EUROPEAN MEDICINES AGENCY
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European Medicine Agency's interaction with industry stakeholders

Biennial report 2020 - 2021

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Executive Summary

This document describes EMA's interaction with industry stakeholders during 2020-2021, two years which were characterised by global and European challenges, as well as ambitious regulatory changes. 2020 was marked by events which substantially impacted EMA's role and priorities most notably, WHO's declaration of the COVID-19 pandemic in March. This resulted in the scope modification and extension of EMA's Business Continuity Planning (BCP), which was already in place to manage the challenges created by Brexit and was adapted to the new pandemic crisis situation (European Medicines Regulatory Network COVID-19 Business Continuity Plan).

In view of the Agency's role and responsibilities throughout this global health crisis, the focus during the reporting period was on our response to the **COVID-19 pandemic**. EMA was at the core of European efforts, facilitating and accelerating vaccines and therapeutics R&D, streamlining evaluations and approvals, monitoring safety and also coordinating European actions to support access and availability of these medicines during the crisis. EMA collaborated as part of the European Medicines Regulatory Network,, through the COVID-19 EMA Pandemic Task force (ETF) and the EU Executive Steering Group on Shortages of Medicines Caused by Major Events (ESG). Stakeholders, including industry, were fully engaged and played a key role in these efforts.

Aside from EMA COVID-19 activities, other industry stakeholder engagement highlights during the reporting period have been:

- The implementation of the **Veterinary Medicinal Products Regulation** (Regulation (EU) 2019/6), which became applicable in January 2022. In this context, a specific stakeholder group (the VMP-Reg Stakeholders Group) was created to best prepare stakeholders for the extensive changes introduced by the new Regulation. These included novel and updated IT systems such as a new Union Product Database and a new Union Pharmacovigilance Database (EVV). To enable this regulatory transition, EMA implemented a change management strategy focused on awareness-raising and engagement, as well as training activities;
- The implementation of the **Clinical Trials Regulation** (Regulation (EU) No 536/2014) which became applicable in January 2022, and the development and preparation for the launch of the

Clinical Trials Information System (CTIS). This new centralised EU portal and database for clinical trials provides a clinical trial search functionality for the public and stakeholders as foreseen by the Regulation;

- The publication, in 2020, of the **European medicine agencies network strategy to 2025**. This document outlines how the network will continue to enable the supply of safe and effective medicines, in the face of developments in science, medicine, digital technologies, globalisation and emerging health threats. COVID-19 demonstrated the importance of keeping pace with innovation to deliver new vaccines and therapeutics and ensure the safety of new technologies for the benefit of public health. This was also supported by the publication, in March 2020, of the **EMA Regulatory Science Strategy to 2025**. Both strategies highlight the need for rapid and close engagement of all stakeholders and partners involved in the development and supervision of medicines in the EU and globally;

- The **UK withdrawal from the European Union**, which became effective from 1 February 2020. The Withdrawal Agreement established a transition period ending on 31 December 2020, with the Protocol on Ireland/Northern Ireland ('IE/NI Protocol') becoming applicable from the end of the pandemic. The Protocol was a topic of necessary dialogue with industry stakeholders concerning the specific consequences with regard to centrally authorised medicinal products and EMA activities;

- The finalisation and publication, in June 2020, of EMA's review of the lessons learnt concerning **nitrosamine impurities in human medicines**. This included recommendations for marketing authorisation holders and applicants to review their manufacturing processes and, where necessary, take measures to limit the presence of nitrosamines in human medicines. In 2021, an EMA and HMA Nitrosamine Implementation Oversight Group (NIOG) was established to oversee the harmonised implementation of the Article 5(3) CHMP scientific opinion across nationally and centrally authorised products;

- The publication, in June 2021, of the **EMA-HMA Big Data Steering Group Workplan for 2021-2023**. This aims to increase the use of Big Data throughout the regulatory process, covering aspects from the quality of data and study methods to the assessment and decision-making. Amongst others, industry stakeholders had the opportunity to discuss the workplan and its implementation in the context of two EU Big Data Stakeholder Forums, held respectively on 15 December 2020 and 7 December 2021. To implement the recommendations of the Workplan, a series of workshops were held in 2020 and 2021 on Big Data related topics, most of them in a multistakeholder format;

- The start, in November 2021, of the dialogue with industry stakeholders and EU Trade Associations concerning the initiation of the **EU Telematics Agile transformation and the transition to EU IT Network activities and new Agile governance model**. This followed the changes in the EMA IT Division structure and the endorsement by the EMA Management Board of the SAFe agile transformation model. This dialogue is expected to continue into 2022, with the piloting of several IT projects (the SPOR PMS, ePI and DADI agile models);

- The **EMA-industry stakeholders platform meetings** resumed in the last quarter of 2020 and during 2021 to support core business activities in the area of human medicines. These covered topics such as support to R&D, centralised procedure evaluation, and post-authorisation/pharmacovigilance areas. In addition, following the appointment of a new Executive Director, EMA-EU Industry stakeholder bilaterals were restored to exchange views on

topics of strategic common interest, as well as to take stock of recent developments in the European pharmaceutical industry sectors;

- The **EMA's SME Office** continued regular engagement with SMEs in the human and veterinary medicines sectors, including providing advice and guidance, training and support to Brexit implementation and beyond. The 15 years of the SME Regulation were celebrated in 2020, with a summary of achievements being published in the SME Office report 2016-2020.

The coming year, 2022, will be an important year for the Agency as it works to implement the EMAN strategy to 2025, together with ongoing initiatives from the RSS2025, which will support EMA and the EU regulatory network's operations in the years to come. This will require the continuous interaction with important stakeholders, including industry. This dialogue will also be a key part of the implementation of the new Veterinary Regulation, the Medical Device Regulation and the Workplan for the HMA/EMA Big Data Steering Group. The EU regulatory network will launch an analysis of the lessons learnt from the pandemic and EMA's mandate will be extended with the aim of using what COVID-19 has taught us to improve how health crises are managed in the future. Close interaction with industry will also continue as part of the transition to the Agile governance model.

Introduction

In accordance with the 'Framework for interaction between the European Medicines Agency and industry stakeholders' (hereafter referred to as "framework") adopted by the EMA Management Board in October 2015 (see Annex 1, and list of eligible organisations in Annex 2), this report provides an overview of EMA's interaction with its industry stakeholders in 2020-2021, covering both human and veterinary medicines. It also includes sections on industry stakeholders' interactions in the context of its IT portfolio and in preparing for the implementation of legislation on clinical trials, veterinary medicines, medical devices and EMA's extended mandate.

In 2020-2021, resources had to be redirected to focus on COVID-19 pandemic activities, as well to prepare for the regulatory provisions for the United Kingdom leaving the European Union.

Due to the pandemic outbreak and EMA's COVID-19 BCP, annual stakeholder engagement reporting did not take place and a biennial report is presented here.

An overview of the main areas where EMA maintained engagement and dialogue with industry stakeholder organisations in 2020-2021 is presented in the following section. Other meetings and events held with industry stakeholders throughout 2020-2021 are listed in Annexes 3 and 4.

Highlights from 2020 and 2021

COVID-19 pandemic response

As the SARS-CoV-2 virus spread through society we have faced with a public health emergency that has fundamentally reshaped how we live, work and interact with each other, the scientific community rose to the challenge. Unparalleled mobilisation and sharing of information between scientists, industry, regulators, healthcare professionals, patient representatives and public health bodies around the world resulted in the approval, in the EU, of a first vaccine against the new disease already in 2020 and another three in 2021. Several products for the treatment of COVID-19 were also authorised. Development and regulatory assessment of new treatments and vaccines proceeded and continue to do so at an unprecedented rate, showing how pharmaceutical interventions can play an important role in controlling the pandemic.

