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Mid-year report 2023

Prepared by the Executive Director of the European Medicines Agency (EMA) and presented to the Agency's Management Board on 5 October 2023.

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Key developments

As indicated in the 2023-25 Single Programming Document and following the WHO's announcement declaring COVID-19 no longer a public health emergency of international concern, both EMA and the European medicines regulatory network (EMRN) took the decision to lift their respective **COVID-19 business continuity** measures in May 2023. These measures were initially put in place to ensure the continuous operation of the Agency's core activities related to evaluating and supervising medicines during the pandemic. EMA's business continuity plan, which originated in 2020, was based on the Brexit and relocation business continuity plan. With this decision the Agency is gradually resuming activities that were previously suspended or reduced due to the pandemic, including the planned restart of clinical data publication for all new active substances later this year. While the temporary measures introduced through the business continuity plan to handle the peak impact of the COVID-19 pandemic are no longer necessary, concerns remain regarding the resourcing of the entire European regulatory network for medicines. The Agency continues to collaborate closely with the EMRN and use insights from the business continuity plan experience to identify and implement sustainable solutions going forward.

EMA continued to serve as **ICMRA**'s Chair. In the first half of 2023, the Coalition met for its regular plenary and Executive Committee meetings as well as for two deep dive discussions on "Rare Disease Cures Accelerator-Data and Analytics Platform (RDCA-DAP)" and on "Regulatory control of excipient supply-chain – Lessons from recent events". During the first half of 2023, 5 ICMRA workstreams have been active. The Agency actively participates in all workstreams while it leads the one on Public Health Emergency Clinical Trials (PHECT) and co-leads the one on Innovation and Real World Evidence. During the DIA meeting in June 2023, ICMRA received the 'Global Award for Outstanding Contribution to Health'.

In 2023 **EMA** and **DG HERA** worked jointly to prevent shortages of antibiotics for the next winter season through EMA's Medicines Shortages Steering Group, the MSSG. Data on the estimated demand and supply of a number of key antibiotics was collected and matched together resulting in a series of recommendations to industry and the public, which were published by the EMA on 17 July. While supply for the next winter season is expected to largely meet demand, EMA has recommended that industry increase supply capacity for a small number of key oral and intravenous antibiotics. A dedicated HERA Board meeting with representatives of the Member States' Ministries of Health, the Commission and the industry took place on Thursday, 20 July to discuss the matter further and agree on possible additional steps.

In February, EMA's additional responsibilities regarding the monitoring and mitigation of shortages of critical medical devices during public health emergencies came into force. The new provisions are the last remaining part to be implemented of **Regulation (EU) 2022/123**, that reinforces EMA's role in crisis preparedness and management for medicinal products and critical medical devices. They entrust the Agency with the responsibility of coordinating, during public health emergencies, the responses of EU/EEA countries to shortages of critical medicines and medical devices, including in-vitro diagnostics. The Medical Devices Shortages Steering Group (MDSSG) has been set up to coordinate urgent actions within the Union in relation to the management of supply and demand issues of medical devices and to make recommendations to prevent or mitigate actual or potential shortages of medical devices in the context of a public health emergency. The MDSSG is supported by the Medical Device Shortages SPOC Working Party (MD-SPOC WP) comprised of Single Points of Contact (SPOCs) for shortages from National Authorities for medical devices, as well as by a sub-network of SPOCs from manufacturers of medical devices, authorised representatives, and if required from importers, distributors, so-called Economic Operators (EO), and notified bodies. EMA worked towards this implementation for more than a year. This has included, amongst other key activities, setting up an ad-hoc drafting group on critical

medical devices consisting of experts from MSs from National Authorities, preparing the setting up of the MDSSG and MD-SPOC WP, and developing a Critical Medical Devices Shortages Reporting System which, once implemented, will allow Economic Operators, NCAs and notified bodies to submit the required information on shortages of critical medical devices.

During 2023, the Agency has continued its work to produce further guidance to implement the annex to the new veterinary legislation (**Regulation (EU) 2019/6**) that defines proportionate and future-proofed technical standards for novel veterinary therapies, particularly biologicals, through the CVMP adoption of two guidelines, namely the "Guideline on the development and data requirements of potency tests for veterinary cell-based therapy products and the relation to clinical efficacy" and the "Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy".

In the area of **antimicrobials** resistance (AMR), the Agency has established the Antimicrobials Dose Review and Adjustment groups (ADRA working group), which includes members of CVMP, AWP and CMDv. The group is developing a questionnaire to gather information from stakeholders in respect of Recommendation number 3 from the CVMP 'PPHOVA' reflection paper. The questionnaire will be sent to CVMP for its agreement in October. Legal and regulatory aspects related to the implementation of the dose review and adjustment are planned to be discussed during Q3-Q4 2023. The Agency has also published the ASU protocols for the collection of sale and use data on antimicrobial medicinal products. The publication of these documents is in line with Article 8 of the Commission Delegated Regulation (EU) 2021/578. They contain technical requirements that Members States need in order to collect and report to the Agency data on the volume of sales and on the use of antimicrobial medicinal products in animals. The documents were developed by EMA together with experts from the 2022 ASU Product Owners group and in consultation with the ESVAC Network. Further training materials (including webinars) to reflect the latest ASU developments are being developed in the second half of 2023.

In the first half of 2023, The Agency has continued to deliver on experimentation and automation through its **Analytics Centre of Excellence (ACE) and Digital Innovation Lab (DigiLab)**. The activities performed include a controlled experimentation with OpenAI and ChatGPT technology to explore whether this technology could be implemented at EMA, the launch of the Agency's first virtual reality powered training, in the area of cybersecurity awareness, the development of an EMA QR code generator to eliminate paper waste and enhance engagement, the launch of new automation tools to reduce manual effort across a number of business areas such as the new Certificate Processing System to enable the generation of medicine certificates faster and in fully digital process, as well as experimentation with new technologies such as Power Platforms to explore areas where these could be implemented.

EMA has continued its effort to increase capacity and expertise across the regulatory network through the work of the **EU Network Training Centre**. During Q1/Q2 the Centre has developed training modules in the area of data science with selected training provider and has launched a tender for services to develop a big data curriculum. Moreover, the Agency has worked for the implementation and roll out (in the context of Annual planning of training with Curriculum leads) of a Learning Design and Development Toolkit to support Course organisers and Curriculum developers; it has continued its work on development of an EU NTC Engagement Portal to provide a single point of access to the EU NTC LMS containing the EU NTC training courses, and it is on target to have the right technology selected by Q3 2023 and start the development phase. Lastly, by adopting an addendum to cooperation agreement between EMA and NCAs the Agency's Management Board took the decision to remunerate NCAs for the development and delivery of training.

The Data Analysis and Real-World Interrogation Network, or **DARWIN EU®**, has completed its first year of operations. Following the establishment of the DARWIN EU® Coordination Centre in February

2022, the first 10 data partners were onboarded. To better understand diseases, populations, and the uses and effects of medicines, the network has launched its first four studies utilising real-world data (RWD) from across Europe. The first four studies start to demonstrate the benefits of DARWIN EU®. The use of a common data model, standardised analytics and agile processes allow faster performance of studies, increased capacity, and lower costs. The design and conduct of these first studies have also supported the establishment of analytical pipelines and processes. The studies were not linked to individual medicines currently under evaluation procedures but selected based on previous procedures and requests for RWE from EMA committees. The Agency has started the selection of additional data partners for phase II and 66 expressions of interests were received. Out of these, 5 have currently entered the onboarding phase and five more will be onboarded by end of 2023. In the month of June EMA has also completed a consultation with industry on a catalogue of standard data analyses. Lastly, DARWIN EU® is participating in a pilot for the European Health Data Space (EHDS), exploring the network's role as a research and data node. DARWIN EU® acts as a pathfinder for the EHDS and will ultimately connect to the EHDS services. In the second half of 2023, DARWIN EU® will continue its collaboration with stakeholders and is working on use case pilots with the European Centre for Disease Prevention and Control (ECDC) and bodies responsible for health technology assessments (HTA) and bodies representing payers.

EMA has continued the work on the HMA-EC-EMA initiative **Accelerating Clinical Trials in the EU (ACT EU**), which aims to develop the European Union further as a competitive centre for innovative clinical research. Notably, in the month of June, the Agency hosted the kick off meeting to establish a multi-stakeholder, neutral platform. Work is continuing to strengthen support academic clinical trials to modernise Good Clinical Practise to embrace novel methodologies to align clinical trial approval with scientific advice and to support expert workforce with training. Planning is progressing for a series of ACT EU workshop in 2023.

On 31 January 2023, the use of the **Clinical Trials Information System (CTIS)** became mandatory for new clinical trial applications. CTIS serves as the single-entry point for submission of clinical trial applications by sponsors and provides joint workspace for EU regulators. This follows one year of transition, during which sponsors could choose whether to submit a new clinical trial application in line with the Clinical Trials Directive or under the new Clinical Trials Regulation (CTR), which entered into application on 31 January 2022.

In the first half of 2023, legal scrutiny of 40 CxMP scientific opinions was completed within the 5-working day deadline in 98% of the cases. Nearly 40 paediatric decisions were also reviewed from a legal standpoint. Extensive legal assistance has also been provided in the context of the new Union draft pharma legislation; for the implementation of the extended EMA mandate, including in respect of medical devices; in the context of the new Fees Regulation and other financial topics such as the remuneration of scientific experts; for the drafting and regular implementation of Agency's Policies; for the implementation of the anti-fraud Action Plan and the interactions with OLAF and the European Ombudsman. In the framework of the Agency's transparency activities, 449 initial decisions and 22 confirmatory decisions on requests to access to documents were scrutinised and co-executed by the Legal Department in the first quarter of 2023.

The number of judicial challenges against EMA and/or the European Commission in connection with alleged breaches of Union pharmaceutical law or procedural irregularities is increasing. The **Legal Department** is currently involved in 15 court cases, without the assistance of any outside counsel. In the first half of 2023, the Court of Justice ruled in favour of EMA on three important cases, widely known as "Tecfidera" (Joined Cases C-438/21 P to C-440/21 P, on the interpretation of the "global marketing authorisation" concept); "Aplidin" (Joined Cases C-6/21 P and C-16/21 P, on the impartiality

of scientific experts involved in EMA's activities); "Hopveus" (Case C-136/22, on the CHMP's discretion to establish and suppress scientific advisory groups and ad-hoc groups as reasonable and appropriate).

In alignment with EMA's Cloud Strategy, the **Information Management Division** has delivered the next generation software-defined data centre (SDDC) facilitating the full migration of its workloads to the cloud. Workload migrations are 98% completed and have been introduced in a non-disruptive manner for EMA's systems and within the target timeline. The new SDDC provides high availability to our important Network systems and state-of-the-art disaster recovery. While enhancing our overall cybersecurity posture, the new data centre will enable EMA to adopt emerging technologies such as artificial intelligence and quantum computing much faster in the future. Furthermore, in alignment with EMA's Information Security Strategy, the Information Management Division enhanced the use of the Security Operations Centre (established in 2022) by expanding the monitored perimeter and establishing proactive vulnerability management. The Security Operations Centre is continuously working to increase the Agency's ability to identify malicious activities while maturing existing monitoring rules to increase efficiency.

The Agency's implementation of the **Scaled Agile Framework (SAFe)** methodology to improve the software product development process and structure has been completed and all projects have transitioned to the Agile governance in the first half of 2023.

Key figures

This report describes the results and achievements of the Agency, working closely with the NCAs, during the first six months of 2023, and thus reflects the situation as of 30 June 2023. Here below we highlight the most relevant deviations from the annual work programme, registered in the first half of 2023. Further developments have taken place since, which have not been included in this document.

Assessment activities for human medicines

Pre-authorisation activities

The **total scientific advice and protocol assistance requests** decreased for the first time in 5 years by 26% compared to the first half 2022, with 358 requests received in Q1/Q2 2023 and a revised annual forecast of 710.

The number of **novel technologies qualification advice/opinions** remained stable with 13 compared to 14 in the first half of 2022 as well as the **requests for classification of ATMPs** remained stable (25 requests).

The first half of 2023 saw a decrease in applications **for orphan medicinal product designation,** (-26%, 116 applications).

Initial evaluation activities

New non-orphan medicinal products applications have seen an increase in the first half 2023 compared to the first half of 2022 (17 vs 14), however with a downwards revised annual forecast for 2023, from 46 to 43.

Generic, hybrid and abridged applications saw a moderate decrease compared to the first half 2022 (9 compared to 8), and a forecast revised upwards by 16% (22 expected in 2023 from initial 19). This increase relates to hybrid, informed consent and well-established use.

On the contrary **similar biological products more than doubled** (9 in Q1-Q2 2023 vs 4 in Q1-Q2 2022).

The number of **COVID-19 related product applications received** dropped, with 2 applications received in the first half of 2023, compared to 5 received in the first half of 2022.

Post-authorisation activities

The number of **type IA variation applications** remained stable compared to Q1-Q2 2022, whereas **type IB variation applications** saw an 8% increase compared to the same period (1,739 vs 1,606). **Type II variation applications** decreased by 19% (499 vs 617).

In the first half of 2023, **line extensions of marketing authorisations** increased by 64% (18 compared to 11 in the first half of 2022).

Article 61(3) applications marked a 43% increase compared to Q1-Q2 2022 (149 vs 104), while the annual forecast remains unchanged (200).

In Q1/Q2 2022**, Plasma Master File annual update and variation applications** dropped in comparison to first half 2022 levels, with 6 applications received (compared to 8 in the first half of 2022).

Pharmacovigilance

Following the COVID-19 pandemic which caused an exceptionally high cumulative number (1,348,258) of **Individual Case Safety Reports (ICSR) for CAPs (reports received)**, the first half of 2023 has seen a decrease of 42% (787,783 in the first half of 2023 vs 1,3348,258 in the first half of 2022), with a downwards correction of the forecast from 1.5 – 2.5 M to 1.5 M.

Assessment activities for veterinary medicines

The number of **Scientific advice requests received** dropped (3 in Q1/Q2 2023, in comparison to 18 in the first half of 2022). The annual forecast has been revised from 23 to 20.

Requests for classification as limited market under Article 4(29) and eligibility under Article 23 (new indicator introduced to reflect changes brought by Regulation (EU) 2019/6) remains stable with 9 requests, (initial forecast 20, revised 20) and volumes aligned with those registered in previous years under **MUMS/limited market requests** (indicator removed).

Initial evaluation applications significantly increased again, by 67% compared to Q1-Q2 2022 (15 vs 9 applications), however, it should be noted that as an overall trend, the volumes have been returning to average compared to 2019. This is leading to a revised forecast for the whole year (initial forecast 24 revised 30, +25%).

The number of **variation applications** indicators have been revised and refer to applications submitted under Regulation (EU) 2019/6 and the new framework for veterinary variations. Overall, the forecast of the variation applications has been revised upwards significantly from 195 to 278 (+43%).

The number of **adverse event reports** (**AER**) saw a decrease, in comparison to the first half of 2022, (-32 % CAPs and -8% NAPs), this was expected considering that in 2022 MAHs submitted a large back-log of non-serious reports to align with the new provisions of Regulation (EU) 2019/6.

There were no **Arbitrations and Community referral procedures** initiated in the first half of 2023, leading to a revision of the forecast for the full year from 6 to 3 (-50%).

Inspections and compliance

The number of **good manufacturing practice** (**GMP**) **inspections** have more than doubled, from 89 in the first half of 2022 to 210 in 2023. The high number of inspections performed is due to the high backlog from the previous year which has been now cleared and the forecast is revised downwards from 326 to 310.

Good clinical practice (**GCP**) **inspections** remained stable compared to the previous year with 47 inspections carried out in the first half of 2023 (53 inspections in Q1-Q2 2022).

