance/IT /Data Management	EMA, Committee or Member States representatives	3-4 times a year
EU Clinical Trial & Union Portal DB meeting with	Clinical Trials/IT	Multi-stakeholders, including Industry Stakeholder	4 times/year

Event name	Topic	Participants	Frequency
stakeholders		Associations, patients, consumers, healthcare professionals, EMA and European Commission	
EU Telematics Management Board	Information Technology	Industry Stakeholder Associations, EU-TMB, EMA	Annually
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
Human eSubmission Harmonisation Group	IT	Industry Stakeholder Associations, EMA, Member State Regulators as appropriate	Fortnightly
eAF Maintenance Group		Industry Stakeholder Associations, EMA, Member State Regulators as appropriate	Monthly
eAF Project team meetings	Re-prioritisation eAF Change Requests for Release 01.18	Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate	Weekly
eCTD v.4 group	IT	Industry Stakeholder Associations, EMA, Member States Regulators as appropriate	Monthly
PSUR Advisory group meeting-PRAG	Improvements to search functionality	Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate	Weekly
Topic Driven Workshops in collaboration with some industry Associations	Various topics	Industry Stakeholder Associations, EMA, Member States Regulators as appropriate	Annually
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