EMA and the network of national competent authorities (NCAs) had to adapt activities and processes to ensure a rapid response to the pandemic whilst maintaining core regulatory activities to protect public and animal health. A business continuity plan set out the principles for operating core activities; existing resources were reallocated and priorities shifted to meet these objectives. EMA has undertook major efforts to support development, authorisation and monitoring of medicines aimed at prevention or treatment of COVID-19, including new activities in the use of real-world data. Staff at EMA and across the European medicines regulatory network (EMRN) demonstrated their strong commitment to the protection of the health of European citizens. Their contributions spanned from early scientific advice during development, rapid evaluation and approval of treatments and vaccines and prompt assessment of post-authorisation changes to expand supply capacity to the robust safety monitoring in the post-authorisation setting. Guidance for stakeholders has been published in these areas. The Agency also led efforts to align regulatory requirements with international regulators, further facilitating medicine development and approval. EMA and the EU network were committed from the start to maximising the transparency of their activities to build EU citizens' trust in the new medicines and vaccines and the understanding of the scientific data underpinning their recommendations. EMA has also issued impartial public-health advice to citizens and healthcare professionals on the safe use of medicines during the COVID-19 pandemic, in particular in those with or at risk of COVID-19 infection.

From the onset, EMA and its partners within the EMRN played a key role in the EU's response. On 4 February 2020, within days of the World Health Organization declaring the novel coronavirus outbreak a public health emergency of international concern (PHEIC -WHO's highest level of alarm), EMA launched its public health threats plan to be ready to support the development of new treatments and vaccines. Lockdown measures, including factories closing, quarantine requirements and travel restrictions, as well as an increase in the numbers of critically ill patients, had a profound impact on all areas of healthcare. There were concerns that the resulting impact on global supply chains could lead to shortages, both for medicines that were critically important for use in intensive care units treating COVID-19 victims, but also for medicines that patients across the EU were reliant on to treat their conditions. Limitations in hospital access for patients not suffering from COVID-19 meant that treatment protocols for certain diseases had to be changed, requiring occasionally regulatory action. Developers of medicines required urgent guidance on how to conduct clinical trials in a situation where participants had to shelter at home and could no longer attend hospital appointments.

The EMA COVID-19 pandemic Task Force (COVID-19 ETF) was established in line with EMA's Health Threats Plan to help EU Member States and the European Commission take quick and coordinated regulatory action on the development, authorisation and safety monitoring of therapeutics and vaccines intended for the treatment and prevention of COVID-19. The activities of the Task Force include:

- reviewing available scientific data on potential COVID-19 medicines and identifying promising candidates;
- requesting data from developers and engaging with them in preliminary discussions;
- offering scientific support in collaboration with the clinical trials facilitation group (CTFG) to facilitate clinical trials conducted in the EU for the most promising medicines for COVID-19;
- providing feedback on development plans of COVID-19 medicines when formal rapid scientific advice is not feasible;
- advising the Scientific Advice Working Party (SAWP) or the CHMP on formal scientific advice and product-related assessments;
- contributing to the activities of the Pharmacovigilance Risk Assessment Committee (PRAC) on emerging safety issues related to COVID-19;

- ensuring close cooperation with stakeholders and relevant European and international organisations.

The Task Force is accountable to EMA's CHMP for all its activities.

EMA and its partners in the network have put measures in place to help prevent and mitigate possible disruptions to the supply of medicines in the EU during the COVID-19 pandemic.
Extraordinarily, EMA is acting as central coordinator in supporting Member States' activities in this area during the pandemic. Lockdown affected the manufacturing, supply and distribution of medicines, leading to constraints in the global medicines supply chain. Demand also increased for some medicines used in patients with COVID-19. These included some anaesthetics, antibiotics and muscle relaxants, as well as some medicines used off-label for treatment of COVID-19. This contributed to shortages. Although the supply situation has improved since May 2020, global supply challenges remain. These are mainly due to:

- decreased manufacturing capacity;
- logistical and transport challenges;
- increased purchasing costs.

The EU Executive Steering Group on Shortages of Medicines Caused by Major Events was established in March 2020 and provides strategic leadership for urgent and coordinated action to prevent and mitigate supply disruption during the pandemic. It also worked on development of methods for the collection and sharing of data on demand for medicines across the EU/EEA and improvement of the forecasting of demand for medicines. The European Commission chairs the steering group. It consists of representatives of EMA, the European Commission, Heads of Medicines Agencies (HMA) and the Coordination groups for Mutual Recognition and Decentralised Procedures for human and veterinary medicines (CMDh and CMDv), as well as risk communication specialists.

The EU Executive Steering Group on Shortages of Medicines Caused by Major Events developed a reflection paper on forecasting demand for medicinal products in the EU/EEA to provide recommendations and to help EU Member States forecast demand for human medicines during global health emergencies such as the COVID-19 pandemic.
An enhanced fast-track monitoring system is in place in the EU since April 2020 to help prevent and mitigate supply issues with crucial medicines used to treat COVID-19 patients. The system allows regulators to:

- detect and monitor common issues;
- spot patterns in medicine supply;
- anticipate future supply disruptions early;
- identify EU/EEA-wide measures to address disruption issues.

The system focuses on medicines used in COVID-19 patients in intensive care units (ICUs) that were in high demand early in the pandemic. EMA identified these medicines in consultation with NCAs. The system oversees EU medicines irrespective of their authorisation route. Each pharmaceutical company has appointed an industry single point of contact ('i-SPOC') who is responsible for reporting on ongoing or anticipated shortages. EMA compiles the information it receives from the i-SPOCs and shares it with the steering group for decision-making. This system is similar to the single point of contact (SPOC) network that EMA and the NCAs use to exchange information on shortages. Pharmaceutical companies should continue to report shortages to the national competent authorities concerned in parallel, in line with their existing obligations.
A dedicated webinar took place on 16 April 2020 to explain to companies how to use the new system and to clarify additional reporting aspects. A 2nd technical webinar on COVID-19 shortage reporting - "Lessons learned" from Phase 1 was held on 30 June 2020.

The European Commission, EMA and the European medicines regulatory network have developed a question-and-answer (Q&A) document to provide guidance to stakeholders on adaptations to the regulatory framework to address challenges arising from the COVID-19 pandemic, with a particular focus on crucial medicines for use in COVID-19 patients.

The impact of the pandemic on European health systems and more broadly on society has also made it necessary for sponsors to adjust how they manage clinical trials and the people who participate in these trials. In this context, in March 2020 the European Commission, the European Medicines Agency (EMA) and national Head of Medicines Agencies (HMA) have published new recommendations for sponsors on how to manage the conduct of clinical trials in the context of the coronavirus disease (COVID-19) pandemic.

Veterinary Regulation implementation preparedness

The Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6), which became applicable on 28 January 2022, will modernise the rules on the authorisation and use of veterinary medicines in the EU. The Regulation aims to reduce the administrative burden for applicants, marketing authorisation holders and national competent authorities, stimulate the development of innovative medicines, improve the functioning of the internal market for veterinary medicines, and strengthen EU action against antimicrobial resistance.

To best prepare stakeholders for the extensive changes, including new and updated IT systems, EMA implemented a change management strategy focused on awareness-raising and engagement, as well as training activities. The VMP-Reg Stakeholders Group, meeting quarterly, established two-way communication with veterinary pharmaceutical companies. Industry volunteers joined the Product Owners Groups of the Union Product Database (UPD) and Union Pharmacovigilance Database (EVV) projects, regularly meeting from late 2020 to define the detailed requirements of the systems and shape their functionalities.

In July 2020, EMA launched a quarterly newsletter providing news on the implementation of the Regulation, which became bi-monthly in 2021 (see all issues). Additional information was regularly published on the dedicated webpage. The mailbox vetchange.programme@ema.europa.eu provided continuous assistance to all stakeholders.

During the second half of 2021, EMA launched a series of learning activities for industry on the systems going live in January 2022 (UPD, EVV, and the Manufacturers and Wholesale Distributors database (MWD)). Industry representatives contributed to the design and delivery of several training sessions, to ensure these would address the needs of their peer users.

After a break due to the relocation and to the pandemic, a number of public online events were organised in 2021, including:

- Veterinary Medicines Info Day I on 25 March 2021
- Info Day for micro, small and medium-sized veterinary enterprises (SMEs) on 28 October 2021
- Veterinary Medicines Info Day II on 30 November 2021.

The open collaboration and the unprecedented participation in all the activities organised reflects the genuine commitment of industry stakeholders towards the successful implementation of the Veterinary Medicinal Products Regulation.