Plasma Master File (**PMF**) **inspections**, showed a notable growth in the first half of 2023 with 88 inspections, representing 340% increase against the same period in 2022 (20 inspections in the first half of 2022), thereby explaining the increased annual forecast of 127 (+59 %) in total for the whole year.

Standard certificate requests marked a significant increase again in the first half this year compared to the previous year first half (2,486 vs 2,012), while **urgent certificate requests** remained stable compared to the first half of 2022 (612 vs 591).

1,038 **parallel distribution initial notifications** were received in the first half of 2023, leading to a downwards revised forecast of (2,100, -13%); **parallel distribution annual updates** remained stable (2,742) with a slight downwards revision of the forecast (5,620 initial forecast vs 5,550 final forecast).

With regards to **meetings,** the Agency has launched a pilot to re-introduce face-to-face meetings in the first half of Q2 2022. With this pilot, the Agency aimed at leveraging lessons learned during the 'virtual only' meeting period imposed by the COVID-19 pandemic, to test new ways of working, by introducing an alternation between face-to-face and virtual meetings for all Committees and one physical meeting a year for Working Parties. In the long term, this new way of working will also significantly reduce the Agency's carbon footprint. For this reason, the number of reimbursed meetings shows again an increase in 2023 compared to 2022. However, in view of the above-mentioned approach that the Agency is currently testing, the number of face-to-face meetings will most likely not go back to previous years' level.

Information and transparency

The number of **requests for information** are currently at the levels of pre-pandemic years (3,642 requests received in the first half of 2023 compared to 3,677 in 2019). **Completed requests for interviews and comments by media representatives** have also significantly decreased and can be compared to pre-pandemic years (645 in Q1 – Q2 2023 vs 564 in Q1 – Q2 2019).

There were less activities related to Covid-19 pandemic and a reduced the number of press briefings related to the topic.

Requests for access to documents (ATD) continued to increase in the first six months of 2023 (416 vs 375 in Q1-Q2 2022).

Annexes

Annex 1: Detailed mid-year report

This part of the report reflects the progress of implementing the adopted Annual Work Programme 2023. The forecasts of the workload indicators are revised during the mid-year reporting exercise to take into account the latest operational developments.

Explanation of symbols used in this document

A traffic light system is used to describe performance against objectives and targets.

	Results more than 10% above mid-year forecast/target
	Results within +/-10% (included) of the mid-year forecast/target
	Results 10%-25% below the mid-year forecast/target
	Results more than 25% below the mid-year forecast/target
	No activity/result to report

However, for some performance indicators, where the optimal results should be lower than the targets, such as average assessment or clock-stop days, the traffic light system is reversed to better reflect the essence of these indicators: results below the 'target' are marked green or blue, while results above the 'target' will appear amber or red.

	Results more than 10% below mid-year forecast/target
	Results within +/-10% (included) of the mid-year forecast/target
	Results 10%-25% above the mid-year forecast/target
	Results more than 25% above the mid-year forecast/target
	No activity/result to report

For indicators that have been included in the work programme for the first time, data on the previous years' results are not provided.

Linear patterns are assumed for workload indicators, and the mid-year forecast is assumed to be 50% of the annual forecast of the adopted 'Work programme 2023'. For performance indicators that are expressed as a percentage, the mid-year target is assumed to be equivalent to the annual target. The forecasts of the indicators are revised during the mid-year reporting exercise to take into account the latest operational developments.

In general, the traffic light system reflects the direction and magnitude of changes, as described above.

Human Medicines Division

Pillar 1 - Product related activities

1.1 Pre-authorisation activities

Workload indicators

Procedure							2023 annual forecast		
	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	Initial	Revised	Change	
Total scientific-advice and protocol-assistance requests	348	470	427	392	337	865	710	-155	-18%
Parallel scientific advice with international regulators requests	2	4	3	4	2	4	4	0	0%
Joint scientific advice with HTA bodies requests	3	3	2	1	10	3	3	0	0%
Scientific advice for PRIME products	6	16	21	19	15	4[1]	11	7	175%
Protocol assistance	59	75	80	65	81	146	125	-21	-14%
Novel technologies qualification advice/opinions	13	14	14	9	9	21	21	0	0%
PRIME eligibility requests received	25	25	29	28	24	55	55	0	0%
Applications for orphan medicinal product designation	116	157	134	123	127	280	255	-25	-9%
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	362	346	368	339	279	801	801	0	0%
Requests for classification of ATMPs	25	25	46	54	27	60	50	-10	-17%

1.2 Initial evaluation activities

Workload indicators

Procedure						2023 annual forecast			
	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	Initial	Revised	Change	
New non-orphan medicinal products	17	14	23	28	18	46	43	-3	-7%
New orphan medicinal products	8	12	10	17	17	29	27	-2	-7%

[1] 2023 SPD indicated "42", this was an editorial error. Correct forecast is 4.

	Similar biological products	8[2]	4	4	7	8	15	17	2	13%
	Generic, hybrid and abridged products	8	9	12	12	20	19	22	3	16%
	Scientific opinions for non-EU markets (Art 58)	0	0	0	0	0	1	0	-1	-100%
	Paediatric-use marketing authorisations	1	0	0	1	0	1	1	0	0%
	Number of granted requests for accelerated assessment	5	0	7	10	3	12	12	0	0%
	ATMP marketing application authorisation requests received[3]	2	1	3	6	n/a	8	8	0	0%
	COVID-19 related product applications received[4]	2	5	14	6	n/a	4	4	0	0%
	Companion diagnostics opinions	3	-	-	-	-	20	20	n/a	n/a
	Reviews on the maintenance of the orphan designation criteria at MAA stage	20	-	-	-	-	30	n/a	n/a	n/a

Performance indicators

Performance indicators related to core business		Target 2023	Outcome at the end of				
			Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
	Average assessment time for new active substances and biosimilars – *reversal of traffic lights*	205	190	199	199	198	205
	Average clock-stop for new active substances and biosimilars – *reversal of traffic lights*	180	185	229	168	175	214
	% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	60%	50%	33%	33%	60%	100%
	% of initial marketing authorisation applications that had received centralised scientific advice[5]	80%	43%	60%	70%	72%	86%

[2] Editorial error corrected from 9 to 8.
[3] New indicator introduced in 2021 Work Programme.
[4] New indicator introduced in 2021 Work Programme.
[5] Scientific advice is not mandatory for applicants, therefore it is not a KPI for the Agency per se. Rather, it could be seen as an indicator of applicants' willingness to engage with the European regulatory system.

1.3 Post-authorisation activities

Workload indicators

Procedure	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2023 annual forecast Initial	Revised	Change	
Type IA variations	1,772	1,778	1,961	1,978	1,898	4,100	3,840	-260	-6%
Type IB variations	1,739	1,606	1,393	1,301	1,011	3,200	3,495	295	9%
Type II variations[6]	499	617	606	630	499	1,300	1,202	-98	-8%
Line extensions of marketing authorisations	18	11	16	24	9	30	29	-1	-3%
Renewal applications	54	58	49	44	42	65	81	16	25%
Annual reassessment applications[7]	12	9	8	7	7	31	31	0	0%
Transfer of marketing authorisation applications	15	25	30	27	39	55	61	6	11%
Article 61(3) applications	149	104	124	66	157	200	200	0	0%
Post-authorisation measure data submissions	571	680	519	403	446	925	925	0	0%
Plasma Master File annual update and variation applications	6	8	7	18	20	25	25	0	0%

Performance indicators

Performance indicators related to core business	Target 2023	Outcome at the end of Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
Average assessment time for variations that include extension of indication – *reversal of traffic lights*	180	177.51	171	162	160	154

1.4 Referrals

Workload indicators

Procedure	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2023 annual forecast Initial	Revised	Change	
Pharmacovigilance referrals started	2	4	2	2	6	5	5	0	0%
Non-pharmacovigilance referrals started	2	0	7	5	4	8	8	0	0%

[6] First half of the year normally sees lower volume of type II variations than the second half.
[7] This is a seasonal procedure and 2/3 of these are submitted in second half of the year.

1.5 Pharmacovigilance

Workload indicators

Procedure							2023 annual forecast			
		2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	Initial	Revised	Change	
	Number of signals peer-reviewed by EMA	822	1,126	858	1,015	1,063	1,800	1,600	-200	-11%
	Number of ICSRs for CAPs (reports received)[8]	787,783	1,348,258	1,458,522	-	-	1.5M-2.5M	1,500,000	n/a	n/a
	Number of signals assessed by PRAC (validated by EMA)	25	26	33	25	35	40	40	0	0%
	PSUSAs (CAPs only) started[9]	253	-	-	-	-	593	586	-7	-1%
	PSUSAs (mix CAP/NAP) started[10]	18	-	-	-	-	43	42	-1	-2%
	PSUSAs (NAPs only) started[11]	107	-	-	-	-	238	255	17	7%
	Number of imposed PASS protocol procedures started	2	6	4	0	6	3	4	1	33%
	Number of imposed PASS result procedures started	4	2	6	3	1	6	4	-2	-33%

[8] New indicator introduced in 2021 Work Programme.
[9] New indicator introduced in 2022.
[10] New indicator introduced in 2022.
[11] New indicator introduced in 2022.

1.6 Inspections and compliance

Workload indicators

Procedure							2023 annual forecast			
		2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	Initial	Revised	Change	
	GMP inspections	210	89	77	127[12]	247[13]	326	310	-16	-5%
	GLP inspections	2	1	0	0	0	1	2	1	100%
	GCP inspections	47	53	15	39	79	92	89	-3	-3%
	Pharmacovigilance inspections	13	10	10	3	3	14	15	1	7%
	PMF inspections	88	20	20	16[14]	66	80	127	47	59%
	Notifications of suspected quality defects	127	131	87	87	93	250	250	0	0%
	Medicinal products included in the sampling and testing programme	75	94	94	70	67[15]	81	81	0	0%
	Standard certificate requests received	2,486	2,012	1,938	1,538	1,284[16]	4,043	4,520	477	12%
	Urgent certificate requests received	612	591	987	729	1,349	1,475	1,186	-289	-20%
	Parallel distribution initial notifications received	1,038	1,012	1,537	1,141	1,265	2,400	2,100	-300	-13%
	Parallel distribution annual updates received	2,742	2851	2331	7,778[17]	1,369[18]	5,620	5,550	-70	-1%

[12] The result has been affected by travel restrictions due to the COVID-19 pandemic. The resources have been redirected to activities granting a high level of responsiveness of the Agency to the pandemic.
[13] Higher than previously forecast results due to further additions to the EMA inspection programme, for example re-inspections after short interval.
[14] The result has been affected by travel restrictions due to the COVID-19 pandemic.
[15] Several products were not on the market at the time of sampling and had to be removed.
[16] Due to resourcing and loss of knowledge as well as increased processing time of standard certificates, a shift towards more requests for urgent certificates took place.
[17] The higher figure is due to the inclusion of notifications of change as well as the backlog of 2018-2019 annual updates which have been processed as of December 2019.
[18] To allow for IRIS implementation annual update, submissions were frozen for 3 months.

Performance indicators

Performance indicators related to core business		Target 2023	Outcome at the end of Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
	Standard certificates issued within the established timelines (30 working days)	90%	100%	100%	99%	97%	14%
	Average days to issue standard certificate – *reversal of traffic lights*	15	4.80	3	16[19]	26	65
	Urgent certificates issued within established timelines (2 working days)	98%	100%	100%	99%	98%	99%
	Parallel distribution notifications checked for compliance within the established timeline	98%	99%	98.80%	98.80%	98%	27%

1.7 Committees and working parties

Workload indicators

Procedure		2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2023 annual forecast Initial	Revised	Change	
	Number of reimbursed meetings	151	24[20]	0[21]	52	143	420	420	0	0%
	Committee meetings[22]	26[23]	11	51	15	38	75	75	0	0%
	Trainings[24]	n/a	1	2	1	12	22	n/a	n/a	n/a
	Workshops	n/a	1	1	0	0	13	n/a	n/a	n/a
	Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	n/a	11	93	36	93	310	n/a	n/a	n/a
	Number of virtual meetings (audio-, video- and web conferences)	2,300	3,000	3,220	2,660	1,659	6,500	6,500	0	0%

[19] The target handling time of 10 working days for certificates requested through the standard procedure has been temporarily extended to 30 working days.
[20] COVID had an impact on face-to-face meetings. So far most of meetings have been cancelled or organised virtually. For Q3 and Q4, it is anticipated an increase in the number of face-to-face meetings. However, the initial number of planned face to face meetings will not be reached.
[21] The significant variation in the figures is due to the COVID-19 outbreak.
[22] Including Management Board meetings from 2019.
[23] In 2023 committee meetings will be held physically and remotely.
[24] Includes EU Network training centre meetings.

	Number of reimbursed delegates	1,680	309	0	1,003	2,856	8,500	8,500	0	0%
	Number of non-reimbursed delegates	517	44	7,129	60	227	1,500	1,500	0	0%
	Herbal monographs, new	0	2	2	0	0	5	2	-3	-60%
	Herbal monographs, reviewed[25]	12	19	8	5	6	22	20	-2	-9%
	Herbal monographs, revised	2	1	0	5	0	6	5	-1	-17%
	EU herbal List entries	0	0	0	0	0	1	1	0	0%
	Working Parties	28	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	Workshops, Forum, Seminars, Infoday	31	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	Other meetings	48	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

Performance indicators

Performance indicators related to core business		Target 2023	Outcome at the end of Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
	Evaluation of declarations of interests of committee members and alternates prior to their participation in committee meetings.	100%	100%	100%	100%	100%	100%

[25] When after review of new data no change in monograph/LE is required, an addendum to the existing assessment report is published.