Clinical Trial Regulation implementation preparedness with focus on CTIS

The Clinical Trials Regulation (Regulation (EU) No 536/2014) which became applicable on 31 January 2022. The Regulation aims to harmonise the assessment and supervision processes for clinical trials throughout the EU, via a Clinical Trials Information System (CTIS). CTIS contains the centralised EU

portal and database for clinical trials and provide the clinical trial search functionality for the public which is foreseen by the Regulation. The EMA sets up and maintains CTIS, in collaboration with the Member States and the European Commission.

The Regulation repeals the existing EU Clinical Trials Directive (EC) No. 2001/20/EC and national legislation that was put in place to implement the Directive. It also applied to trials authorised under the previous legislation if they are still ongoing three years after the Regulation has come into operation.

Following an independent audit, the EMA's Management Board confirmed on 21 April 2021 that CTIS is fully functional and meets the required functional specifications. This audit was required for the application of the Regulation.

The authorisation and oversight of clinical trials remains the responsibility of Member States, with EMA managing CTIS and supervising content publication on the public website.

In 2021 EMA focused on:

- Addressing the findings of the system audit;
- improving usability, quality and stability of the CTIS;
- knowledge transfer to prepare users and their organisations for CTIS.

Throughout 2020-2021 EMA delivered an extensive modular online training programme to help clinical trial sponsors, national competent authorities, ethics committees, European Commission and EMA staff prepare for using CTIS. The training programme consists of several modules, covering the full lifecycle of clinical trial submission, authorisation and supervision and is overarched by a guide on how to use the online CTIS training material developed by EMA. The CTIS training and support web page on the EMA website was revised in 2021 to include references for sponsors and for MS, support materials and information and recordings from trainings and events. CTIS user personas and sponsor organisation models were developed to facilitate the organisational planning for implementation of CTIS. In addition, EMA prepared and published a CTIS Sponsor Handbook that summarises information and provides useful references for clinical trial sponsors. All training and supportive materials were developed in liaison with stakeholders to ensure their fit for purpose.

A number of online events were organised to support stakeholders with the move to CTIS:

- CTIS webinar: dynamic demo of sponsor workspace on 21 September 2020;
- Two-part training for clinical trial sponsors from SMEs and academia on 22 February 2021 and 4 March 2021
- CTIS webinar for sponsor organisations on 29 July 2021
- CTIS virtual information day on 26 October 2021
- Webinar for SMEs and academia on CTIS on 29 November 2021

Training and supporting materials on how to use CTIS for clinical trial sponsors, NCAs, ethics committees, European Commission and EMA staff are available on the EMA website:

- Clinical Trials Information System: training and support
- Clinical Trials Information System (CTIS): online modular training programme

In October 2021 a European Union Clinical Trials Information System CTIS: Go-live Planning document was published on EMA website

An EMA CTIS Highlights Newsletter was established in 2020 and issues are regularly published and distributed to subscribers to provide key updates on the evolvement of CTIS.

Regulatory Science Strategy to 2025 implementation status

EMA published its Regulatory Science Strategy to 2025 in March 2020. Developed over two years in consultation with a wide range of stakeholders, including healthcare professionals, patients, the pharmaceutical industry, academia and regulatory bodies, the strategy aims to advance regulatory science over the next five years, covering both human and veterinary medicines. It is the Agency's response to the dramatic acceleration of the pace of innovation in recent years and the need for regulators to be ready to support the development of increasingly complex human and veterinary medicines that combine different technologies. The COVID-19 pandemic highlighted the need for rapid and close engagement of all stakeholders and partners involved in the development and supervision of medicines in the EU and globally, which is one of the fundamental principles of this strategy. The learnings from this public health crisis and how the European medicines regulatory network dealt with it will be incorporated so that processes can be adapted, where needed. The strategy sets out key areas where new or enhanced engagement of the EU network is essential and where advances in regulatory science are necessary. It identifies strategic goals for such engagement for human and veterinary medicines and includes core recommendations and underlying actions to support these.

The five key goals of the strategy are: catalysing the integration of science and technology in medicine development; driving collaborative evidence generation to improve the scientific quality of evaluations; advancing patient-centred access to medicines in partnership with healthcare systems; addressing emerging health threats and availability/therapeutic challenges; enabling and leveraging research and innovation in regulatory science. The goals, and the recommendations and actions stemming from them, aim to ensure that regulators can advance public health and that medicine regulation in the coming years is designed in a way that delivers optimal outcome for the European citizens. Deliverables of the Regulatory Science Strategy continue to be embedded in EMA's multiannual work programmes and implementation plans of EMA's scientific committees, working parties and other groups involved in medicine evaluation

One of the first concrete outcomes of the Regulatory Science Strategy was the implementation of a new, more agile organisational structure to ensure that the Agency operates as efficiently as possible to deliver high-quality outputs for public and animal health. The changes were implemented in March 2020 and took into account the rapidly evolving landscape for pharmaceutical research and development that requires regulators to keep up with advances in science and technology and prepare for future challenges at an ever-accelerating pace. They were also driven by the need to recalibrate to a reduced workforce following the relocation of the Agency to Amsterdam in 2019, while also dealing with an increased workload due to the pandemic and the implementation of various new pieces of legislation extending the scope of EMA's activities. The main, high-level changes were as follows: Operations in the area of human medicines have been integrated into one Human Medicines Division. The structure of the Veterinary Medicines Division remains unchanged.

In addition, four mission-critical task forces were established to support the human and veterinary medicines divisions, bringing together expertise to drive transformational change in the following high priority areas:

- The Digital Business Transformation task force
- The Data Analytics and Methods task force
- The Regulatory Science and Innovation task force
- The Clinical Studies and Manufacturing task force

Further reviews and operational changes were introduced in the course of 2020, with the aim of continually improving the quality of EMA's regulatory and scientific output and level of service for its stakeholders. This included the new structure of the Information Management Division, which came into effect on 1 July and aims to evolve the delivery and maintenance of information systems to be

more customer-focused, agile, integrated and innovative and to provide stakeholders with the right information management tools, technologies and services to deliver quality medicines to EU citizens

Brexit final steps

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a 'third country'. The Withdrawal Agreement established a transition period ending on 31 December 2020. As from the end of the transition period, the Protocol on Ireland/Northern Ireland ('IE/NI Protocol') applies.

The Protocol on Ireland / Northern Ireland forms part of the Withdrawal Agreement that established the terms of the UK's withdrawal from the EU. Based on this Protocol, EU pharmaceutical law applies to and in the UK in respect of Northern Ireland only, as of 1 January 2021.

The EU-UK Trade and Cooperation Agreement has also been concluded between the EU and the UK and contains a specific annex on medicinal products, which covers the recognition of good manufacturing practice inspection outcomes carried out by EU and UK authorities.

On 30 November 2021 a webinar on the "UK withdrawal from the European Union – End of transition period" was held to continue to promote open dialogue on Brexit-related matters and inform industry on the specific consequences on the Ireland and Northern Ireland protocol with regard to centrally authorised medicinal products and EMA activities.

EMA prepared a Questions and answers document to provide guidance to industry stakeholders on the implementation of the Protocol on Ireland/Northern Ireland on the applicable rules in Northern Ireland after the transition period with respect to EMA activities and medicinal products for human and veterinary use within the framework of the centralised procedure.

Human medicines

EMA-Industry stakeholders' platforms and bilateral meetings

To support core business activities in the area of human medicines, **EMA-industry stakeholders platform meetings** were resumed in the last quarter of 2020. In total in 2020 and 2021, three platform meetings were held on research and development support, three on centralised procedure and two on pharmacovigilance.

- Topics addressed in the R&D support meetings (16 November 2020), 4 June 2021, 23 November 2021) included the evolution of the scientific advice framework, learnings from the accelerated scientific advice for COVID medicines, the biosimilar pilot, the launch of IRIS for scientific advice, practical arrangements regarding drug-device combination products under the Medical Device Regulation, preparation for companion diagnostics review under the In vitro Diagnostics Regulation, paediatric medicines, Advanced Therapy Medicinal Products, the five year review of PRIME scheme, the submission of Real-World Evidence in Marketing Authorisation and Extensions of Indications applications, patient-centred development in practice, including the ICH reflection paper on proposed ICH guideline work to advance patient focused drug development
- The pharmacovigilance platform meetings (30 October 2020, 17 November 2021) covered topics such as monitoring of COVID-19 products, the EudraVigilance Operational Plan, the preparations for the end of the transition period for the UK's withdrawal from the EU, and Reference Safety information.

- The Industry platforms meetings on Centralised Procedure (3 December 2020, 30 June 2021, 1 December 2021) covered topics such as the launch of IRIS for reporting changes on Marketing Status, Key Performance Indicators (KPIs) of the Centralised Procedure: Initial Marketing Authorisation Application and use of checklist, electronic Certificates of conformity issued by the EMA (eCPPs), Analysis on Accelerated Assessment and Conditional Marketing authorization, Working Parties new Operational Model, Summary of follow-up items, Pilot project 'Market Launch of Centrally Authorised Products, CHMP Workload and Co-Rapp Involvement, interactions with patients and consumer groups across the product lifecycle, EMA Strategy on digitalization, Pre-submission queries, Security of data, Working Parties new governance etc.

Following the appointment of EMA's new Executive Director, Emer Cooke, on 16 November 2020, bilateral meetings with Industry EU Trade Associations were reconvened to exchange views and promote open and direct dialogue on topics of strategic common interest and take stock of the European pharmaceutical industry sectors. The following bilateral meetings between EMA and EU trade associations high level management took place:

- **EMA – EFPIA bilateral** meeting on 10 February 2021

  Topics: EFPIA's Regulatory Road to Innovation in the context of EU Pharmaceutical Strategy; EMAN Strategy 2025 and RSS 2025; COVID-19 Lessons Learned; EMA expanded scope to health crises - European Health Union; EU Telematics Strategy.

- **EMA - Medicines for Europe bilateral** meetings

  Topics from 23 March 2020: Global supply chain/shortages management discussion; EMA-EMRN 2025 Network Strategy update and EMA reorganisation; Medicines for Europe strategic priorities 2020 onwards;

  Topics from 26 January 2021: Medicines for Europe priorities for the next 5 years taking into account EU strategies; Telematic strategy and digitalisation of the network; COVID-19 Shortage management and Lesson learned; Global development, biosimilars, standard setting; Medicines approvals and maintenance for off-patent medicines; Brexit and Nitrosamines - status update; How to optimize Medicines for Europe-EMA cooperation in the future;

- **EMA – EuropaBio bilateral** meetings

  Topics from 20 May 2020: EuropaBio Life Sciences and Biotechnology vision, COVID-19 – Regulatory lessons from the on-going pandemic response.

  Topics from 5 May 2021: Biotechnology pipeline and key trends; Economic footprint of biotechnology: Bioproduction of the future; Global biotech convergence and international regulatory convergence; Preparing the regulatory environment for the next wave of innovative products;

- **EMA – GIRP bilateral** meeting on 18 January 2021

  Topics: Presentation of GIRP Organisation, strategic objectives and next 2 years plans; Medicine shortages management in Europe; COVID-19 Lesson Learned and better preparedness for the future; COVID-19 Vaccines distribution across Europe;

- **EMA – MedTech Europe bilateral** meeting on 25 June 2021;

  Topics: Key development in the medical device space and future of Medical Technologies: digital products, services and health as seen by MedTech Europe; EMA pharmaceutical and device cross-sectorial activities convergencies; Current and future collaboration between EMA and MedTech Europe;

- **EMA – Affordable Medicines Europe bilateral** meeting on 1 July 2021

  Topics: EMA Metrics and analysis in PD submission Affordable Medicines feedback to EMA on experiences with new procedures and assessments; Affordable Medicines feedback of EMA communication/consultation impacting PD sector; Affordable Medicines updates on trademark law stance divergencies; Update on EMA activities related to PD;

- **EMA – Nuclear Medicines Europe bilateral** meeting on 23 September 2021

  Topics: Functioning of NMEu and identification of the stakeholders in radiopharmaceuticals; Potential and peculiarities of radiopharmaceuticals; Current regulatory environment of radiopharmaceuticals;

- **EMA – COCIR bilateral** meeting on 8 November 2021

  Topics: COCIR EU Trade Association role, responsibilities, membership and priorities for the next 5 years; Digitalisation and the use of health data, including AI and real-world data; interplay between pharmaceutical and medical technology industries; The role of EMA in a European Health Union and a European Health Data Space

New Industry stakeholder forum: Nitrosamines Implementation Oversight Group (NIOG)

In June 2020, EMA finalised its review of nitrosamine impurities in human medicines and recommended companies to review their manufacturing processes and, where necessary, take measures to limit the presence of nitrosamines in human medicines. These measures are meant to ensure that nitrosamines are either not present or are present below levels identified to protect public health. In November 2020, the Agency adopted an opinion on the impact of the above review on the outcome of the review for sartans with a tetrazole ring that was finalised in January 2019. This led to an amendment of the previous conclusions, now requiring companies to carry out risk assessments, establish control strategies and carry out testing for nitrosamines at the level of the finished product.

In June 2020, the European medicines regulatory network published the outcome of a **lessons learned** exercise on the presence of nitrosamines in sartan medicines (also known as **angiotensin II receptor antagonists**). This includes **recommendations** to help reduce the risk of impurities in medicines and ensure that regulators are better prepared to manage cases of unexpected impurities:

- Lessons learnt from presence of N-nitrosamine impurities in sartan medicines

Guidelines for industry in the form of Q&A documents were issued and are regularly updated:

Questions & Answers for Marketing Authorization holders/applicants on the CHMP Opinion for the Article 5(3) of regulation (EC)No 726/2004 referral on nitrosamines impurities in human medicinal products

Questions & Answers on implementation: Impact of the Article 5(3) scientific opinion on nitrosamines in human medicinal products on the Opinion adopted pursuant to Article 31 of Directive 2001/83/EC for angiotensin-II-receptor antagonists (sartans) containing a tetrazole group (candesartan, irbesartan, losartan, olmesartan, valsartan

Marketing authorisation holders should now review their manufacturing processes for all products containing chemically synthesised or biological active substances to identify and, if necessary, mitigate the risk of presence of nitrosamine impurities.

EMA gave companies until the 31 March 2021 to complete the risk evaluation. To complete the testing, companies had until 26 September 2022 for chemical products and until 1 July 2023 for biological medicines.

In 2020, discussion continued within the EU network to establish a robust process to oversee, manage and monitor the implementation of Article 5(3) opinion, with adequate and relevant interactions with industry stakeholders.

In the beginning of 2021, the Nitrosamines Implementation Oversight Group (NIOG) was established by EMA and HMA to oversee the implementation of the Article 5(3) CHMP Scientific Opinion as part of the European Medicines Regulatory Network (EMRN) and facilitate an harmonised implementation across nationally and centrally authorised products. The NIOG is co-chaired by EMA and CMDh and includes members from the CMDh, the CHMP, QWP, SWP, BWP, EDQM and EMA and reports progress to HMA and EMA Management Board. The kick-off meeting took place on 10th March 2021 and NIOG will continues to meet every 2 months. The activities included in the NIOG mandate are defined in the EMRN implementation plan. As an oversight group, NIOG acts as the primary interface for pharmaceutical industry stakeholders concerning nitrosamine topics. As part of this interaction, it is expected to discuss priority topics to engage on and advise on the most appropriate fora for topics to be followed up. The NIOG liaises with the EU Network relevant standing working parties to ensure relevant scientific topics are addressed and will monitor their progress. NIOG meets with industry stakeholders twice per year. Specialised expert interactions between industry stakeholders and regulatory authorities take place via dedicated nitrosamine Interested Parties (IP) meetings with QWP and SWP.

The first meeting of the NIOG with industry stakeholders was held on 31 March 2021, where the NIOG's mandate and operating methods, and future interactions with industry on specific nitrosamine-related topics were explained. The NIOG Workplan and topic prioritisation, updates in Industry Stakeholders Nitrosamines calls for review and identified challenges were amongst the topics discussed at this first industry stakeholders meeting.

The second NIOG-industry meeting was held on 8 December 2021. Here, updates were provided on EMA and industry status on call for review and EMA update on progress of NIOG Workplan as well as discussion on outstanding issues to prioritise in 2022: Quality, safety, multidisciplinary and procedural topics.

Implementation of Big Data recommendations

Since 2017, EMA and HMA have led a thorough assessment of the challenges and opportunities posed by big data in medicines regulation. This culminated in January 2020 with the publication of recommendations for regulators to evolve their approach to data use and evidence generation.