Pillar 2 – Public health activities

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Support the STAMP scientific advice pilot for repurposing established medicines	1.1 (ECP 1, ECP4)	Several prioritised established medicines are enlisted in the pilot	Delayed	Initiating of the SA process for the selected champions with a tailored process introducing further steps to support the champions to shape their briefing documents to kick-off the SA procedure (conduct of academia preparatory meetings, then few rounds of review of draft briefing documents, SA pre-submission meetings).
Provide parallel/joint EMA/HTA scientific advice, also in anticipation of and with the new HTA Regulation; Progress with the HTA consortium the objectives of and tools for post-licensing evidence generation; Launch a pilot for prospective evidence planning with payer's representative, to explore potential scope and feasibility; Strengthening guidance through scientific advice, also aiming at reinforcing the coordination with guidance on clinical trial conduct	1.2 (ECP 1)	Scientific evidence for marketing authorisation is serving different decision-makers	On track	Completion of scheduled requests for parallel Joint Scientific Consultation together with the EUnetHTA 21 consortium, under the framework of their service contract. Establishment of transitional arrangements for parallel consultation between September 23 and December 23, including publication / communication (see https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-parallel-ema/hta-body-htab-scientific-advice-interim-period_en.pdf)
Provide updated guidance for key regulatory outputs (assessment reports, labelling) to enhance usefulness for down-stream decision makers; Conduct product-specific reviews with	1.2 (ECP 1)	Stakeholder communication about regulatory assessment is enhanced	On track	EMA/EUnetHTA 21 bilateral with focus on ATMP assessment held Q1 2023 (see https://www.ema.europa.eu/en/documents/minutes/minutes-european-medicines-agency/european-network-health-technology-assessment-meeting-march-2023_en.pdf)

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
HTA assessors at time of licensing/launch for products of mutual interest and review the experience: perform debriefings of payers on regulatory outcomes				
Set up and operate a Quality Innovation Group to serve as platform for interactions with developers and academia aiming at identifying bottlenecks and facilitating innovative manufacturing technologies and methods; Deliver on International activities relating to Pharmaceutical Quality Knowledge Management System (PQKMS); Enable use of risk-based approaches to manufacturing and control strategies by implementing ICH Q12	3.1 (ECP 1) & 5.5	The implementation of novel manufacturing technologies and capacity enablers is facilitated	**On track**	- QIG group operationalised, listen-learn-focus group meeting held in March 2023, meeting report published in May 2023, product support initiated, 2nd LLFG meeting planned for Oct 2023. - ICMRA pilot initiated, 2 pilot procedures supported (PACMP assessment), lessons-learnt review conducted - ICH Q12 principles considered in Pharma strategy variations proposal, implementation pending Pharma strategies outcome
Deliver tailored engagement with academics and the community of ATMP developers Strengthen support to developers of ATMPs via the development of targeted training modules, and relevant	3.1 (ECP 1)	Increased support to the integration of scientific and technological progress in the development of ATMPs	**On track**	Application form and Q&A on EMA ATMP support pilot for academia published; information webinar for academic developers held Q1 2023, together with successful roll-out of the pilot at external events. Selection process for additional candidates initiated Q2-23, with a targeted decision by Sep-23.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
guidance, e.g., on the safety and efficacy follow-up of ATMPs				
Adaptation of GMP guidance, delivery of strategic priorities for harmonisation/convergence of practices and training with the Pharmaceutical Inspection Co-operation Scheme, extend EU-US mutual recognition agreement to other medicines, and implement recognition of FDA's third country inspections for products already in scope of US MRA	5.3	Reinforced responsibility for product quality by harmonising and reinforcing guidance	**On track**	Adaptation of GMP guidance: Several GMP guidance are under revision at IWG in collaboration with PIC/s for convergence at different stages of finalisation. Following the adoption of revised Annex 1 and in advance of entry into force in August 2023, training activities for the revised annex are being prepared in collaboration with PIC/s. The drafting group on Annex 11 and Chapter 4 (Documentation) are under way, working on a revision of the guidelines following a public consultation finalised at the beginning of 2023. Training in collaboration with PIC/s: IWG group on training has developed a strategy paper on training for EU GMP and GDP Inspectorates, this leverages ongoing collaboration with PIC/s on training. EU-US MRA: The US MRA extension to veterinary products has been finalised and applies as of 30 May 2023. There is also operational progress on the other 2 areas of the MRA expansion: on vaccines and plasma derived products the extension (delayed to July 2025) and on the recognition of third country inspections where an equivalency report has been prepared.
Develop guidance for MAH's to undertake a risk assessment of supply chain and have a 'resilience plan' including shortage prevention and management; Start a pilot for key medicines including training	5.4	Promoted supply chain resilience and reliability of supply of APIs and medicinal products	**On track**	Good practice guide for industry on the prevention of shortages discussed during the multi-stakeholder workshop on shortages held on 1 March 2023. Guidance finalized and published on 17 May 2023. As a follow up action the Joint HMA/EMA TF-AAM TWG1 will develop a shortage prevention and mitigation plan (SPMP) template.
Undertake pilots applying quantitative benefit-risk	6.2	Improved benefit/risk communication	**Delayed**	Pilot planned

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
assessment for initial marketing authorisations and select and pilot communication tools for quantitative benefit-risk assessment				
Draw lessons from COVID-19 evaluations by applying regulatory agility while maintaining high standards for quality, safety and efficacy with an aim to reduce assessment time; Develop simplifications/reductions of post-authorisation procedures; Increase sustainability and availability of expertise in the European Network by matching expertise with the existing product pipeline and ensuring adequately trained experts to perform the assessment; Invest in accelerated approval pathways to target unmet medical needs and where the Agency provides enhanced support for development under the Priority Medicines (PRIME) scheme	6.2 (ECP 2)	Regulatory innovations and flexibilities to accelerate the availability of medicines are identified, and where feasible, are progressed for implementation	**On track**	Analysis completed and proposal forwarded to the EC through concept papers in the context of the pharma strategy.
Promote more tailored supervision of API	5.2	Review Annex 15 of the GMP		The revision of Annex 15 to consider extending mandatory scope for API

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
manufacturers through assessment and inspection of their API development and risk management practices in technology transfer		guideline on Qualification and Validation to investigate potential extension of scope to APIs; Support PIC/s in the revision of the PICs aide memoire "Evaluating management of quality risks at GMP facilities" for reference to development of APIs and identification of impurities"		manufacturers (currently optional), plus other changes, has been agreed with PIC/s and a drafting group is due to be formed. The PIC/s aide memoire entitled "Assessment of quality risk management implementation" is currently being updated in light of the ICH Q9 R1 revision in 2023, and is expected to be finalised by end 2024.
Increase supervision of sites that produce medicinal products for a significant number of EEA markets or very significant numbers of products, with dedicated cooperative supervision between MS and strategic international partners	5.2	Improve the exchange of information among MRA and PIC/s partners through international programmes, such as the API International Programme and PICs and ICMRA initiatives on hybrid inspections, in order to increase collaboration on reliance and hybrid inspections as needed	**On track**	Discussion currently ongoing with API Programme partners on revising and enhancing the collaboration scheme for exchange of information on supervision of API manufacturing sites. The ICMRA Collaborative Pilot on hybrid inspections is progressing with 2 agreed and published documents concerning the protocol for the hybrid inspection and the expectations for a hybrid inspections. Two hybrid inspections currently being planned for 3Q23 and 1Q24.
Management of Medical Devices Expert Panels:		Experience gained to establish scientific advice	**On Track**	The pilot for advice from the expert panels to manufacturers on class III devices started in February 2023, with the first 6 selected applications in the pilot in the

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Conduct a pilot for providing scientific advice to medical device manufacturers and have lessons learnt to establish an effective scientific advice service Develop a training curriculum on medical devices for scientific staff with experience on medicinal products to increase medical device expertise at the Agency		for medical devices Reinforced competencies on medical devices		progress phase. The second phase of the pilot has started with a deadline for application on 15 September. Another tranche of at least 6 applications will be selected. end of the pilot targeted for Q2 2023. Drafting of the training curriculum is ongoing, the current training toolkit contains 18 training video sessions. Further development of the training curriculum to be expanded next year with specific training modules on CECP, PECP and SA processes.
Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual	3.2 (ECP 1)	Finalisation of ICH E6 (R3) GCP (principles and Annexes 1 and 2).	**On track**	Expert Working Group (EWG) comments reviewed and document updated for step 1 sign off for the principles and Annex 1 (substantive part of the document) Endorsement by the Members of the ICH Assembly under Step 2 and release for public consultation for principles and annex 1. Annex 2 (high level part of the document focusing on novel trial types and methodology) concept paper endorsed
Drive development and adoption of novel practices that facilitate clinical trial authorisation, GCP and HTA acceptance at EU and international level;	3.2 (ECP 1)	Finalisation of ICH E6 (R3) GCP (principles and Annexes 1 and 2).	**On track**	Expert Working Group (EWG) comments reviewed and document updated for step 1 sign off for the principles and Annex 1 (substantive part of the document) Endorsement by the Members of the ICH Assembly under Step 2 and release for public consultation for principles and annex 1. Annex 2 (high level part of the document focusing on novel trial types and methodology) concept paper endorsed
Promote the inclusion of neglected populations such as pregnant and lactating	3.2 (ECP 1)	Use the revision of ICH E8 and E6 to remove barriers and to	**On track**	Expert Working Group (EWG) comments reviewed and document updated for step 1

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
women, the elderly and those of diverse ethnicity		encourage the inclusion of neglected populations in clinical trials		sign off for the principles and Annex 1 (substantive part of the document) Endorsement by the Members of the ICH Assembly under Step 2 and release for public consultation for principles and annex 1. Annex 2 (high level part of the document focusing on novel trial types and methodology) concept paper endorsed

Veterinary Medicines Division

Pillar 1 – Product-related activities

2.1 Pre-authorisation activities

Workload indicators

Procedure	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2023 annual forecast Initial	Revised	Change	
Innovation Task Force briefing requests (Vet)	7	0	4	2	3	5	5	0	0%
Scientific advice requests received	3	18	11	14	12	23	20	-3	-13%
Requests for classification as limited market under article 4(29) and eligibility under article 23	9	11	-	-	-	20	20	0	0%

Performance indicators

Performance indicators related to core business	Target 2023	Outcome at the end of Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
Scientific advice procedures completed within set timeframes	100%	100%	100%	100%	100%	100%

2.2 Initial evaluation activities

Workload indicators

Procedure	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2023 annual forecast Initial	Revised	Change	
Initial evaluation applications	15	9	4	7	13	24	30	6	25%
New MRL applications	0	0	0	0	2	2	1	-1	-50%
MRL extension and modification applications	0	0	1	1	0	2	1	-1	-50%
MRL extrapolations	0	0	0	0	0	1	1	0	0%
Art 10, Biocides	0	0	0	0	0	0	0	0	n/a
Review of draft Codex MRLs[26]	0	0	0	3	0	0	0	0	n/a

[26] From 2022 includes also Codex extrapolations.

Performance indicators

Performance indicators related to core business	Target 2023	Outcome at the end of Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
Initial procedures completed within legal timeframes	100%	100%	100%	100%	100%	100%

2.3 Post-authorisation activities

Workload indicators

Procedure	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2023 annual forecast Initial	Revised	Change	
Variations requiring assessment, of which[27]	147	-	-	-	-	195	278	83	43%
Variations level 1	1	-	-	-	-	3	2	-1	-33%
Variations level 2	53	-	-	-	-	55	97	42	76%
Variations level 3	27	-	-	-	-	71	59	-12	-17%
Variations level 4	66	-	-	-	-	60	120	60	100%
Transfers of marketing authorisations	1	0	8	5	2	5	2	-3	-60%

Performance indicators

Performance indicators related to core business	Target 2023	Outcome at the end of Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
Post-authorisation applications evaluated within legal timeframes	100%	100%	100%	100%	100%	100%

[27] Variations requiring assessment: New indicators introduced following Regulation (EU) 2019/6. For an explanation of the different Variation Levels, please refer to the Explanatory note on general fees payable to the European Medicines Agency (https://www.ema.europa.eu/en/human-regulatory/overview/fees-payable-european-medicines-agency).

2.4 Arbitrations and referrals

Workload indicators

Procedure							2023 annual forecast			
		2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	Initial	Revised	Change	
	Arbitrations and Community referral procedures initiated	0	3	0	1	2	6	3	-3	-50%

Performance indicators

Performance indicators related to core business		Target 2023	Outcome at the end of				
			Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
	Referral procedures managed within the legal timelines	100%	100%	n/a[28]	100%	100%	100%

2.5 Pharmacovigilance activities

Workload indicators

Procedure							2023 annual forecast			
		2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	Initial	Revised	Change	
	Total AERs, of which:	70,899	91,939[29]	31,000	31,944	34,491	75,000	75,000	0	0%
	Adverse-event reports (AERs) for CAPs	38,950	57,211	15,000	14,195	16,057	37,500	37,500	0	0%
	Adverse-event reports (AERs) for NAPs	31,949	34,728	16,000	17,749	18,434	37,500	37,500	0	0%

[28] No procedures were concluded in the first half of 2022.
[29] Please note that a large backlog was received this year, hence the figures are higher than average for mid-year reporting.

Performance indicators

Performance indicators related to core business	Target 2023	Outcome at the end of Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
AERs for CAPs monitored within the established timelines	95%	n/a[30]	n/a[31]	95%	95%	96%

Pillar 2 – Public health activities

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Produce further guidance to implement the annex to the new veterinary legislation (Regulation (EU) 2019/6) that defines proportionate and future-proofed technical standards for novel veterinary therapies, particularly biologicals.	3.1 (ECP 1)	Guidance for novel therapies and biologicals developed	**On track**	The "Guideline on the development and data requirements of potency tests for veterinary cell-based therapy products and the relation to clinical efficacy" has been adopted by CVMP at its June 2023 meeting and published on the website. The draft "Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy" was adopted by CVMP in January 2023 and published for 4 months consultation.
Assess the possible impact of any change in approach to consumer exposure estimation on CVMP guidance, approach to MRL assessment and existing MRLs, and initiate the necessary	3.1 (ECP 1)	Analysis of impact and plan for future work on guidance and processes	**On track**	The impact analysis prepared by SWP-V was presented to CVMP in April 2023. The launch of the next phase of the consumer exposure project has been outlined with EC and EFSA. In view of the development of the future common calculation tool, draft comments on the PRIMo4 EFSA tool have been prepared.

[30] The new systems are not yet 100% up and running and several products have not yet been migrated, therefore, at the moment is not possible to calculate the percentage of AERs monitored by the established timeline.
[31] The new systems are not yet 100% up and running and several products have not yet been migrated, therefore, at the moment is not possible to calculate the percentage of AERs monitored by the established timeline.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
preparatory and follow-up work				
Implement in the veterinary medicines field the recommendations of the "Report on development of a harmonised approach to exposure assessment methodologies for residues from veterinary medicinal products, feed additives and pesticides in food of animal origin"	3.1 (ECP 1)	Harmonised methodology in place: legislation, guidelines and templates revised; exposure assessment tool made available to CVMP experts	**On track**	In 2023 development of the common calculation tool started and as a first step draft comments on the PRIMo4 EFSA tool have been prepared.
Together with stakeholders, develop new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database;	3.1 (ECP 1)	Guidance for surveillance and signal detection developed Enhanced communication with the network	**Delayed**	Development of guidance for surveillance and signal detection is ongoing as the P-SMEG pilot progresses. The pilot has been extended for another year (2024) and a final report with recommendations to be published is expected once the pilot has finished (estimated 2024-2025). An interim report on the progress of the pilot is planned by end of 2023.
Using data on the sales of veterinary products, develop methodology to collate, analyse and communicate information about the incidence of adverse reactions related to medicines' use.	3.1 (ECP 1)	Methodology established and guidance developed	**On track**	The form to collect the sales data has been established by the UPD product owners together with the EVVET product owners. The methodology for deriving the dose factor has been drafted and will be discussed and adopted by the PhVWP-V in Q3-Q4 2023.
Establish stakeholder expert groups for different food-	3.1 (ECP 1)	Expert group established with mandate and objectives	**On track**	Two Focus Groups meetings, one with poultry and another with aquaculture experts, have been planned for October and November 2023 respectively.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
producing species to access actual-use data of products in the field, both off and on label.				
Contribute to the evaluation of novel approaches to ERA, and the EC considerations on the feasibility of establishing active substance monographs for all substances, including legacy active substances for which there is limited environmental information, providing input as required.	3 (additional RSS recommendation)	Support EC in the monographs feasibility study	**Delayed**	A pilot study is being performed at the request of the EC.
Increase cooperation in the field of ERA with European agencies, particularly ECHA, EFSA and EEA, and establish cooperation with international institutions, academic organisations and relevant initiatives.	3 (additional RSS recommendation)	Establish ERA framework with EU and international partners Harmonised approach on ERA assessment	**On track**	Ad hoc basis cooperation with other Agencies and academia has started. In 2023, the ERAWP/EMA started an ongoing cooperation with EFSA concerning the elaboration of an approach for the environmental risk assessment of veterinary medicinal products/feed additives intended for use in aquaculture.
Provide scientific support to the European Commission and the EU network to ensure that a "One	3 (additional RSS recommendation)	Support to EC provided 'One Health' approach for ERA implemented	**On track**	EMA provides input to EC/other Agencies when requested on ERA "One Health" topics. No specific request was received in the first 6 months of 2023.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Health" approach is applied to ERA.				
Expand current data-collection system to include other antimicrobials	4.1 (ECP 1)	Collection of data expanded to include all antimicrobials	**On track**	Development of the ASU IT System is ongoing, and the following milestones have been achieved: the user interfaces of ASU and UPD have been merged and aligned, functionality to submit data on use of human antimicrobial medicinal products, functionality to submit TRACES animal population data, Power BI reports to validate submitted antimicrobial use and animal population data and completion of RMS and SMS mapping, among others. Furthermore, the ASU test Platform was opened to testers from all Member States in January 2023 and has since undergone 3 more releases with new functionalities being made available for testers each time.
Establish contributions to JIACRA under CVMP guidance and develop new processes that maintain Member State input and ensure EMA oversight.	4.1 (ECP 1)	Establish governance for JIACRA report under EMA and CVMP	**On track**	The mandate, objectives and rules of procedure for the European Sales and Use of Veterinary Antimicrobials Working Group (ESUAvet Working Group) have been adopted by CVMP in November 2022. A call for nomination of experts was circulated in Q1 2023, the group started its operations in June 2023.
Implement use data collection by animal species	4.1	Collection of data on the use of antimicrobials per animal species and animal categories as foreseen in Article 15 of the Commission Delegated Regulation (EU) 2021/578	**On track**	The development of the ASU IT system to collect antimicrobial sales and use data is ongoing. Simultaneously, the design and development of Power BI reports to validate and analyse the future use data are also underway. These Power BI reports will serve to assist EMA in the preparation of the first report including both sales and use data.
Communicate effectively on consumption data	4.1	The outline of the ESVAC report reviewed to improve communication Group of experts to define the outline of	**On track**	The call for data was open in February 2023, and the reference population correction unit (PCU) was made available in April 2023. Protocols and support were provided to countries submitting sales and PCU data (all datasets received).