Following this preparatory work, the Big Data Steering Group was established in February 2020 to advise the EMA Management Board and HMA on the implementation of ten priority recommendations.

The Big Data Steering Group, set up by EMA and the Heads of Medicines Agencies (HMA), published its first workplan 2020-21 which set actions for the years 2020-21. The workplan aimed to progress evolution to data-driven regulation through smart working, leveraging collaboration with stakeholders and the use of remote expert workshops.

The Workplan 2021-2023 published in June 2021 aimed to increase the use of big data throughout the regulatory process, from the quality of data and study methods, to assessment and decision-making. Stakeholders had the opportunity to discuss the workplan and its implementation in the context of two EU Big Data Stakeholder Forums, held respectively on 15 December 2020 and 7 December 2021

To implement the recommendations of the above, a series of workshops were held in 2020 and 2021 on Big Data related topics, most of them in a multistakeholder format which included industry:

- 29 September 2020: Workshop on the General Data Protection Regulation (GDPR) and secondary use of data for medicines and public health purposes
- 12 April 2021: Technical workshop on real-world metadata for regulatory purposes
- 19-20 April 2021: Joint HMA/EMA workshop on artificial intelligence in medicines regulation
- 18 May 2021: Data Standardisation Strategy stakeholder workshop
- 30 November2021: Learnings initiative webinar for optimal use of big data for regulatory purpose.

The key achievements in 2021 have been the setting up of DARWIN EU, its advisory board, the publication of ENCePP Real World Evidence (RWE) methods guide and registry studies guideline, the development of RWE use cases with EMA Committees (pilot initiatives), the development of a data standardisation and veterinary data strategies.

There are still a number of key developments planned for 2022 as part of the Big Data EMA-HMA recommendations to enable the transformation to data-driven regulation.

Veterinary medicines

In addition to the interactions involving Veterinary Medicines Regulation implementation, EMA engaged with industry stakeholders during events like Veterinary Big Data stakeholder forum which was the first opportunity to bring together regulators, the pharmaceutical industry, farm management system providers, academia, consumers and practitioners to build awareness on the use of innovative digital technologies in the veterinary regulatory environment, share needs, ambitions and opportunities and inspire future activities shaping the development of the European Veterinary Big Data Strategy.

Support for SMEs for human and Veterinary medicines

SMEs are recognised as a driver of innovation in the EU. The Agency promotes innovation and the development of human and veterinary medicines by SMEs through the provision of financial and administrative assistance to these companies.

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 by Commission Regulation (EC) No 2049/2005, for company specific advice, support and training.

The Agency's SME office report 2016-2020 highlighted the achievements of the regulation on its 15-year anniversary, and feedback received from SMEs and stakeholders acknowledging the importance and relevance of Commission Regulation (EC) No 2049/2005 and its incentives.

Operation of the European Medicines Regulatory Network

EU Telematics agile transformation and transition to EU IT Network initiation

In June 2021, the EMA Management Board endorsed the new Agile governance model to manage the EMA IT portfolio following a six-month review of existing ways of working, which highlighted weaknesses with the existing governance and decision-making processes. The new governance model will significantly reduce the number of project-specific boards, steering committees, and other governance bodies while streamlining processes and reporting.

The Agency is now in the process of implementing the new governance structure and ways of working based on Agile principles and the Scaled Agile Framework (SAFe) methodology to better meet the IT software development needs of the EMRN. It is being implemented in a phased approach, with new governance bodies (Network ICT Advisory Committee, Network Portfolio Advisory Group) having been established in autumn 2021 and operationalised, and a pilot of selected IT projects operating according to the agile methodology. In 2022 an additional part of the IT portfolio will adopt the agile way of working.

This work incorporates both IT programmes and projects, as well as the evolutive maintenance of in-house production of IT applications and systems. This effort contributes to the delivery of the vision in the 'European Medicines Agencies network strategy' and is a key part of the overall 'Technology capability investment plan 2022-2025' (adopted by EMA's Management Board in March 2022).

The transformation is divided into three workstreams:

- General Agile transformation (value streams and pilot; change effort; planning, contracting, budget; agile portfolio office)
- Governance and ceremonies (new governance bodies and portfolio ceremonies)
- Pilot projects (existing in-flight projects DADI, SPOR PMS, ePI)

In 2020 and 2021, EMA carried out IT development work on the following programmes and projects:

- developing a Clinical Trials Information System to support the implementation of the Clinical Trials Regulation;
- delivering the EU Veterinary medicines legislation including an enhanced EudraVigilance Veterinary system and a Union Product Database;
- digitalising EMA's administrative processes;
- providing further releases of the IRIS platform;
- delivering the Substance, product, organisation and referential (SPOR) master data services;
- providing data analytics services;
- supporting EMA's information classification and implementation of the EU Data Protection Regulation (EUDPR).

The EU Telematics strategy and implementation roadmap 2020-2021 was published on the EMA website and will guide ongoing Telematics developments until the European medicines regulatory network develops a new EU IT Network strategy and implementation roadmap for 2020–2025.

In November 2021 EMA held a meeting with industry stakeholders to present the new Agile governance framework.

New and enhanced EudraVigilance system

During the COVID-19 pandemic, the EMA published the Detailed guidance on ICSRs in the context of COVID-19 and determined and elaborated the impact on reporting into EudraVigilance in a Notice to Stakeholders (Questions and Answers on regulatory expectations for medicinal products for human use during the Covid-19 pandemic)

Preparations for the impact of Brexit, including the implementation of the Northern Ireland protocol, were communicated in the Notice to Stakeholders on the Withdrawal of the United Kingdom and EU rules for medicinal products for human use and veterinary medicinal products published on 13 March 2020. The relevant changes include the categorisation of UK cases as non-EEA cases from 1 January 2021, and the possibility to use the country code XI to identify the cases from Northern Ireland within the United Kingdom, thus facilitating the ICSR reporting requirements. Cases with country code XI are considered EEA cases in the database.

In 2020, the EudraVigilance training activities and stakeholder engagement were been adapted to virtual mode in order to maintain the support to the operability of the system. The training page reflects all the training, guidelines and stakeholders support activities. In the context of stakeholders' engagement, the EudraVigilance Expert Working Group with representatives from NCAs, MAHs and Clinical Trial Sponsors, finalised and published its work programme for 2021-2022. Following a PRAC recommendation in October 2019 and the confirmation and announcement by the EMA Management Board in December 2019, a key milestone will be the mandatory use, from 30 June 2022, of the ISO Individual Case Safety Report standard as referred to in Article 26(2)(a) of the Commission Implementing Regulation (EU) No 520/2012 and the modalities on how to use this ISO ICSR standard defined in the ICH E2B(R3) documentation, as well as the ISO terminology on pharmaceutical dose forms and routes of administration referred to in Article 25(1)(f) of Commission Implementing Regulation (EU) No 520/2012, in relation to reporting obligations to EudraVigilance.

Using this internationally agreed format and standard terminology will be a major step towards strengthening data quality and analytical capabilities in EudraVigilance. EMA will continue to support stakeholders in this important initiative to ensure their readiness. In this context, a revision of the EU ICSR Implementation Guide was published in March 2021. With the application of the new Clinical Trial regulation (Reg (EU) No 536/2014)), EudraVigilance will also facilitate the forwarding of suspected unexpected serious adverse reactions from EudraVigilance Clinical Trial Module to the Member States concerned.

SPOR – ISO IDMP implementation updates

EMA is continuing to implement 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.

Throughout 2020 Industry was engaged through the SPOR Task Force meetings (in April, May, July, September and December 2020) and Key User Group meetings. It was agreed to focus on supporting stakeholders in preparation for the implementation and to further breakdown Product Management Service (PMS) implementation into two steps to limit impact to stakeholders. As a result, most of 2020 was dedicated to work on the PMS EU Implementation Guide (EU IG) Version 2 (V2). This was drafted

and underwent public consultation in summer 2020, with comments finalised throughout the year's third and fourth quarter. On the Substances the focus was on Veterinary Substances cleansing to be completed in time to support the Union Product Database (UPD).

In 2021, engagement with industry continued through the SPOR Task Force meetings (in April, July and October 2021), Key User Group meetings and dedicated webinars around Referentials Management Services (RMS) and Organisations Management Service (OMS). These covered five main webinars and more than fifty sessions, involving around 3000 users, and reaching 5000 views, as well as a dedicated technical webinar on SPOR API (with around 200 users). The use of OMS data became mandatory for Centralised Procedure (CAP) applications as of 1 November and work is ongoing to integrate OMS data with EudraGMDP. These milestones were accompanied by dedicated communications. PMS EU IG V2 was published in February 2021 to support the implementation of PMS step 1 in the CAP and an updated V2.1 was published in July 2021 to allow for an alignment with Digital Application Dataset Integration (DADI) requirements. Migration of product CAP data from the EMA Database to PMS has been completed. Such data is in ISO IDMP compliant format, as per dossier business rules, validated by EMA and is already in use by IRIS Inspections via PMS. Migration of XEVMPD and consolidation with EMA data for CAPs is progressing and to be validated in User Acceptance Testing. With regards to substances, Vet NCA Substance data has been mapped and Human chemical substance cleansing was completed in 2021.

Integrated Regulatory and Scientific Information Management (IRIS)

IRIS

The EMA IRIS platform has successfully integrated orphan designation procedures, parallel distribution regulatory procedures, briefing meeting requests with the EMA's Innovation Task Force (ITF), Scientific Advice procedures and lastly GMP Inspections.

In this context the IRIS guide has been updated to cover all these new topics
From 1 October 2021, marketing authorisation holders and applicants need to use EMA's IRIS system to communicate with EMA on Good Manufacturing Practice (GMP) inspections requested by the Agency's scientific committees.

Using IRIS for GMP inspections is expected to improve efficiency by harmonising and automating processes and re-using master data held by EMA. It will also simplify retrieving and reporting data.

With the implementation of IRIS for EMA coordinated inspection procedures, applicants/Marketing Authorisation Holders as well as EU/EEA inspectorates are able to interact with EMA via a single platform. This is expected to streamline the EMA inspection co-ordination process, ensure more secure information exchanges as well as increase data quality through integration with other EMA systems.

During the development, EMA established an industry stakeholders volunteers group to support the implementation of IRIS for inspections. The group participated in a small number of webinars to receive demonstrations and provide feedback on the usability of the online portal for inspections. The group also provided training as appropriate at industry level and advocated on the implementation of IRIS for EMA inspections.

DADI

The Digital Application Dataset Integration Project (DADI) will replace current PDF-based electronic application forms with new web-forms. DADI will replace the form for variations for human medicinal products first in 2022, followed by other submissions forms in 2022-2023 for centrally and nationally

authorised products. Introducing new technology for forms is a key step to optimizing submissions handling processes and enabling the full use of product management services master data. A Q&A document, project outline and list of features of the human variations forms were published in the eSubmission website in 2021.

Towards electronic product information (e-PI) for EU medicines

Throughout 2021, EMA, national competent authorities and the European Commission conducted an ePI set-up project to develop an EU Common Standard for ePI. An EU Common Standard for ePI refers to a common standard for the technical features of ePI agreed by regulators and stakeholders. The draft EU Common Standard was the subject of an open public consultation in summer 2021.

EMA hosted virtual an Information Workshop and Exploratory Workshops on 5-8 July to support the consultation. Feedback from the workshops aimed to ensure that the Common Standard meets the needs of its future users. Following the consideration of submissions received during the public consultation, the EU ePI Common Standard was adopted by the EU Network Data Board on behalf of the network. The standard will be the basis of follow-up piloting in 2022 and 2023 and implementation plans for ePI in Europe.

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

Implementation of Clinical Trials Legislation and Veterinary medicines Regulation

Both the Clinical Trials Regulation and the Veterinary Medicines Regulation (Regulation (EU) 2019/6), became applicable at the end of January 2022. All the specific industry stakeholder interactions during the period covered by this report have been previously described.

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

The **Medical Devices Regulation** (Regulation (EU) 2017/745) came into force on 26 May 2021, following a four-year transition period. Manufacturers must comply with the Regulation when placing new medical devices on the market. The Regulation repeals Directive 93/42/EEC on medical devices and the Directive 90/385/EEC on active implantable medical devices.

The **In-Vitro Diagnostic Devices Regulation** (Regulation (EU) 2017/746) will apply from 26 May 2022, following a five-year transition period. The ongoing proposal by the European Commission is to introduce transition periods depending of the class risk of the device, meaning that for 'legacy' companion diagnostic (mainly class C devices and potentially class D), the transitional periods would be until 26 May 2026 (class C) and 26 May 2025 (class D).

In the meantime, manufacturers can opt to place in-vitro diagnostic devices on the market under Directive 98/79/EC or under the new Regulation if they fully comply with it.

On 27 November 2020 EMA hosted a targeted multi-stakeholder workshop in preparation for the changes introduced by Article 117 of Regulation (EU) 2017/745 on medical devices (MDR) for integral drug-device combinations (products falling under the second sub-paragraph of Article 1(8) and Article 1(9) of the Regulation). The workshop facilitated a discussion and an exchange of views and

experience based on practical examples between European Union regulators, the European Commission, notified bodies, the pharmaceutical industry and medical-device manufacturers. It specifically addressed lessons learned from the notified body opinion process and lifecycle management.

In June 2021 EMA published a major update of the Question-and-Answer document on the implementation of the new Regulations to provide practical guidance to Applicants, Marketing Authorisations Holders and notified bodies. The Agency also issued a final guideline on quality documentation for medicinal products when used with a medical device. The guideline clarifies scientific quality requirements for medicinal products used in combination with medical devices which includes integral drug-device combination, co-packaged device and device referenced in the PI but obtained separately.

In December 2021 EMA published the draft procedural guidance for the consultation procedure on companion diagnostic by the notified bodies (for public consultation) together with the Rapporteur/CHMP/CAT assessment report template and the related application form.

Finally, EMA engaged with industry stakeholders in the context of implementation of MDR/IVDR on a number of other occasions throughout 2020-2021, including the EMA Research and Development platform meetings organised in December 2020 and June and November 2021, The Joint HMA/EMA workshop on artificial intelligence in medicines regulation (19-20 April 2021) and in the context of extended mandate.

Plans for 2022

Looking ahead to 2022, EMA will review of the initial lessons learned from the pandemic, together with the European Network of Medicines Agencies, and engage and support the European Commission Pharmaceutical legislation's future review.

In addition to the successful Go-Live of the Clinical Trials Regulation and the New Veterinary Regulation at the end of January 2022, the EMA will be looking at starting the implementation of the new Regulation on the EMA Extended Mandate and engaging with industry stakeholders in that context.

Following the publication of EMA's Regulatory Science strategy 2025, a reflection will be initiated towards its implementation and how its goals and objectives will be taken forward as part of the joint European medicines agencies network (EMAN) strategy to 2025. This strategy will pave the way for the next five years. Through its high-level goals and recommendations, it will shape and feed into the more detailed workplans of the Network's members in future years. The implementation of both strategic initiatives will require important dialogue and interactions with industry stakeholders.

As advances on research and innovation bring new treatment opportunities and important changes throughout the lifecycle of medicines, regulators will need to adapt in order to deal with this wave of innovation; active and continuous dialogue with stakeholders, including industry, will be necessary to foster adequate progress in this respect.

Engagement with industry stakeholders will also be critical in continuing to deliver on the joint HMA/EMA Big Data Steering Group and its Working Party to 2023 with the objective to enable the use of RWE and its value across the spectrum of regulatory use cases. It is expected that the DARWIN EU network, as part of the EU Health Data Space, will continue to be developed to support better decision-making via its network of expertise, access to data and established analyses. A review of EU and international guidelines and standards available will be developed to help industry and regulators

develop and supervise medicines. In this context, EMA will continue to work with stakeholders to deliver data transformation to support the development and use of better medicines for patients.