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		the volumes of sales and use of antimicrobials (Article 17 of the Commission Delegated Regulation (EU) 2021/578)		Data quality control activities are ongoing and additional support is being provided to countries to validate their dataset. Drafting of the report is planned to commence in August. In September, the first and 2nd draft of the report will be sent for review to the Sales Expert advisory group and the ESVAC Network. Publication date is estimated for third week of November 2023.
Adjust the methodology for analysis of antimicrobial data, by considering approaches developed internationally.	4.1 (ECP 1)	Analyse international approaches and integrate where possible in methodology	**On track**	A survey was sent in Q4 2022 to contacts of the ESVAC network (as representatives of MSs) regarding national animal population statistics. The results of the survey were analysed in Q1-Q2 of 2023 and a draft guideline on denominators and indicators was adopted by CVMP in June 2023 and published for 1 month consultation. The guideline is expected to be finalised and published in Q4 2023.
Define requirements for harmonised sales and use data collection for antimicrobial medicinal products used in animals.	4.1 (ECP 1)	Define new requirements and develop guidance on new requirements based on Commission Delegated Regulation (EU) 2021/578 and Commission Implementing Regulation (EU) 2022/209	**On track**	The ASU Protocols (for sales and use) have been published on 9 January 2023 on EMA website. The publication of these documents is in line with Article 8 of the Commission Delegated Regulation (EU) 2021/578. They contain technical requirements that Members States need in order to collect and report to the Agency data on the volume of sales and on the use of antimicrobial medicinal products in animals. The documents were developed by EMA together with experts from the 2022 ASU Product Owners group and in consultation with the ESVAC Network. Further training materials (including webinars) to reflect the latest ASU developments are being developed in the second half of 2023.
Inform policy decisions via enhanced cooperation with European institutions (EFSA,	4.1 (ECP 1)	Policy decisions based on the outputs from JIACRA reports	**On track**	The 4th JIACRA report is under drafting and is planned to be finalised by the end of 2023. The report will be published on all the three Agencies' websites. This report will also include a simplified

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
ECDC) to collate data on antimicrobial use with information on AMR in animals, humans and food.				summary for policymakers to assist with implementation.
Participate in international initiatives to reduce the risk of AMR.	4.1 (ECP 1)	Actively participating in international fora	**On track**	In Q1-Q2 2023, EMA veterinary colleagues actively participated in the following international fora: - AGES/MVN-Workshop on Benchmarking of veterinary antimicrobial use data – digitalization, regulation, best practice exchange, June 2023; - Participation in the TATFAR video conference, March 2023; - Participation in four TATFAR working group meetings April – June 2023; - Participation in two EU coordination meetings in April and May, preparing for the TATFAR face-to-face conference in Luxembourg in November 2023; - OneHealth EJP conference "Collaborating to face future One Health challenges in Europe", June 2023; - WOAH AMR WG meeting March 2023, and four subgroup meetings to revise chapter 6.10 of the Terrestrial Animal Health Code on prudent and responsible use of antimicrobials; - Evaluation of the PAHO/European Union Action "Working together to fight antimicrobial resistance (AMR)".
Update existing guidelines, and initiate new guidance concerning development of antimicrobials veterinary medicinal products	4.3 (ECP 3)	Develop and revise relevant guidance	**On track**	The Efficacy working party started the revision of the "Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances" and the "Guideline on the conduct of efficacy studies for intramammary products for use in cattle". Both guidelines will be reviewed by the Antimicrobial working party before being presented to CVMP for adoption.
Finalise the CVMP reflection paper on antimicrobial	4.3 (ECP 3)	Reflection paper finalised and published	**Delayed**	The reflection paper was finalised and published in February 2021.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
resistance in the environment, in the light of comments received. Invite CHMP to derive conclusions for human medicines based on CVMP reflection paper.		Review of novel risk assessment methodologies for AMR in the environment		No action has been initiated for the 2nd deliverable yet.
Foster development of POC diagnostics for veterinary use	4.2	Review ability and characteristics of diagnostic tests	**On track**	The concept paper on the development of the reflection paper on Diagnostic Tests was adopted by CVMP at its meeting in July 2023 and released for public consultation until 31 October 2023.
Prioritise and trigger referral procedures and/ or support MS in activities to review available data on emerging AMR risks, clinical effect, PK/PD, dose regimens	4.2	Support CVMP on VMP referrals and act on the recommendations from the Reflection paper on dose review and adjustment of established veterinary antibiotics in the context of SPC harmonisation	**On track**	The Antimicrobials Dose Review and Adjustment group (ADRA working group) was established with members from CVMP, AWP and CMDv. A questionnaire is under development to gain information from stakeholders in respect of Recommendation #3 from the CVMP 'PPHOVA' reflection paper. The questionnaire will be sent to CVMP for its agreement in October. Legal and regulatory aspects for the implementation of the dose review and adjustment will be discussed in Q3-Q4 2023.
Develop a regulatory approach/framework to promote alternatives to conventional antimicrobials and novel paradigms.	4.3 (ECP 3)	Framework developed Communication with stakeholders	**On track**	This activity has been further discussed at the CVMP Veterinary Domain and an internal plan has been established. The topic will be also discussed at the Informal CVMP meeting to be held in Spain in Q3 2023.
Communicate on available tools like AMEG categorisation to stakeholders to ensure proper implementation to support responsible AM use	4.3 (EPC 3)	Preparation and delivery of publications, infographics, presentations at conferences, training to network (e.g., EU NTC)	**On track**	A scientific article on "The use of aminopenicillins in animals within the EU, emergence of resistance in bacteria of animal and human origin and its possible impact on animal and human health" was published in the Journal of Antimicrobial Chemotherapy in May. This article is based on the CVMP's reflection paper.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				The authors are AWP members and EMA staff members
Update existing guidelines, and initiate new guidance concerning development of antimicrobials veterinary medicinal products	4.3 (ECP 3)	Develop and revise relevant guidance	**On track**	The Efficacy working party started the revision of the "Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances" and the "Guideline on the conduct of efficacy studies for intramammary products for use in cattle". Both guidelines will be reviewed by the Antimicrobial working party before being presented to CVMP for adoption.
Finalise the CVMP reflection paper on antimicrobial resistance in the environment in the light of comments received. Invite CHMP to derive conclusions for human medicines based on CVMP reflection paper	4.3 (ECP 3)	Reflection paper finalised and published Review of novel risk assessment methodologies for AMR in the environment	**Delayed**	The reflection paper was finalised and published in February 2021. No action has been initiated for the 2nd deliverable yet.
Develop a regulatory approach/framework to promote alternatives to conventional antimicrobials and novel paradigms;	4.3 (ECP 3)	Reflection paper developed Communication with stakeholders	**On track**	This activity has been further discussed at the CVMP Veterinary Domain and an internal plan has been established. The topic will be also discussed at the Informal CVMP meeting to be held in Spain in Q3 2023.
Enhance the promotion of responsible use of antimicrobials via updated and/or new regulatory guidance and scientific opinion.	4.3 (ECP 3)	Guidance development Communication with stakeholders	**On track**	A Q&A document on the inclusion of clinical breakpoints in the SPC for generic antimicrobial VMPs was finalised and published in June 2023. A concept paper on Diagnostic Tests was adopted by CVMP at its meeting in July 2023 and released for public consultation until 31 October 2023.
Provide scientific and regulatory support to encourage	4.3 (ECP 3)	Guidance development on ATAm	**On track**	A workshop on bacteriophages took place on 11 May 2023. Information on the workshop, including links to presentations, is available from

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
development of veterinary antimicrobials and alternatives, to fill therapeutic gaps, without adversely impacting public health.				https://www.ema.europa.eu/en/events/focus-group-meeting-bacteriophages-veterinary-medicines. The draft guideline will now be revised to take into account the comments received during the public consultation.
Work in partnership with EC, other EU Agencies and regulators and international bodies to promote the responsible use of antimicrobials and their alternatives.	4.3 (ECP 3)	Cooperation at EU and International level for events Common approach agreed	**On track**	Under TATFAR Action 1.1, a paper is being developed on reporting of sales and use of antimicrobials per animal species. EMA is collaborating with EFSA, ECHA, ECDC and EEA on a scientific opinion on the impact of the use of azole fungicides on resistance in Aspergillus. Good progress is being made on term of reference 1, 2 and 3.
Include AMR as a regular topic at meetings with HMA and veterinary stakeholders	4.5	Actively propose AMR topics for HMA and stakeholders' meetings	**On track**	A joint HMA/EMA AMR workshop is planned for 18-19 October to be held under the Spanish Presidency of the EU Council.
Acknowledge that different benefit-risk approaches are required for assessment of specific vaccine types (e.g., vaccines for zoonotic diseases, limited markets, exceptional circumstances).	4 (additional RSS recommendation)	Identify different benefit-risk approaches per type of vaccines Guidance on benefit-risk	**Delayed**	Following comments from the EC, the work on these guidelines has restarted in 2023. The guidelines on quality requirements for biological VMPs and the guideline on safety and efficacy requirements for IVMPs were discussed by CVMP at its July 2023 meeting and are expected to be adopted for release for public consultation at the September 2023 meeting.
Participate actively in international initiatives that aim to develop strategies to combat antiparasitic resistance and to establish best	4 (additional RSS recommendation)	Improve interaction with International organisations Best practices embedded in guidance	**On track**	The final meeting of the WOAH Electronic Expert Group on Antiparasitic Resistance was held on 17 April 2023. The WOAH will reflect on the new topics to be addressed and new groups to be constituted, depending on the expertise needed.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
practices on the use of veterinary antiparasitic medicines.				
Promote responsible use of antiparasitics in the EU.	4 (additional RSS recommendation)	Awareness events and enhanced dissemination of information	**On track**	Revised VICH guidelines on efficacy of anthelmintics: the EWP/CVMP have provided a first set of responses to the comments received from stakeholders during public consultation. Reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations (which also addresses reduction in the antiparasitic resistance): comments from stakeholders on the antiparasitic resistance section have been addressed and the section has been revised accordingly. Guideline for the demonstration of efficacy of ectoparasiticides: a concept paper for the revision of the guideline was adopted by the CVMP at its July 2023 meeting and published for a 3-months period of public consultation.
Prepare for and implement Veterinary Medicines Regulation	6.1	Prioritised guidance, processes and IT systems in place in time for implementation	**On track**	The Veterinary Medicines Regulation is applicable since 28 January 2022. Procedures have been aligned with the changed requirements. The development of required IT system is either completed (UPD, EVV, MWD) or on track to be completed in 2023 (ASU - see related activities); all projects have been transferred to the Agency value stream model in 2022 (see pillar III). Recommendation to EC: - The "List of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6))" has been adopted by CVMP in June 2023.
Promote systematic application of structured benefit-risk methodology	6.2 (ECP 2)	Analysis of current methodologies, development of harmonised	**On track**	A drafting group of the CVMP is working on a revision of the "CVMP recommendation on the evaluation of the benefit-risk balance", to improve the current benefit-risk methodology and

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
and quality assurance systems in the approach to assessment and consistency of decision-making.		approach and guidance		align with the Regulation (EU) 2019/6 provisions. A concept paper for consultation was published in Q4 2021 and comments received have been reviewed by the drafting group. A draft guideline has been discussed at the informal CVMP Presidency meeting in October 2022, the draft is expected to be released for consultation in Q4 2023 and finalised by Q2-Q3 2024. The guideline will need to be aligned with the EC Guidance to Applicants.
Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders, especially for novel technologies.	6.2 (ECP 2)	Analysis of current methodologies, development of harmonised approach and guidance Enhanced communication with stakeholders	**On track**	In addition to the work of the NTWP, the list of EMA/CVMP stakeholders has been revised and interaction between CVMP (and its working parties) and stakeholders were discussed. The EMA Veterinary Medicines Info Day was held in February 2023, a Focus group meeting on bacteriophages was held in May 2023, the CVMP Interested Parties Meeting was held in June 2023. In the second half of 2023, the Veterinary Awareness day meeting and the 3rd Veterinary Big data stakeholder Forum are planned.
Coordinate and implement the Veterinary Big Data Strategy by analysing the landscape of veterinary data, engaging stakeholders, and providing training	2 (ECP 2)	Compilation of a Veterinary data sources catalogue and metadata analysis Define and implement the Big Data Strategy workplan Hold events, workshops, and training to engage and communicate with stakeholders	**On track**	A research study to develop a data sources catalogue was initiated in Q1 2023.
Contribution to Chemical Strategy for Sustainability, particularly on the	ECP 3	EMA data and legal requirements to be provided in the frame of the EU	**Delayed**	EMA is requested by the EC (DG ENV and DG SANTE) to provide input to the relevant legislative drafts and other types of documents, as well as to make a

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
'One substance one assessment' (1S1A) initiative, including the establishment of the EU Common Data Platform for Chemicals (EU-CDPC). Consequently, implement the initiative as/if required.		policy-making process Implementation of the initiative as/if required		resource estimation for the activities envisaged.

Task forces

Digital Business Transformation (TDT)

Pillar 2 – Public health activities

Workload indicators

Procedure		2023 annual forecast								
		2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	Initial	Revised	Change	
	New scientific, regulatory and network portfolio curricula developed	0	0	0	3	1	2	1	-1	-50%
	Number of training events advertised to the EU Network	49	36	36	20	27	60	60	0	0%
	Number of reimbursed training events to the EU Network	0[32]	1	0	1	7	12	5	-7	-58%
	Number of NCAs that have opened their training for inclusion in EU NTC learning management system	0[33]	7	10	6	6	10	6	-4	-40%
	Number of Epics[34]	25	-	-	-	-	34	34	0	0%

[32] Events taking place in Q3 and Q4 2023.
[33] Majority of courses in 2023 have been organised by EMA with involvement of NCA speakers. There are 3 face to face courses planned for Q3–Q4 2023, hosted by NCAs.
[34] New indicator introduced in the context of the EMA Agile Transformation. Number of Epics completed or ongoing.