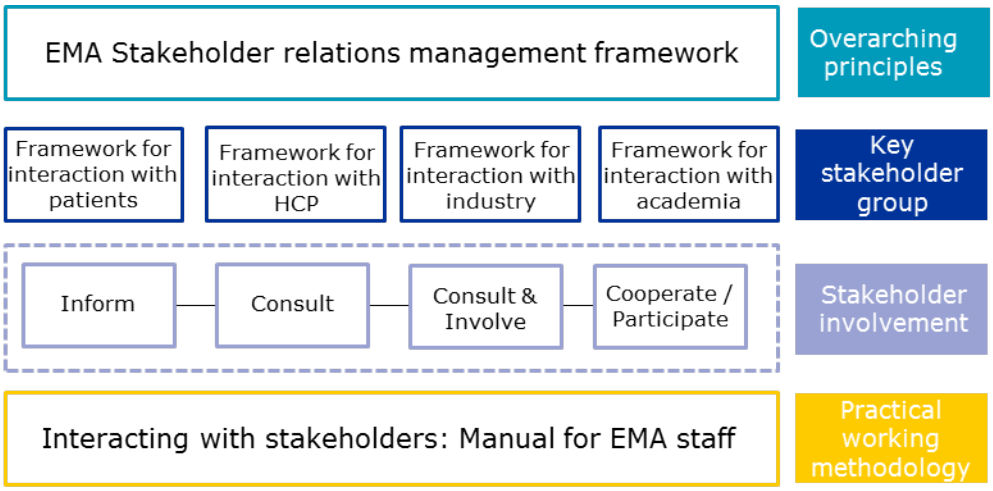
This report on interactions with industry stakeholders was presented to the Management Board during its June 2022 meeting.

Annex 1

Stakeholder relations Management Framework

EMA has defined guiding principles for 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 industry stakeholders, 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.

Figure 1: Illustration of stakeholder relations management framework



EMA framework for interaction between the European Medicines and industry stakeholders is here enclosed.

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).

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

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 in Annex 2.

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.

Annex 2

List of eligible industry stakeholder organisations (January 2020-December 2021)

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
Access VetMed (previously known as European Group for Generic Veterinary Products)	N/A	https://accessvetmed.eu/
Active Pharmaceutical Ingredients Committee	APIC	http://apic.cefic.org/
Alliance for Regenerative Medicine	ARM	www.alliancerm.org
AnimalhealthEurope (previously known as IFAH-Europe)	N/A	www.animalhealtheurope.eu
Affordable Medicines Europe (previously known as European Association of Euro-Pharmaceutical Companies)	N/A	https://affordablemedicines.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/
Avicenna Alliance	N/A	https://avicenna-alliance.com/
ECA Foundation	ECA	https://www.eca-foundation.org/
European Association for Bioindustries	EuropaBio	www.europabio.org/
European Association for Logistics and Transportation in Healthcare	EALTH	www.ealth.org/
European Coalition on Homeopathic & Anthroposophic Medicinal Products	ECHAMP	www.echamp.eu/
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry	COCIR	https://www.cocir.org/
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 Healthcare Distribution Association	GIRP	www.girp.eu/
European Industrial Gases Association	EIGA	www.eiga.eu
European Industrial Pharmacists Group	EIPG	www.eipg.eu
European Manufacturers of Autogenous Vaccines & Sera	EMAV	www.emav.be
Europharm SMC	Europharm SMC	www.europharmsmc.org/
Eye-Care Industries European Economic Interest Grouping	ECI-EEIG	www.eci-eeig.org
Health Sciences Records & Archives Association	HSRAA	https://the-hsraa.org
International Plasma and Fractionation Association	IPFA	https://ipfa.nl/
International Society for Pharmaceutical Engineering	ISPE	www.ispe.org/
Medicines for Europe	N/A	www.medicinesforeurope.com/
Medtech & Pharma Platform	MPP	https://www.medtech-pharma.com/home/
MedTech Europe	MTE	www.medtecheurope.org/
Parenteral Drug Association	PDA	https://www.pda.org/
Plasma Protein Therapeutics Association	PPTA	www.pptaglobal.org/
Vaccines Europe	VE	www.vaccineseurope.eu/

Annex 3

Regular stakeholder meetings with industry representation held in 2020-2021

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 - Medicines for Europe, 23 March 2020 link - EuropaBio, 26 May 2020 link, 5 May 2021 link - GIRP, 18 January 2021 link - Medicines for Europe, 26 January 2021 link - EFPIA, 10 February 2020 link - MedTech Europe, 25 June 2021, link - Affordable Medicines Europe, 1 July 2021 link - Nuclear medicines Europe,23 September 2021 link - COCIR, 8 November 2021 link
Industry Platform meeting on research and development support	Research and Development	Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate	1-2 times/year - 16 November 2020 link - 4 June 2021 link - 23 November link
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 but reduced due to EMA Brexit BCP implementation. - 30 October 2020 link - 17 November 2021 link

Event name	Topic	Participants	Frequency
Industry Platform on the operation of the centralised procedure for human medicines	Centralised procedure	Industry Stakeholder Associations, EMA, Committee and Member States Regulators as appropriate	4 times/year but reduced due to EMA Brexit BCP implementation. - 3 December 2020 link - 30 June 2021 link - 1 December 2021 link
EMA Risk Management Information Day	Pharmacovigilance	Multi-stakeholders, including Industry Stakeholder Associations, patients, consumers, healthcare professionals. EMA, Committee and Member States Regulators as appropriate	- 15 June 2021 link
EudraVigilance training	Pharmacovigilance / Information Technology	Users of EudraVigilance, including "human" Industry Stakeholder Associations, EMA and Member States Regulators	11 trainings held in 2020 12 trainings held in 2021
EU clinical trials information system information day	Clinical Trials/ Information Technology	Multi-stakeholders, including "human" Industry Stakeholder Associations, patients, consumers, healthcare professionals, EMA and European Commission	2-3 times/year 26 October 2021 link
Clinical trials webinar	Clinical Trials/ Information Technology	"human" Industry Stakeholder Associations	21 September 2020 22 February 2021 link 4 March 2021 link 29 July 2021 link 29 November 2021 link
European Union International Organization for Standardization (ISO) for the identification of medicinal products (IDMP) / Substance, Product, Organisation	Data Management Standards/ Information Technology	"Human and veterinary" Industry Stakeholder Associations, Software Vendors, EMA, Member States Regulators as appropriate	2-4 times/year + additional virtual meetings on ad hoc basis - 24 April 2020 link - 10 July 2020 link - 25 September 2020 link

Event name	Topic	Participants	Frequency
and Referential data (SPOR) task force meeting			- 9 December 2020 link - 12 April 2021 link
European network of paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meetings	Paediatrics	Multi-stakeholders, including "human" Industry Stakeholder Associations, patients, consumers, healthcare professionals, EMA	2-3 times/year - 21 February 2020 link - 22 June 2020 link - 28 September 2020 link - 2 March 2021 link - 29 June 2021 link
Veterinary Big Data Stakeholder forum	Big Data	"Veterinary" Industry stakeholders, farm management system providers, academia, consumers and practitioners	- 1 June 2021 link
Union Pharmacovigilance Database: webinar on signal detection and analysis	Pharmacovigilance	"Veterinary" Industry stakeholders	23-24 November 2021 link
Union Pharmacovigilance Database: webinar on adverse event collection and recording	Pharmacovigilance	"Veterinary" Industry stakeholders	6 October 2021 link
Integration of EudraGMDP and OMS - Webinar for industry	Inspection/ IT/Data Management Standards	"Veterinary" Industry stakeholders	12 October 2021 link
EU Big Data Stakeholder Forum	Big Data	"Human and veterinary" Industry stakeholders, farm management system providers, academia, consumers and practitioners	15 December 2020 link 7 December 2021 link
Nitrosamine Implementation Oversight Group (NIOG) - meeting with pharmaceutical industry	Nitrosamines	human "Industry Stakeholder Associations	31 march 2021 link 8 December 2021 link

Event name	Topic	Participants	Frequency
COVID-19 Public Stakeholder meeting	COVID-19	General public meeting including "human" industry stakeholders	11 December 2020 link 8 January 2021 link 26 March 2021 link 25 November 2021 link