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Develop a digital skills framework for EMA and lead on digital capability building		Validated Digital Skills framework for EMA Creation of introductory training on topics in the digital skills framework with links to further learning on each topic to enable deeper skill development Creation of a platform to act as entry point to the introductory training content Deliver agency-wide awareness campaign to engage staff and create engagement through gamification and events	**On track**	Continuation of development and launch of new modules within the Digital Skills Framework of the Digital Academy, including on Robotic Process Automation (RPA), Artificial Intelligence (AI) and Lean. These modules complement existing ones on Digital Mindset and Digital Wellbeing, with the intention to expand a set of these to the EMRN by making the first modules available to NCAs in Q3 /Q4 2023, through the EU NTC. Total number of module views: 528 Total number of collections views: 197
Establish a digital innovation lab to explore, pilot and develop solutions and processes, across the drug regulation spectrum, that leverage novel digital technology and artificial intelligence to support increase in efficiency and regulatory decision-making.	2.2 (ECP 2)	Build pragmatic and innovative solutions for new and existing EMA business needs using data analytics and experimentation with new emerging technologies	**On track**	The Agency has continued to deliver on experimentation and automation through its Analytics Centre of Excellence (ACE) and Digital Innovation Lab (DigiLab), including: - Controlled experimentation with OpenAI and ChatGPT technology to explore whether this technology could be implemented at EMA - Different initiative from the EXB request on automation - Launch of the Agency's first virtual reality powered training, in the area of cybersecurity awareness - Development of an EMA QR code generator to eliminate paper waste and enhance engagement - Launch of new automation tools to reduce manual effort across a number

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				of business areas such as the new Certificate Processing System to enable the generation of medicine certificates faster and in a process 100% digital - Experimentation with new technologies such as Power Platforms to explore areas where it can be implemented - Change management bootcamp pilot
Establish an EU collaboration on AI with other Agencies in the EU Network.	2.2 (ECP 2)	Develop and promote AI community Increase synergies, re-use, and efficiency Share knowledge and increase maturity Collaborate for the implementation of common AI initiatives and projects	**On track**	This year the community has started its works in Q2 2023. During the beginning of its activity, the community has been focusing on organising different session for the second half of the year. Those sessions are focused on how the community should work to get tangible outcomes from the collaboration in the network, defining common projects or sharing AI tools already implemented in each agency. During the second half of the year, the Community will organise working sessions (online and in person), EU AI talks with specific topics and another EU AI talk open to the public.
Develop capacity and expertise across the regulatory network through curriculum development and knowledge-sharing initiatives on data science, digital technologies and artificial intelligence-related solutions, products and endpoints, and their applications in the regulatory system	2.3	Develop a future state learning delivery model and landscape that serves new and existing audiences, in co-creation with the EU-NTC	**On track**	Ongoing work on the development of training modules in the area of Data science with selected training provider, further, to tender for services to develop a big data curriculum. Implementation and roll out (in the context of Annual planning of training with Curriculum leads) of a Learning Design and Development Toolkit to support Course organisers and Curriculum developers. Continuation of work on development of an EU NTC Engagement Portal to provide a single point of access to the EU NTC LMS containing the EU NTC training courses. On target to have

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				the right technology selected by Q3 2023 and start development. Improvements to the EU NTC Learning Management System (LMS) / Automation of user management processes: Self-service password reset implemented. On track to eventually integrate LMS with EMA account – allowing users to have same login details for LMS as for other EMA systems EU NTC webpage published on EMA's corporate website. Process for remuneration of NCAs for the development and delivery of training through addendum to cooperation agreement between EMA and NCAs adopted by the Management Board in June
Develop the integrated evaluation pathways in cooperation with medical device authorities and notified bodies Strengthen coordination between relevant actors for the assessment of combinations of medicinal products with medical devices and of companion diagnostics	3.4	Design and implement an integrated regulatory pathway for the assessment of medical devices and IVDs intended to be used with medicinal products or support their development Ensure an overall more efficient and consolidated input in the development and management of such products	**On track**	A first draft of the integrated pathways roadmap document was developed. Useful comments were received for implementation in the update of the roadmap document that will be then circulated as second draft. Planning of workshops and drafting of relevant guidance documents have been considered in the roadmap document.
Identify and enable access to the best expertise across Europe and internationally	3.4	Map all current working groups (i.e., at EMA, HMA/CAMD, NCA, EC) working on medical devices and in vitro diagnostic where there is a	**On track**	The planning of a mapping exercise of the currently available medical device expertise (including NCAs) has been described in the first draft of the integrated pathways roadmap document. Furthermore, in March 2023 the Medical Devices Implementation

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		connection to medicinal products and identify common tasks/topics. Establish a more formal link between the current groups and the experts at the NCA's facilitating systematic interaction.		Group (MDIG) has been established in EMA. MDIG is a cross-organisational group of EMA experts formed for the coordination of EMA's implementation activities according to MDR/IVDR provisions as well as for discussion of and information / knowledge sharing across the Agency on EMA's MDR/IVDR implementation activities including also expert panel related activities.

Data Analytics and Methods (TDA)

Pillar 2 – Public health activities

Workload indicators

Procedure		2023 annual forecast								
		2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	Initial	Revised	Change	
	Number of MLM ICSRs created	4,796	-	-	-	-	9,000	9,000	0	0%
	Number of healthcare data sets to which EMA access and therefore its committees can integrate analyses into assessments	6	-	-	-	-	8	6	-2	-25%

Performance indicators

Performance indicators related to core business		Target 2023	Outcome at the end of				
			Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
	Number of individual reaction-monitoring reports supplied to the Member States according to the agreed timelines and data quality indicators	95%	100%	-	-	-	-

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Deliver a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis Real World Interrogation Network -DARWIN EU) Build a business case with stakeholders and secure funding to establish and maintain a secure EU data platform that supports better decision-making on medicines, by informing those decisions with robust evidence from healthcare	2.1 (ECP 2)	DARWIN EU Coordination Centre established EU regulatory network routine access to RWE established DARWIN EU pilot with EHDS initiated Processes for EMA oversight of DARWIN EU activities in place, including review of all deliverables and DARWIN EU outputs	**On track**	Since February 2023, phase II has been launched and delivery is on target according to contract and milestone plan (8 studies on-going: 5 OTS and 3 complex). Selection of data partners for phase II (n=10 to get 20 in total by the end of 2023): 66 expressions of interest received at the end of the first call for expression of interest (by end of April); mix of EU and non-EU and healthcare settings; 5 are currently under on-boarding phase; we expect some additional information on 6 others before possibly proceeding to the next step. Consultation of industry on catalogue of standard data analyses done in June. Implementation of the comments, if relevant, during Q3.
Build capacity and capability to receive, store, manage, and analyse raw data	2.1 (ECP 2)	Determine the regulatory and public health benefit of analysis of raw data.	**Delayed**	Reached/secured 4 out of 10 pilot procedures in the raw data pilot by Q2 2023. Raw data submitted for 3/4 included procedures in the raw data pilot by Q2 2023. Network community on 'Raw Data' established in Q1 2023. First communication activity with this community took place in February 2023.
Data standardisation in medicines regulation across the lifecycle of a medicine: Develop a data standardisation strategy, drive standardisation of	2.1 (ECP 2)	Enable effective interrogation of scientific information across the lifecycle of medicines and for multiple types of users within and across regulatory procedures. Drive	**On track**	'Clinical Trial Navigator: Significant progress on PoC of ingesting data using FHIR resources and developing a User Interface to search and display content of clinical trial protocols, i.e., created a search tool that tenders to different user needs and will allow users to search within

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
regulatory submissions across the lifecycle of a medicine, search the unstructured data stored at the Agency, collaborate with worldwide standards data organisations		up the quality of data submitted to EMA through the use of standards		and display specific fields to obtain fast access to summarised information across trial protocols; allows users to compare different protocol versions (amendments). Onboarded external FHIR expert to support the extension of FHIR resources. Onboarded external consultants. Developed change management plan and aligned communication plan with other projects. Initiated stakeholder analysis. Presentation to EMA Data Board and initiated next steps for CDISC membership. Scientific Explorer: Concluded the tool PoC in Q1 with excellent engagement and collaboration of many business units across the Agency resulting in better understanding of business needs across EMA, with limited business results of the Machine Learning capabilities of the tool and positive feedback on other areas like document annotation. Plan next steps to extend the internal PoC using pattern matching capabilities in Q1. Epic presented and approved by the Portfolio Board in Q1. Business consultancy (Change management) onboarded in Q2. Aligned with ACE for the delivery approach for Discover and Scientific Explorer on the target architecture and future approach.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Completed UX concept and UI design. Defined data design, combining unstructured and structured data. Mapped data to IRIS. Completed solution architecture design. DEV/TEST environment provisioned and validated. Initiated ingestion mechanism of scientific advice letters and strategy briefing documents. Use of large language processing models (LLMs) in extracting complex terms e.g., primary endpoint. Data Governance: Mandate of the EU NDB and BDSG finalised & adopted Q2 2023 by EMA MB and HMA for publication. BDSG mandate available on EMA website and a new page to be created Q3 for information on the NDB, including the mandate. EMA Data Board meeting monthly.
Strengthen EU Network on methodology and RWE in committee advice and assessment Develop Big Data learning initiative where submissions on complex methodology and RWE are forecast and tracked, work with international partners on RWE to develop roadmap and guidance	2.2 (ECP 2, ECP 4)	Embed identification of submissions with complex methodological and RWE aspects into EMA forecast and tracking processes Establish a systematic lessons-learnt process for challenging methodological regulatory procedures	**On track**	First draft of Reflection Paper on RWE completed. MWP endorsement of Data Quality Framework (included in the MWP workplan). Methodology ESEC set up and populated, including identifying specific expertise and interest in RWE and AI.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		Fully integrate RWE and AI as key expertise in the methodology domain Start a European Specialised Expert Community (ESEC) Prioritise RWE topics that need guidance development		
EMA business processes to identify the need for RWE and to deliver that evidence into the regulatory decision making	2.4 (ECP 2)	Process established to identify the committees' needs and feed RWE in their decision-making processes for prioritising analytical requests established Processes for the drafting and review of study protocols and study reports Processes for choice of analytical strategy depending on research question and committees' needs (in-house analysis, use of framework contracts, feeding into DARWIN EU) Users' training on utilisation of IHD and analytical templates	**On track**	Since 2022, the recently published report on the RWD studies performed by the EMA to support regulatory decision making has shown that 1 pilot study has been done for CAT, 3 for PDCO, 5 for COMP, 1 for CHMP, and 3 for SAWP (more are on-going). IHD trainings are provided as needed. Processes for interaction with different committees are in place and regularly adapted (when needed) to ensure needs are fulfilled.
Support EMA operations and Committees with advice and epidemiological expertise on:		Guideline on evidentiary standards, methodological aspects, formats, and contents of	**On track**	Participation and contribution to SAWP, pre-submission, PRIME, and other relevant meetings where RWE is addressed.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
- methods for RWE collection, analysis, and reporting in the fields of health care and medicinal products evaluation - portfolio of real-world data sources existing in Europe and elsewhere to answer research questions -identification of research questions appropriate for further investigation and their translation into study protocols - evidentiary standards and formats and contents of RWE submitted by MAAs/MAHs - lessons learnt from review of RWE submitted by MAAs/MAHs - literature review of published articles with RWE on utilisation, safety, and effectiveness of medicinal products		RWE used for regulatory purposes Templates and checklists for feasibility analyses on appropriateness of RWE data sources used in regulatory decision-making (e.g., registries and electronic health care records) Participation and contribution to SAWP, pre-submission, PRIME, and other relevant meetings where RWE is addressed		Tracking table of SAWP, pre-submission and PRIME meetings is up to date. Screening of the ESPEDITE report received once a month to identify new initial applications that include keywords related to RWD, review and feedback to CHMP members with epidemiology expertise for preparation of the CHMP plenaries. Collaboration with eSubmission team to include tick boxes related to RWD in the eSubmission form so applications including such data are automatically flagged to us for further screening.
To pilot the use of AI to increase efficiency to extract information from EMA documents and real-world data, including development of good practices and training		Report on lessons learnt from the test Paper on methods developed and published Application to extract and communicate data extracted from SmPCs, other documents, and RWD	**On track**	Draft reflection paper ready in June for adoption adopted by CHMP and CVMP. Health data lab activities (AI for health data) initiated in June; pilots will start in Q3/4 2023 AI glossary concluded (https://analytics.emea.eu.int/ai-glossary) Application to extract ADRs from SmPCs tested on 1000+ documents

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		Reflection paper on gaps in guidance on use of AI and on how to validate AI-based algorithms in healthcare and medicine AI glossary		
Establishment of a monitoring system in the post-authorisation safety and effectiveness monitoring of vaccines		Core infrastructure for prioritisation, launch and supervision of vaccine studies Establish and operate working arrangements with ECDC Identification of EU networks with capacity to perform representative and reliable studies Identification of the need for studies Management of public calls and monitoring of funded studies Results of studies that are publicly available and made available to EU decision-makers	**On track**	Steering Group meets monthly and drives strategic aspects and needs for studies Secretariat meets biweekly and oversees operational aspects of the platform, with support of the Steering Group Joint advisory board (IVMAB) convened its first meeting of 2023 (virtual, June 2023); the second meeting (F2F, hosted by ECDC in Sept 2023) is in preparation A survey to the IVMAB allowed to finalise the VMP research agenda The EMA work plan to address key topics of the research agenda has been developed, with one new Framework Contract effectiveness tender awarded in May, and additional studies using the FWC or DARWIN EU in preparation. One publication with EMA co-authors accepted (BMJ)
Enable data discoverability; the final output will be to interlinked public catalogues - one of EU RW data sources, the other of EU observational studies. This will be built on the RW metadata list and replace the ENCePP	2.1 (ECP 2)	MINERVA final study report (EMA/2017/09/PE/16) Design and delivery of a Catalogue of Observational Studies Design and delivery of a Catalogue of Real-World Data sources	**On track**	Data Quality Framework (DQF) - addressed comments arising from public consultation, consulted stakeholders. Drafting of DQF for RWD (Real-World Data) kicked-off. Conducted in-depth stakeholder consultation on the drafting of a specific RWD use-case. Collected metadata for a further 65 data sources.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
resources database and EU PAS register Identify key meta-data for regulatory decision-making on the choice of data source, strengthen the current ENCePP resources database to signpost to the most appropriate data, and promote the use of the FAIR principles (Findable, Accessible, Interoperable and Reusable)				Delivered several features of the catalogues, following an Agile methodology for delivery. On track for delivery of the catalogues by end of year.
Resolve the current difficulties that PhV Office and HCD teams are experiencing with the tools used for Signal Detection and ICSR data analysis, and future-proof EV based on data security SPOR and cloud technology		Replacement of the current EV analytics system and integration with EMA systems (SPOR) to increase performance, security, usability and reduce maintenance costs	**Delayed**	Financial terms agreed with the software vendor Preliminary DPIA prepared in collaboration with DPO Project artifacts preparatory to the procurement phase finalised Engagement with Industry for feedback on current system Transition to Value Stream completed
Implement the Clinical Trials Safety Monitoring Implementing regulation		Deliver IT tools and processes described in Art. 11 of the IR of the Clinical Trials Regulation	**On track**	Prioritisation of functional requirements completed Follow up meeting is planned
Collaborate with international initiatives on Big Data Support the development of guidelines at international multilateral fora, a data standardisation strategy delivered through standards		Standardise clinical study protocols and reports and enable data exchange	**On track**	Progressed on development of logical model for clinical trial protocols and presented to ICH M11 in June 2023 Drafted and committed to timelines of finalisation of logical model for clinical trial protocols in collaboration with HL7 Vulcan Accelerator and CDISC Launched call for external SME to support work of ICH M11

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
bodies, and bilateral collaboration and sharing of best practice with international partners				Initiated stakeholder mapping and change management plan Contribution to the standardisation of regulatory submissions and preparation of a core clinical trial template: Public consultation completed on 27 February 2023 In the EU, 1300, 60 and 150 comments were collected respectively for the template, guideline and technical specifications Adjudication of comments has started and is on track Since March 2023, the EWG includes an EU topic lead and an EU deputy topic lead, and the regulatory chair is from the EU/EMA Meetings for the EWG have been attended by EU team on a weekly basis Workplan updated in April 2023
Support an initiative with the EC and HMA to transform CT in Europe, including modernisation of CT design and good clinical practice Strengthen EU-level governance of CT; leverage data on CT to support regulatory decision-making		Establish EMA support to ACT EU Engage external stakeholders and lay foundations for a multi-stakeholder platform Develop business case for CT data analytics Establish a roadmap for methodologies guidance Adopt a plan for GCP modernisation implementation Deliver CT training curriculum with links to universities and SMEs	**On track**	ACT EU governance bodies established in 2022, with the ACT EU steering group, and trilateral programme board. ACT EU has continued to promote increased information sharing on clinical trials, with the following activities taking place: - launch of Public consultation on CTIS transparency rules with the aim to stimulate the discussion on balancing clinical trial transparency with confidentiality requirements while simplifying user experience and reducing the risk of data breaches; - publication of interim guidance on protection of CCI and PPD while using CTIS.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		Develop RACI matrix for network governance groups Launch a scheme to support large multinational CTs One stop-shop for academic sponsors		The priority action on methodologies has agreed a set of deliverables and has communicated on these to stakeholders at the multi-stakeholder platform kick-off meeting in June. Stakeholders had the opportunity to provide feedback on the most relevant trends in clinical trial methodology for which regulatory guidance is needed. Continue to monitor CTR implementation, with regular publication on monthly basis of KPI reports. Multistakeholder platform kick-off meeting held in June 2023. Clinical trials data analytics internal strategy agreed, and multi-stakeholder event planned for January 2024. GCP modernisation underway with multi-stakeholder workshop on the ICH E6 R3 public consultation.
Go live of CTIS and CTR: Training and operations and IT project	2.2	Deliver CTIS to support the Clinical trial regulation, continue to provide training of users, change management and deliver IT project by providing new functionality	**On track**	Operations (change management and communication) Updated CTIS sponsor handbook (Last update in April 2023) With the mandatory use of CTIS for initial trials on 31.1.2023, continuously measured and improved CTIS' performance. Daily business meetings to prioritise Service desk tickets, continuously answering CTIS Level 3 tickets Implemented a measurement tool for tracking the number of ongoing Service desk tickets, and their status

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				2 CTIS webinars/Public Info events (January and July 2023) 6 CTIS walk-in clinics 3 CTIS Bitesize talks 2 CTIS Stakeholder Fora (March, April 2023) Sponsor End-user trainings, organised for EMA by DIA - 3 sessions Vanguard (data fixes, RMP, Transparency) Continuous follow up of the RMP: Risk Mitigation Plan Published the redaction Guideline to protect CCI and PPD After a public consultation, revisited the transparency rules for the new public portal Provided several hundreds of data fixes on the CTIS data base to deblock particular trials in the submission and assessment phase Launched the business intelligence for CTIS for the Member States` Rearguard (code delivery, governance) Provided 13 CTIS releases (bug fixes) and published 11 Release notes (including dual version of the MS API, lock mechanism for RFI responding, improved organisation search, improved downloading of documents) Continuous improvements for submission and evaluation of large trials Implemented and communicated Multifactor authentication for CTIS Successfully obtained that CTIS is WHO data provider

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				With IM division migrated CTIS to a high availability data centre Have more than 700 Initial trials with a decision in CTIS 6 Ordinary POEG meetings 1 POEG meeting on 1st transition year alignment with MS (11 January 2023) 1 Ad hoc POEG on Delivery Plan 2023/2024 (19 April 2023) 1 Ad Hoc POEG on Transition to SAFe Agile (26 April 2023) Implemented successful split over CTS and CTT teams
Full Implementation of the EU-DPR and monitoring of compliance	6.2	In the initial implementation phase, assistance and guidance to Internal Controllers regarding data protection obligations (update existing and develop new records, data protection notices, DPIA reports, joint controllership agreements; adopt instruments for international data transfers; conclude appropriate contracts with data processors). Following the first implementation phase, as necessary, update and adopt further annexes to 0055-2020 Internal Guidance of Personal Data Protection. Update, develop and deliver	**On track**	Activities are on track, as of Q2 2023, quarterly activity reporting to ED and internal controllers has been initiated summarising the key data protection activities and reflecting the tasks carried out by the Data Protection Officer (DPO) and the work performed by the Data Protection Coordinators (DPCs), the applicable project teams, IT and business leads and AF-INS security experts in accordance with the Agency's data protection governance. Data Protection Activity Report Q2 2023 provides an overview of the work performed on Data Protection Notices and Records of Processing Activities, DPIAs etc Review of Internal Guidance on Data Protection including Annexes has been initiated (updates currently under review by DPCs): Annex I on Personal Data Breach Management Annex II on Handling Data Subjects Requests

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		data protection trainings on request or upon own initiative.		Annex III on Cloud Technology Selection and Data Protection Impact Assessments Annex IV EMA Data Security Requirements Annex V Personal data protection compliance in procurement procedures Annex VI Personal Data Retention Annex VII International Transfer Data protection trainings organised with participation of representatives of the EU Medicines Regulatory Network: Module 1 – Data Protection Definitions, Roles & Responsibilities Module 2 – Data Protection Principles and Documentation Module 3 – Legal Basis, Personal Data Breaches Module 4 – Data Protection Impact Assessments and International Transfers Module 5 – Data Subject Rights 3 Classroom Sessions – Questions & Answers

Regulatory Science and Innovation (TRS)

Pillar 2 – Public health activities

Workload indicators

Procedure		2023 annual forecast								
		2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	Initial	Revised	Change	
	Innovation Task Force briefing meetings	17	16	21	15	11	35	35	0	0%
	Innovation Task Force consultation: CHMP opinion requests according to Regulation (EC) No 726/2004 Art. 57 and MDR Art. 4 / IVDR Art. 3[35]	0	1	0	0	0	4	4	0	0%
	Business Pipeline briefing meetings[36]	10	8	6	-	-	18	18	0	0%
	Regulatory assistance, including SME briefing meetings[37]	83[38]	97	105	-	-	183	183	0	0%
	Requests for SME qualification	268	240	312	303	328	516	516	0	0%
	Requests for SME status renewal	124	210	131	178	134	1,260	1,260	0	0%

Performance indicators

Performance indicators related to core business		Target 2023	Outcome at the end of Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
	Satisfaction level of SMEs	80%	88%	n/a[39]	89%	88%	n/a

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Improve further the collaboration with international partners on shortages at the level of ICMRA and the Global Regulators Working Group,	1.1 (ECP 1, ECP 4)	Established framework for collaboration with international regulators	On track	Collaboration with international partners continues - for shortage case management and strategic topics - on

[35] Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), applying to 2021 onwards for MDR and 2022 onwards for IVDR.
[36] New indicator introduced in Work Programme 2021.
[37] New indicator introduced in Work Programme 2021.
[38] 77 requests received for administrative assistance and 6 SME briefing meetings on regulatory strategy.
[39] Satisfaction level is usually evaluated following events Q3/Q4.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
including in the area of supply disruptions due to manufacturing quality issues				quarterly basis through the Global Regulatory Shortage Working Group and ICMRA. Bilateral exchanges with FDA continue on set cadence (i.e., every quarter).
Improve expertise to accommodate rapid evolution of the regulatory system	3.1 (ECP 1)	Relevant areas of emerging science and technology identified Steps taken to increase expertise availability both within EMA and the Network	**On track**	17 Innovation Task Force meetings with involvement of network expertise; Onboarding of 7 collaborating expert programme to progress a variety of regulatory science topics
Identification of new technologies via HS and scientific advice activities and their integration into the EU-NTC	3.1 (ECP 1)	New technologies identified and integrated within EU-NTC	**On track**	Conducted RNA and Genome editing workshops as implementation steps following HS Reports; EMA Horizon scanning substantive exchange within STOA, EU ANSA and with Swissmedic
Identify, in consultation with research institutions, academia and other relevant stakeholders, fundamental research and associated training/education topics in strategic areas of regulatory science relevant to patients	3.3	Topics for network training identified and communicated to EU-NTC	**On track**	EU4Health work program discussion and contribution at EU-Innovation Network; Regulatory and scientific virtual conference on RNA-based medicines workshop in February 2023; EMA & EIT Health Expert workshop on genome editing on 21 March 2023; Planning for EU-IN academic multi-stakeholder workshop for September 23
Establishment of platform for systematic dissemination and exchange of knowledge and expertise on emerging innovation	3.4	Network systematically informed of evolving trends in innovation via platform meetings and facilitated by development of the TRIP system	**On track**	EU-IN platform monthly dissemination of ITF topics; Dedicated monthly presentation to relevant WPs and Committees (incl. PROM) of upcoming briefing meetings;

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Dedicated 2022 trend analysis presented to Committee and relevant WPs (Q1 2023); Dedicated lunch talk combined trend analysis BPM and ITF; Dedicated BPM and ITF trend analysis to H-TA Department; Continued development of horizon scanning platform (TRIP) to facilitate such dissemination; EU IN collaboration on six Horizon scanning topics; Agile development of TRIP advancing, User Testing in October 2023
Integrate EMA's Regulatory Science Strategy into the EMRN strategy, conduct horizon-scanning to ensure understanding of and preparedness for emerging technologies in medicines, identify gaps in expertise and provide continuous training through the EU Network Training Centre;	6.1	RSS integrated within EMAN Strategy Implementation tracked systematically to ensure delivery	**On track**	RSS integrated into EMAN Strategy; Midpoint implementation report published in March 2023; New Horizon scanning reports started on AMR, Health/Digital Health 2050, future vaccines and complex clinical trials as well as Alzheimer and open science/open government; Liaison with EU-NTC to assess potential for training in relation to HS findings - continued collaboration; Recording of EMA's 2023 RNA workshop available in the EMA's video channel
Review of the mandate of EMA to include the activities of the EU Executive steering group, the I-SPOC, and the EU SPOC Network	1.1 (ECP 1, ECP4)	Fulfilment of the requirements established by EMA's extended mandate for availability of medicines	**On track**	The MDSSG and the Medical Device Shortages SPOC WP have been established and are now operational. Finalisation of the minimum viable product of EMA's Critical

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Medical Devices Shortages (CMDS) system. Reporting obligations for Industry for medicines included in the lists of critical medicines for COVID-19 and Mpox PHEs, as defined under Regulation (EU) 2022/123, ceased to apply upon declaration to an end of the abovementioned PHEs by the WHO. EMA preparedness activities continue in light of SPOC WP and MSSG established mandates.
Improve monitoring of shortages and enhance communication of supply problems to EU citizens, their representatives and HCPs	1.1 (ECP 1, ECP4)	Enhanced communication of supply problems to stakeholders to facilitate mediating action	**On track**	The HMA/EMA multi-stakeholder workshop on shortages took place on 1-2 March. This event brought together (300+) representatives of national competent authorities, industry, patient and healthcare professionals as well as veterinary medicine representatives from across the EU/EEA to learn about the Task Force activities and share perspectives and initiatives to address availability issues and discuss how these can contribute to the future deliverables of the Task Force. A pilot with HCPs on shortage detection and reporting to EMA is currently ongoing. EMA presentations on shortages to multiple Pts/HCPs platforms (inc. PCWP & HCPWP) have taken place aligned with

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				EMA stakeholder engagement plans.

Advisory functions (International affairs, Internal audit, Legal department)

Workload indicators

Procedure		2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2023 annual forecast Initial	Revised	Change	
	Number of product-related interactions with international stakeholders – including requests for information and requests for documents[40]	127	-	-	-	-	130	130	0	0%
	Number of participations in external forums[41]	15	-	-	-	-	60	60	0	0%
	Number of external participants in training organised by International Affairs[42]	441	-	-	-	-	150	150	0	0%
	Number of visits to EMA / fellowships organised by International Affairs[43]	8	-	-	-	-	10	10	0	0%

Pillar 2 – Public health activities and Business Services

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
ICMRA secretariat, including COVID-19 response	1.1 (ECP 1, ECP 4)	Continue demonstrating leadership of ICMRA: regulatory convergence and in particular, vaccine safety monitoring collaboration Regulatory communication Provide strategic directions for	On track	Support to EMA Executive Director as chair and management of the ICMRA secretariat continued in the first semester of 2023. During the first semester of 2023 the following meetings/workshops were organised virtually:

[40] New workload indicators starting in 2023.
[41] New workload indicators starting in 2023.
[42] New workload indicators starting in 2023.
[43] New workload indicators starting in 2023.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		enhanced collaboration, improved communication and approaches to jointly address common challenges		Executive Committee meetings in February, April and July Plenary meeting in May Regulatory Forums deep dive discussions in April (on: Rare Disease Cures Accelerator-Data and Analytics Platform (RDCA-DAP) and June (on regulatory control of excipient supply-chain - Lessons from recent events) Workshop on COVID-19 variant in May 2023 The following documents were published on the ICMRA website: ICMRA COVID-19 variant workshop report (May 2023) ICMRA statement on safety of COVID-19 vaccines (June 2023) In June 2023, ICMRA received the 'Global Award for Outstanding Contribution to Health' at DIA 2023 in Boston
ICMRA workstream leadership and contribution	1.1 (ECP 1, ECP4)	1- Track and Trace (T&T) (currently on hold pending Executive Committee decision) 2- Pregnancy and Lactation (P&L) 3- Pharmaceutical Quality Knowledge Management System (PQKMS) 4- (Public Health Emergency Clinical Trials Working Group)	**On track**	Currently there are 5 ICMRA workstreams active and meeting regularly: Pharmaceutical Quality Knowledge Management System (PQKMS) Public Health Emergency Clinical Trials (PHECT) Innovation Network Vaccine Pharmacovigilance Network RWE and observational studies.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				EMA is actively participating to all this groups, leading on the PHECT and co-leading on innovation and RWE.
Anti-Tuberculosis Medicines Project		Submissions of MAA by industry of child-friendly first-line anti-TB medicines that represent an unmet medical need in the EU.	**On track**	EMA has approached DG HERA with identification of very specific need for children friendly formulation in the EU and asked whether it is in the mission of DG HERA to support companies financially DG HERA agreed that they can engage with companies provided that the board is consulted and supports it. If green light from DG HERA MB: DG HERA will organise a call using EU4health funding and organise a call for tender. This procurement procedure should be launched and managed by the European Health and Digital Executive Agency in September. The subject of this call for tender is to conclude service contracts for the purchasing of clinical and non-clinical services to provide access to tuberculosis medicines for children in the EU.
International Cooperation Platform (IntCoP)		Strengthen the exchange of information and coordination by promoting a harmonised EU approach to	**On track**	Meetings held March and June 2023 Increased sharing of information, moving towards better coordination of EC

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		international cooperation on medicines between NCAs, DG SANTE/EC and EMA.		positions, and greater engagement of NCAs
Pregnancy and Lactation Cluster (P&L)		To foster a consistent global approach across regulatory jurisdictions to assure evidence-based safe and effective use of medicines and vaccines during pregnancy and lactation	**On track**	P&L cluster meetings took place on a monthly basis; chaired by EMA since March. Agendas include a mix of specific product related and general topics. Work ongoing at ICH level - E21 (Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials). EMA collaborating with FDA in a project to compare Post Marketing requirements (EMA/FDA) related to pregnancy and breastfeeding.
Nitrosamines	1.1 5.5 (ECP 1, ECP 4)	Participation in Nitrosamines International Steering Group (NISG)	**On track**	Continuous collaboration with international regulators in identifying new medicines containing Nitrosamine impurities, new Nitrosamines acceptable intakes, CAPAs and supporting safety information through participation in the Nitrosamines International Steering Group (NISG).
Extension of US MRA	1.1 5.5 (ECP 1, ECP 4)	Extension to vaccines and plasma-derived products and veterinary medicines	**On track**	Extension to veterinary medicines The EU-US MRA for veterinary medicines was implemented as of 31 May with the recognition by US FDA of the capability 16 EU