Annex 4

Overview of stakeholder events involving industry stakeholders in 2020-2021

Meeting date	Meeting title	Stakeholder type	EMA website
21 February 2020	European network of paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meeting	Multi-stakeholder	link
23 March 2020	EMA - Medicines for Europe bilateral meeting	Industry stakeholder	link
24 April 2020	European Union (EU) International Organisation for Standardization (ISO) for identification of medical products (IDMP)/Substance, Product, Organisation and Referential (SPOR) data Task Force meeting	Multi-stakeholder	link
26 May 2020	EMA – EuropaBio bilateral meeting	Industry stakeholder	link
22 June 2020	European networkof paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meeting	Multi-stakeholder	link
10 July 2020	European Union (EU) International Organisation for Standardization (ISO) for identification of medical products (IDMP)/Substance, Product, Organisation and Referential (SPOR) data Task Force meeting	Multi-stakeholder	link
21 September 2020	EMA Clinical Trial Information System (CTIS) webinar: dynamic demo of sponsor workspace	Multi-stakeholder	link
22 September 2020	Workshop on benefit-risk of medicines used during pregnancy and breastfeeding	Multi-stakeholder	link
24 September 2020	Online training: how to register for access to IRIS; what research product identifiers (RPI) are and how we use them	Industry stakeholder	link
28 September 2020	2020 annual meeting of the members and Coordinating Group of the European network of paediatric research at the EMA (Enpr-EMA)	Multi-stakeholder	link
29 September 2020	Workshop on the General Data Protection Regulation (GDPR) and secondary use of data for medicines and public health purposes	Multi-stakeholder	link
13 October 2020	Online training: How to submit initial and follow-up scientific advice applications (human) using IRIS	Industry stakeholder	link
14 October 2020	Online training: How to submit Initial and follow-up scientific advice applications (veterinary) using IRIS	Industry stakeholder	link

Meeting date	Meeting title	Stakeholder type	EMA website
19 October 2020	Workshop on the draft guideline on registry-based studies		link
22 October 2020	25 Years of EMA: building, learning and adapting to new challenges	Multi-stakeholder	link
30 October 2020	15th industry stakeholder platform - operation of European Union (EU) pharmacovigilance	Industry stakeholder	link
16 November 2020	5th industry stakeholder platform on research and development support	Industry stakeholder	link
27 November 2020	Multi-stakeholder webinar to support implementation of the Medical Devices Regulation on drug-device combinations	Multi-stakeholder	link
30 November 2020	Workshop on support for orphan medicines development	Multi-stakeholder	link
30 November 2020	Industry stakeholder webinar on the UK withdrawal from the European Union – End of transition period	Industry stakeholder	link
3 December 2020	5th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines	Industry stakeholder	link
9 December 2020	European Union (EU) International Organisation for Standardization (ISO) for identification of medical products (IDMP)/Substance, Product, Organisation and Referential (SPOR) data Task Force meeting	Multi-stakeholder	link
11 December 2020	Public stakeholder meeting: development and authorisation of safe and effective COVID-19 vaccines in the EU	Multi-stakeholder	link
15 December 2020	Heads of Medicines Agencies (HMA) / European Medicines Agency (EMA) Joint Big Data Task Force meeting: EU big data stakeholder virtual forum	Multi-stakeholder	link
8 January 2021	Public stakeholder meeting on the approval and roll-out of COVID-19 vaccines in the EU	Multi-stakeholder	link
18 January 2021	EMA – GIRP bilateral meeting	Industry stakeholder	link
26 January 2021	EMA - Medicines for Europe bilateral meeting	Industry stakeholder	link
10 February 2021	EMA – EFPIA bilateral meeting	Industry stakeholder	link
22 February 2021	SME and academia Clinical Trials Information System (CTIS) two-part training webinar - Day 1	Multi-stakeholder	link

Meeting date	Meeting title	Stakeholder type	EMA website
2 March 2021	European network of paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meeting	Industry stakeholder	link
4 March 2021	SME and academia Clinical Trials Information System (CTIS) two-part training webinar - Day 2	Multi-stakeholder	link
25 March 2021	European Medicines Agency / AnimalHealthEurope veterinary medicines info day 2021	Industry stakeholder	link
26 March 2021	Public stakeholder meeting: approval, safety monitoring and impact of COVID-19 vaccines in the EU	Multi-stakeholder	link
30 March 2021	Webinar on reporting suspected side effects following administration of veterinary medicines	Industry stakeholder	link
31 March 2021	Nitrosamines Implementation Oversight Group (NIOG) – meeting with pharmaceutical industry	Industry stakeholder	link
12 April 2021	Technical workshop on real-world metadata for regulatory purposes	Multi-stakeholder	link
12 April 2021	European Union (EU) International Organisation for Standardization (ISO) for identification of medical products (IDMP)/Substance, Product, Organisation and Referential (SPOR) data Task Force meeting	Multi-stakeholder	link
19-20 April 2021	Joint HMA/EMA workshop on artificial intelligence in medicines regulation	Multi-stakeholder	link
5 May 2021	EMA – EuropaBio bilateral meeting	Industry stakeholder	link
18 May 2021	Data Standardisation Strategy stakeholder workshop	Multi-stakeholder	link
1-2 June 2021	Veterinary Big Data stakeholder forum	Multi-stakeholder	link
4 June 2021	Sixth industry stakeholder platform on research and development support	Industry stakeholder	link
15 June 2021	EMA Risk Management Information day	Multi-stakeholder	link
25 June 2021	EMA – MedTech Europe bilateral meeting	Industry stakeholder	link
29 June 2021	European network of paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meeting	Multi-stakeholder	link
30 June 2021	Sixth meeting of the industry stakeholder platform on the	Industry stakeholder	link

Meeting date	Meeting title	Stakeholder type	EMA website
	operation of the centralized procedure for human medicines		
1 July 2021	EMA-Affordable Medicines Europe bilateral meeting	Industry stakeholder	link
5-8 July 2021	ePI information workshop and exploratory workshop	Multi-stakeholder	link
29 July 2021	Clinical Trials Information System (CTIS) webinar: How sponsor organisations can prepare for CTIS	Multi-stakeholder	link
15 September 2021	Union Product Database: webinar for marketing authorisation holders	Industry stakeholder	link
23 September 2021	EMA – Nuclear Medicines Europe bilateral meeting	Industry stakeholder	link
12 October 2021	Integration of EudraGMDP and OMS – Webinar for industry	Industry stakeholder	link
21 October 2021	Introduction to Organisation Management Service (OMS) / Referentials Management Service (RMS) services and activities: Industry webinar	Industry stakeholder	link
26 October 2021	Clinical Trials Information System (CTIS): Virtual information day	Multi-stakeholder	link
28 October 2021	Info day for micro, small and medium-sized enterprises (SMEs): EMA support for SMEs under the new Veterinary Medicinal Products Regulation	Industry stakeholder	link
8 November 2021	European Medicines Agency and COCIR bilateral meeting	Industry stakeholder	link
10 November 2021	SPOR webinar: How to access and use the SPOR API	Industry stakeholder	link
10 November 2021	Union Pharmacovigilance Database: webinar on adverse event collection and recording	Industry stakeholder	link
17 November 2021	16th industry stakeholder platform - operation of European Union (EU) pharmacovigilance	Industry stakeholder	link
23 November 2021	Seventh industry stakeholder platform on research and development support	Industry stakeholder	link
24 November 2021	EudraVigilance and signal management information day	Industry stakeholder	link
25 November 2021	Public stakeholder meeting	Multi-stakeholder	link

Meeting date	Meeting title	Stakeholder type	EMA website
29 November 2021	Webinar for small and medium-sized enterprises (SMEs) and academia on the Clinical Trials Regulation and the Clinical Trials Information System (CTIS)	Multi-stakeholder	link
30 November 2021	Learnings initiative webinar for optimal use of big data for regulatory purpose	Multi-stakeholder	link
1 December 2021	Seventh meeting of the industry stakeholder platform on the operation of the centralized procedure for human medicines	Industry stakeholder	link
7 December 2021	Heads of Medicines Agencies (HMA) / European Medicines Agency (EMA) Joint Big Data Task Force meeting: EU Big Data Stakeholder Forum	Multi-stakeholder	link
8 December 2021	Nitrosamines Implementation Oversight Group (NIOG) – meeting with pharmaceutical industry	Industry stakeholder	link
8 December 2021	Webinar on veterinary pharmacovigilance (PhV) inspections and systems, their quality management systems and PhV system master files: Introduction and principles	Industry stakeholder	link

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