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Member States Competent Authorities to carry out good manufacturing practice (GMP) inspections for certain veterinary products at a level equivalent to the US. The EU also recognised the FDA as an equivalent authority for GMP inspections of sites manufacturing veterinary medicines. The remaining Authorities will be assessed by FDA in accordance with an agreed schedule. Extension to vaccines and plasma derived products Inspection plans continue to be exchanged between EMA and FDA in order to identify opportunities for joint inspections. Some joint inspections have already taken place. EC started planning for FDA audits for vaccines and plasma derived products; a proposal for the audit of vaccines to take place in Q1 2024 was made to the FDA but no reply received. Improvement of MRA for human medicines A number of topics have been discussed between EC/EMA and FDA to increase the efficiency

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				of the MRA for human medicines. FDA agreed on the development of a GMP Summary Document; the content of the document/template has been discussed and agreed; however it has not yet been implemented as it is currently awaiting FDA IT development. Clarification on the application of Art. 11 of the MRA by FDA has been sought; examples of FDA requests to different MS have been sent to FDA and a technical meeting has been requested to further discuss.
Fostering reliance on EMA scientific outputs: EU-M4all	1.2 (ECP 1)	Provide scientific opinions on high-priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU) in collaboration with WHO Support to developers and promotion of parallel art 58 and centralised submissions	**On track**	Possible Art 58 - pre-submission meetings Repurposing of bevacizumab for macular degeneration as an art 58 with Academia BioNtainer for Comirnaty manufacturing in Africa with MAH, Generic formulation of risdiplam with KEI, Booster vaccine against tetanus and diphtheria for adults with Stable Pharma (SME), New single injection formulation of ivermectin to reduce malaria transmission with MEdincel (SME) A meeting with WHO disease program re 3

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				products for rabies mAbs licenced in India/China but they cannot be procured if they are not authorised by a SRA. Art 58 -Scientific Advice Fexinidazole for Treatment of human African trypanosomiasis Art 58 submission Arpraziquantel for the treatment of schistosomiasis in children Art58-Workshop Workshop WHO-EMA-Swissmedic on EU-M4all and MAGHP with industry representatives and other interested stakeholders to identify and analyse the strengths, challenges, communalities, opportunities and areas of improvement for the two procedures, and share best practices and recommendations.
Fostering reliance on EMA scientific outputs: Collaborative registration and other reliance pathways	1.2 (ECP 1)	Engagement with WHO, NRAs and applicants, to promote and support use of the WHO-SRA collaborative registration procedure, facilitated approvals and other pathways Capacity building in low- and middle-income countries	**On track**	Pyramax - updated following two quality variations; Ervebo extension of indication; Facilitation meeting for the national approval of mosquirix.
Provide assistance to candidate countries (IPA), to align their standards and	6.1	Facilitate EU integration to EU candidate countries	**On track**	Delivered advanced virtual EMA training on genotoxic impurities on

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
practices with those established in the European Union, and to further foster their integration process, in particular via scientific and regulatory training activities		and Potential candidate countries Increased visibility of EMA Training on acquis Communautaire of candidate and accessing countries		3 April (200 participants). Delivered two-day F2F advanced EMA training on quality and inspections from 15-16 June in Amsterdam (60 in-person participants, incl. Moldova, Georgia and Ukraine delegations) and up to 180 participants joining remotely) Signed ad-hoc CA with the 7 IPA beneficiaries
Support to priority countries	5.2	India and Russia joining PIC/S and ICH, GMP and GCP improved compliance	**Delayed**	Activities with Russia suspended due to international political situation. Activities and dialogue with India and China have restarted post-pandemic, mostly in matters related to GMP inspections. Inspections in China from EU competent authorities have restarted post-pandemic. A meeting with Indian authorities and HMPC chair and members (EDQM as observer) on ayurvedic medicines was held in March 2023.
OPEN project	6.5	Active collaboration of selected regulatory authorities in CHMP and European Task Force for COVID-19 vaccines and therapeutics; extension of the OPEN model to other	**On track**	OPEN pilot on COVID vaccines and therapeutics terminated. OPEN framework extended to AMR, PRIME and unmet medical needs products and medicinal product responding to public health emergency. ANVISA from Brazil has

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		therapeutic areas		now joined the framework. Products falling under the OPEN framework for 2023 and corresponding OPEN partners identified. Revised Q&A, open process and playbook finalised.
Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU	6.1	Support training and capacity building of non-EU regulators	**On track**	Launch of pilot for non-EU regulators
Re-start of the International awareness sessions for regulators	6.1	Increase the awareness of the EU system through dedicated sessions	**Delayed**	No international awareness sessions for non-EU regulators were organised in first half of 2023. Plans for re-launch are being developed for 2024.
Collaboration in the establishment of the African Medicines Agency (AMA)	6.1	Capacity building through providing adequate guidance	**On track**	Project team created to prepare EMA proposal for DG INTPA contribution agreement Internal and external communication and engagement with stakeholders Participation and engagement with AUDA-NEPAD/AMRH technical committees
Launch tailored communications on biosimilars and provide updated guidance on the evidence needs for biosimilars	1.1 (ECP 1, ECP4)	Increased awareness to facilitate the uptake of biosimilars	**On track**	Revised and updated statement on interchangeability of biosimilars (April 2023); Explainer video on interchangeability (March 2023) - What is a Biosimilar? - Video Explainer – YouTube; EMA/HMA Multi-stakeholder meeting on shortages incl. breakout

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				on biosimilars (March 2023) HMA/EMA multi-stakeholder workshop on shortages Tool Kit for information under development by HMA Working Group expected to be finalised in Q4/23-Q1/24.
Foster development of POC diagnostics for human and veterinary use	4.2 (ECP 1)	Inclusion of diagnostics in the discussion on a new business model on the antibacterial agent	**Suspended**	This activity has not yet started and will be taken up after the AMR strategy is defined.
Define approaches for review of data with international regulators	4.2 (ECP 1)	Build on the experience acquired with COVID to establish the approach for future emergencies.	**Delayed**	Aspect to be addressed as part of the lessons learned exercises.
Communicate proactively with key stakeholders on benefit-risk using evidence-based tools to tackle vaccine hesitancy	4 (additional RSS recommendation)	Interaction with the ECDC and public health authorities and ICMRA.	**On track**	A joint statement with ECDC on COVID adapted vaccines was prepared in June 2023.
Engage with public health authorities and NITAGs to better inform vaccine decisions	4 (additional RSS recommendation)	Attend meetings of the NITAG and contribute.	**On track**	Regular TCs with NITAGs are taking place.
Establish a platform for EU benefit-risk monitoring of vaccines post-approval	4 (additional RSS recommendation)	Set up the platform and conduct first studies.	**On track**	IVMAB is operative and meetings are taking place.

Stakeholders and Communication Division

Pillar 2 – Public health activities

Workload indicators

	Procedure						2023 annual forecast		
		2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	Initial	Revised	Change	
	Number of cases of patient/consumer engagement in EMA (medicines-related) activities[44]	n/a[45]	275	289	358	333	500	n/a	n/a	n/a
	Number of cases of healthcare professionals' engagement in EMA (medicines-related) activities	n/a[46]	200	105	64	1,102	300	n/a	n/a	n/a
	Number of professional membership organisation events attended by participating Agency staff	12	-	-	-	-	25	30	5	20%
	Number of sessions with Agency representatives	116	-	-	-	-	120	158	38	32%
	Number of messages circulated via 'Early Notification System'	277	329	635	373	215	500	500	0	0%
	Number of EMA communications pro-actively sent to stakeholders	106	109	110	101	68	200	200	0	0%
	Number of EPAR summaries and EPAR summaries updates published	81	97	118	164	144	250	160	-90	-36%
	Number of summaries of orphan designation published	87	99	0	64	55	150	0[47]	-150	-100%

[44] These include any interaction a healthcare professional may have with EMA, in addition to those occurring with healthcare professionals nominated by the national agencies.
[45] In 2018, the Public and Stakeholder Engagement department changed it's methodology to reporting on the number of medicine-related activities where patients and healthcare professionals were involved (described in stakeholder engagement report (https://www.ema.europa.eu/en/documents/report/stakeholder-engagement-report-2018-2019_en.pdf)
[46] In 2018, the Public and Stakeholder Engagement department changed it's methodology to reporting on the number of medicine-related activities where patients and healthcare professionals were involved (described in stakeholder engagement report (https://www.ema.europa.eu/en/documents/report/stakeholder-engagement-report-2018-2019_en.pdf).
[47] Forecast should be adjusted to 0 to reflect move to public register in IRIS for orphan designations.

	Access to documents, requests received	416	375	342	316	362	750	750	0	0%
	Access to documents, documents released	652	497	568	382	792	2,000	1,500	-500	-25%
	Requests for information received	3,624	4,559	5,915	3,597	3,677	10,000	8,000	-2,000	-20%
	Clinical Data Publication (CDP), Procedures published[48]	27	-	-	-	-	45	45	0	0%
	Clinical Data Publication (CDP), Documents published[49]	471	-	-	-	-	750	750	0	0%
	Number of documents published on EMA website	3,834	3,787	4,071	3,628	3,533	7,500	7,500	0	0%
	Number of pages published and updated on EMA website	2,076	1,779	1,883	1,681	1,821	3,500	3,500	0	0%
	Number of press releases and news items published	64	87	122	86	63	140	140	0	0%
	Numbers of press briefings conducted	3	9	18	3	-	10	5	-5	-50%
	Numbers of social media posts published	667	488	975	484	-	1,300	1,300	0	0%
	Completed requests for interviews and comments by media representatives	645	996	4,057	598	564	1,500	1,500	0	0%
	Number of reports, brochures, leaflets laid out or printed, social media visuals	360	437	300	214	33	800	800	0	0%

Performance indicators

Performance indicators related to core business		Target 2023	Outcome at the end of Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
	Satisfaction level of patient and consumer organisations	90%	100%	n/a	92%	n/a[50]	n/a[51]
	Satisfaction level of healthcare professionals organisations	85%	88%	n/a	90%	n/a	n/a

[48] Numbers based on publications solely linked to Covid-19 related medicinal products.
[49] Numbers based on publications solely linked to Covid-19 related medicinal products.
[50] Questionnaire to be sent at the end of the year.
[51] Footnote 2019 - No survey due to BCP.

	Triage of incoming requests received via AskEMA within set timelines[52]	100%	99%	99%	99%	-	-
	Responses to ATD within set timelines[53]	90%	91.40%	89%	92%	86%	92%
	Responses to RFI within set timelines (for EMA)	95%	82%	89%	85%	92%	96%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	75%	73%	68%[54]	82%	82%	89%
	Satisfaction level of partners/stakeholders with EMA communications as per "EMA perception survey for communication"[55]	n/a	n/a	n/a	n/a	-	n/a[56]
	Average rating of pages on corporate website during the year	3.6	3.8	3.1	3.5	3.7	3.2

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
- Design communication campaigns in collaboration with relevant stakeholders to proactively approach to key public-health areas (e.g., vaccines) - Improve communication for patients, healthcare professionals and other stakeholders including HTAs and payers - Enhance professional outreach through scientific publications & conferences	1 (additional RSS recommendation)	Delivery of communication campaigns on key topics, with focus on COVID-19	**On track**	Communication campaigns delivered: on the transition period for CTIS; European Immunisation Week; best practices for industry to avoid shortages Communication plans are drafted and implemented for: RWE, Cancer, revision of the pharmaceutical legislation, ACT-EU/CTIS, OPEN initiative. Social media strategy is being finalised; new tools and channels are being tested, e.g., two LinkedIn live interviews, one on mRNA technology (conducted in cooperation with

[52] New indicator introduced in 2021 Work Programme.
[53] Calculated according to the legal timeline stated in Regulation (EC) No 1049/2001 and from the date on which the requester is informed of the start of the procedure.
[54] Low response rate (6.4%) doesn't allow a strong conclusion on this indicator.
[55] Survey carried out every 2 years.
[56] No survey due to BCP.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				LinkedIn Europe), one on DARWIN-EU (organised, marketed and conducted by EMA) A plan for communication about COVID-19 in 2023 and beyond is under development; additional content on the safety of COVID-19 vaccines was developed and disseminated; two press briefings on COVID-19 were held in 2023. A framework to tackle mis/disinformation is under development A plan for media relations beyond COVID-19 has been adopted; a press briefing on mRNA technologies was held under this plan. New audiovisual tools have been created: three explainer videos (biosimilars, orphan medicines, EUM4all) were published; new videos are under development on: CHMP, interaction with HCPs, ACT-EU, corporate video, RWE, COVID-19 vaccine safety; the corporate brochure was updated and is published; Human and Veterinary Highlights and the Annual Report 2022 were published and revamps for all these products are currently under development.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				EMA's crisis communication plan is being reviewed in light of the COVID-19 experience. A workshop was held, and the discussion results are currently being collected to update the plan. A communication plan in support of the 10-year anniversary of ICMRA has been drafted; a video is currently under development. The corporate identity manual is being updated and an asset management system has been launched. Preparation of a number of templates to enable better design across EMA is under development. Periodic update of LTT on COVID-19 vaccines Lessons learned report on COVID-19 being drafted ICMRA statement on safety of COVID-19 vaccines published Biosimilar toolkit from HMA WG on biosimilar reviewed Ongoing implementation of the consolidated Scientific Publication Strategy 53 scientific articles published 8 Open Access assessments 15 Scientific articles published

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Attendance to several outreach events to PCOs and HPCs 4 positions papers under development with HCP POG. Topics include medicines for frail and older people, shortages of medicines, surrogate endpoints, pharmacovigilance with focus on medical errors.

Information Management Division

Workload indicators

Procedure		2023 annual forecast								
		2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	Initial	Revised	Change	
	Number of information services/IT systems provided by EMA	28	-	-	-	-	28	28	0	0%

Performance indicators

Performance indicators related to core business		Target 2023	Outcome at the end of				
			Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
	Satisfaction of EMA internal and external users	80%	95%	96%	96%	88.17	84%
	Availability of IT systems and corporate website	98%	98%	98.20%	99.50%	99.06	98%

Administration Division

Performance indicators/Forecast activity

Performance indicators related to core business		Target 2023	Outcome at the end of				
			Q2 2023	Q2 2022	Q2 2021	Q2 2020	Q2 2019
	Posts on the Agency establishment plan filled	100%	97%	99.50%	97%[57]	98%	99%
	Average time to run selection procedures from vacancy notice to establishment of reserve list	100% average <3 months	3.0 calendar months	2.8 months	66% < 3 months[58]	<3 months	3 months
	Revenue appropriations implemented[59]	97%	42%	45%	45%	50%	41%
	Expenditure appropriations implemented[60]	95%	71%	70%	67%	75%	67%

[57] The figure does not include the posts linked to the new mandate, which are subject to the development of the legislative process.
[58] The current average selection procedure time is 2.53 months. Specifically, 11% of selection procedures were standard (single post) and their average completion time was 1.4 months; 66% of selection procedures were medium selections (a few posts for multiple requirements) and their average completion time was 2.6 months; 23% were large selection procedures (multiple requirements across the Agency) and their average completion time was 2.8 months.
[59] Invoices issued.
[60] Annual target to be reached at year-end.

	Payments against appropriations carried over from year N-1	95%	61%	60%	70%	87%	71%[61]
	The maximum rate of carryover to year N+1, of total commitments within the title:						
	Title 1	10%	n/a	n/a	n/a	n/a	2.19%
	Title 2	20%	n/a	n/a	n/a	n/a	10.79%
	Title 3	30%	n/a	n/a	n/a	n/a	29.16%
	Payments made within 30 days' time	98%	97.53%	97%	97%	94%	96.13%
	Receivable overdue for more than 30 days (including provision for bad debts)[62]	<10%	3.76%	3.03%	2%	8.47%	-
	Balance sheet volume (as proxy for treasury mgmt., accounts receivable/payable transactions, audits, financial analysis, and reporting) (in million EUR)[63]	400	n/a	n/a	n/a	n/a	n/a

	Procedure						2023 annual forecast			
		2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	Initial	Revised	Change	
	Total TA staff recruited against vacant posts	27	30	40	13	23	50	50	0	0%
	Staff turnover rate (staff leaving against total no. of staff TA & CA)	3.10%	4%	3%	2%	4%	5%	5%	0%	0%
	Total TA, CA, END at the Agency[64]	927	-	-	-	-	930	930	0	0%
	Onboarding of staff (TAs, CAs, ENDs)[65]	77	-	-	-	-	75	0	75	0%
	Staff entitlements management[66]	935	-	-	-	-	950	0	950	0%
	Procurement procedures implemented[67]	n/a	-	-	-	-	56	n/a	n/a	n/a
	Contracts under management (excluding expert contracts)[68]	n/a	-	-	-	-	364	n/a	n/a	n/a
	Financial transactions initiated (in thousands)[69]	n/a	-	-	-	-	14	n/a	n/a	n/a
	Financial Transactions verified (in thousands)[70]	n/a	-	-	-	-	24	n/a	n/a	n/a

[61] Includes C8 and C2 - at acceptable level at the end of Q2.
[62] New indicator included in 2020 Work Programme.
[63] New indicators introduced in 2023.
[64] New indicators introduced in 2023.
[65] New indicators introduced in 2023.
[66] New indicators introduced in 2023.
[67] New indicators introduced in 2023.
[68] New indicators introduced in 2023.
[69] New indicators introduced in 2023.
[70] New indicators introduced in 2023.

	Invoices issued (as proxy for workload linked to registering and processing applications, solving questions of fee interpretation and invoicing) (in thousands)[71]	n/a	-	-	-	-	50	50	0	0%
	Procurement procedures finalised	11	n/a	n/a	n/a	n/a	n/a	56	n/a	n/a
	Financial commitments initiated	641	n/a	n/a	n/a	n/a	n/a	1,500	n/a	n/a
	Payment transactions initiated	16,066	n/a	n/a	n/a	n/a	n/a	27,000	n/a	n/a
	Number of sales orders	13,104	n/a	n/a	n/a	n/a	n/a	40,000	n/a	n/a
	Number of registration activities	6,319	n/a	n/a	n/a	n/a	n/a	15,000	n/a	n/a
	PRE financial queries and disputes	160	n/a	n/a	n/a	n/a	n/a	400	n/a	n/a

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Implement the revised human resource and talent management strategy (HR strategy)	6.2	The HR strategy will consolidate practices into coherent system and practices and will lead to continuously improving approaches in domains of staff wellbeing, leadership and management, talent management and culture Staff engagement survey carried out in Q4 2022	**On track**	Strategy endorsed by the EXB Implementation plan delivered. Progress on 2023 priorities
Implement the new competency management framework	6.2	Competency framework (behavioural and technical competencies); revised role descriptions with embedded competency profiles and proficiency levels of	**On track**	Completed in 2022.

[71] New indicators introduced in 2023.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		competencies leading to higher effectiveness, contributing to job satisfaction and development opportunities.		
Potential replacement of the human resource management and the financial systems taking into account the discontinuation of the support for the current system by vendors	6.4	Gradual replacement of the financial and HR system in line with the future project plan.	**On track**	Analysis to have a gradual replacement for SAP HR And SAP FIN is taking place as planned. Regarding the SAP HR, a draft roadmap has been already drafted by HR Scrum master and solution architect and now the feasibility is being looked at.
Implement the Agency's new intranet and migrate or develop related content	6.4	The new intranet implemented. Content is gradually rolled out taking into account the business capacity	**On track**	Completed in 2022.
Further develop the procurement and contract management practices and implement the procurement tool	6.4	The procurement and contract management process is further improved with the further developed vendor management and market research capabilities A tool supporting procurement processes implemented	**On track**	Completed in 2022.
New Fee Regulation: optimisation and review of revenue and expenditure process	6.3	Implementation of the New fee regulation with an optimised and more efficient revenue and expenditure process	**On track**	The Enabler Epic and work with the consultant company on the analysis and impact assessment progressed during the first half of the year 2023 resulting in the following achievements: • review of the New Fee Regulation

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				impact on the current EMA processes • identification of the future state addressing open items and key interdependencies • review of the proposed roadmap to implement the NFR changes
Improve efficiency of certain administrative processes	6.3	The identified improvement in the accounts receivable (AR) and customer data management processes implemented	**On track**	The implementation of SAP FIN AR enhancements was completed between in 2022. The Customer Master Data process improvement is to be mastered within OMS (SPOR) and implemented in the context of the New Fee Regulation which analyses the revenue and expenditure process flows or in the context of Customer Relationship Management (CRM) epic. Some elements of the One-Stop-Shop solution for applicants (CRM) will also be implemented in the context of the New Fee Regulation, for example with the adaptation of IRIS to cater for pre-payment of fees at submission.

Annex 2: Pillar III Network Portfolio

Following the implementation during 2022 of the SAFe Agile methodology, the Agency has migrated all of its former programmes and projects into the new governance. To reflect this change, the 2023 Single Programming Document no longer includes a separate Annex XIV with programmes and projects. Instead, all activities falling under Pillar III have been centralised in this new chapter. The table below details the main products and deliverables (epics) currently planned for 2023, which are reviewed during quarterly Programme Increment planning ceremonies.

Progress and delivery as of 30 of June 2023 against what was planned in the work programme 2023 is reported using the following statuses:

- *On Track*
- *Delayed*
- *Suspended*
- *Achieved*

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results Q1/Q2 2023
Product Lifecycle Management Value Stream (PLM VS)						**Budget 2023 (M€) 17.6**
Electronic Application Form (Product Lifecycle Management Portal) *(Formerly DADI)*		2021	2024	– Human Variations Form – Human + Vet Marketing Authorisation Application (MAA) – Vet Variation Form – Renewals – Product User Interface (for viewing, submitting and correcting product data)	On track	Knowledge base live on PLM Portal Publication of variations roll-out plan Human Variation electronic Application Form (eAF) available for optional use for Centrally Authorised Products (CAP)
Regulatory Procedure Management for PLM (IRIS)		2022	2024	– Process Core (Variations, Transfers, Art 61.3) – PSURs, post-authorisation measures – MAA + additional functionality	On track	First User Acceptance Test (UAT) completed for variations, transfers and Art. 61.3 procedures, in preparation for launching the first phase of replacing SIAMED later in 2023. User support to adopt new ways of working
Electronic Product Information (ePI)		2022	2023	– Authoring Portal – Publishing and Consuming – Pilot planning	On track	Editor with rich text editing functionality available in PLM portal for authoring and updating ePI, uploading ePI in FHIR format, downloading/exporting PI in FHIR or Word format. Repository available for ePI built on the FHIR data exchange standard and API available to enable ePI access. Started pilot for set of CAPs and NAPs to test the business process and develop guidance for inclusion of ePI in regulatory procedures
Expert Panels for Medical Devices (EXPAMED)	– Regulation (EU) 2022/123 of 25 January 2022 on a reinforced role for the European Medicines	2022	2023	– Procedure Management – Collaboration Enablement	Achieved	Go-live on 3 April 2023 of collaboration platform for expert panels for medical devices in support of EMA extended mandate.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results Q1/Q2 2023
	Agency in crisis preparedness and management for medicinal products and medical devices					Support to platform users
Medicinal Product Management System (PMS)	– Regulation 726/2004, art.57(2) - Regulation (EC) 520/2012, art.25 and 26 - Clinical trials reg. 536/2014, art.8193) - Pharmacovigilance fees reg. 658/2014, art.7 – Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU	2017	2024	– XEVMPD Integration (Data migration/transformation into ISO IDMP format) – IDMP Implementation (Data migration/transformation into ISO IDMP format) – XEVMPD Integration (Feedback Loop – capabilities to ensure XEVMPD and PMS are fully synchronised) – FHIR Ingestor (Capabilities to import IDMP compliant product data to PMS) – IDMP compliance (Capabilities to validate ISO 11615 compliance)	On track	Migration and synchronisation of product data from SIAMED into PMS Continuous implementation of IDMP standards and compliance to enhance data quality for reuse across the product lifecycle
eCTD4 (eSubmissions incl. EURS/CR)		2021	2026	– eCTD v4.0 preparation and implementation	On track	Review of Implementation Guide and Specification for eCTD v4.0 in the European region launched and underway
Veterinary Union Product Database (UPD)		2021	2023	– Union Product Database (UPD)	On track	UPD v 1.6.25 deployed on 1 June 2023 New training materials published. Stabilisation and bug fixes to improve UPD performance and reliability

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results Q1/Q2 2023
Research and Development Value Stream (R&D VS)						**Budget 2023 (M€) 14.7**
Clinical Trials Information System (CTIS)	– Regulation (EC) 536/2014, art.80-82 – Art. 11(3) of Implementing Regulation to Regulation (EC) 536/2014	2014	tbc	– After go-live version for January 2023 – Transition to the agile governance model	On track	Mandatory use for submissions of initial clinical trials since 31 January 2023 Continuous improvements to CTIS user experience.
Regulatory Procedure Management for R&D (IRIS)		2023	2023	– Priority Medicines (PRIME) – Maintenance activities (Scientific Advice, Orphan Designation, Innovation Task Force)	On track	Main PRIME Eligibility process onboarded onto IRIS platform on 10 July supported by communication and change management activities.
Lifecycle Regulatory Submission Metadata (LRSM)		2020	~~2023~~ 2024	– Scientific Explorer: regulatory and scientific documents searching interface – Clinical Trial Navigator: Proof of concept for the interrogation of Clinical Trial Study Protocol and development of the logical and conceptual data model	On track	Scientific Explorer: completion of architecture design, ingestion mechanisms and UI/UX design. Clinical Trial Navigator: user interface ready for UAT as a proof of concept for the interrogation of structured clinical trial study protocols; development of the logical and conceptual data model ongoing.
T.R.I.P. (Horizon Scanning)		2023	2023	– Platform to support horizon scanning capability (identify futures innovations and trends earlier to support development)	On track	First version of web app completed. Ingestion of prioritised external types of sources of information deployed.
Real World Metadata & Studies catalogues		2021	~~2025~~ 2023	– Catalogues of real-world evidence data sources and studies	On track	Two UATs completed successfully (access management and institutions registration).
Data Analytics Accelerator (new)		2023	2024	– A dashboard to compare the impact of the CTR v CTD – Enhanced interoperability of onboarded data sources	On track	Platform core set-up completed. First iteration of data model and dashboard created

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results Q1/Q2 2023
Monitoring Value Stream (MON VS)						**Budget 2023 (M€) 13.2**
European Shortages Monitoring Platform (ESMP)	– Regulation (EU) 2022/123	2022	2023	– Monitoring of events in preparation for major crisis or Public Health Emergency (PHE) – Monitoring of Critical Medicines during PHE/ME – Support the work of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)	On track	ESMP roadmap adopted by MSSG. Change management capabilities in place. Bulk upload of MAH data and download of reporting template with in-scope CAP products (crisis). Security and access management for MAHs. Methodology for matching of supply and demand established.
Critical Medical Devices Shortages (CMDS)	– Regulation (EU) 2022/123	2022	2023	– IT implementation medical devices shortages	On track	Change management capabilities in place Transactional component concluded and in production
Inspections and Parallel Distribution				– Inspections – Parallel Distribution	On track	Inspections: Change management capabilities in place; CoprGxP legacy database decommissioned; Efficiency improvements Parallel Distribution: Efficiency improvements
Veterinary Union Pharmacovigilance Database (UPhV, formerly EVVet3)	– Regulation (EC) 726/2004, art.57(d) – Regulation (EU) 2019/6; associated implementing acts	2017	2023	– UPhV MVP completion and improvements	On track	UPhV vision and roadmap approved and communicated Datawarehouse improvements to signal detection and signal evaluation dashboards Improvements to signal submission interface Datawarehouse pre-calculation at product name level for signal detection dashboard Draft adverse event report Improvements to bulk export

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results Q1/Q2 2023
Antimicrobial Sales & Use (ASU)		2021	2023	– Transfer reporting functionalities for sales data from existing ESVAC	On track	Change management capabilities in place ASU test platform opened and release of new functionalities for external users to test ASU and Union Product Database user interfaces successfully merged
Signal and Safety Analytics (SSA)		2022	2024	– Conclude implementation of the new solutions – Implement change management plan		*(not started yet)*
Managing the Agency Value Stream (MTA VS)						**Budget 2023 (M€) 8.8**
Expert Database replacement		2022	2023	– Expert Database replacement	Achieved	Experts Management Tool go-live on 29 March 2023 as a single system to manage declarations of interests (DoIs) for medicines experts, medical device experts and Management Board (MB) members, and to manage experts-related legal and financial commitments User support to accompany the tool release
Admin Data Quality		2022	2023	– Admin data quality management	Achieved	Corporate Data governance model and process approved Review of Power BI reports in four corporate business areas
SAP Finance replacement		2023	2025	– Start implementation of selected solution	On track	Analysis of SUMMA project (EC) feasibility to replace EMA SAP FIN tool, and assessment of other solutions ongoing
SAP HR replacement		2023	2025	– SAP HR on-premise migration		*(not started yet, to start in Q3/2023)*

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results Q1/Q2 2023
New Fee Regulation	*(Regulation expected to be adopted in December 2023)*	Q4/2022		– Analysis and impact assessment	On track	Analysis and impact assessment completed. Draft process maps for implementation completed
E-procurement		Q4/2022	2023	– E-procurement suite	Achieved	PPMT e-procurement suite launched in Q1/2023 Several procurement procedures successfully prepared, launched and completed in PPMT Streamlined and improved process for publishing ex-ante advertisements and procurement procedures using an integration with eTendering
EU Network Training Centre (EU NTC)		Q4/2022	2023	– EU NTC website	Delayed	Draft content development completed. Technology selection ongoing
Intranet (new)		Q4/2022	2023	– New intranet – Archive old intranet	Achieved	New intranet launched on 15 March 2023 Migration from old to new intranet completed. Training of new intranet editors completed. Old intranet archived on 30 June 2023
Technology Lifecycle Management and Information Security Value Stream (TLM VS)						**Budget 2023 (M€) 18.2**
Information Security		2022	2024	– Cyber and Information Security enhancements – Operational Security enhancements – Application Security enhancements	On track	Rollout of Service Now SecOps module for security incident investigations completed. Rollout of Virtual Reality pilot (cybersecurity training) completed. External and internal penetration tests to identify vulnerabilities completed. Migration of applications to Azure AD authentication ongoing

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results Q1/Q2 2023
						Better control and management of endpoints using Microsoft Intune solution ongoing. Development of the Secure Development Lifecycle framework ongoing
Data Centre 2.0		2022	2023	– Migration from data centre to cloud provider	On track	65% of migrations completed

Annex 3: Terms and abbreviations

Term/abbreviation	Definition
ACE	Analytics Centre of Excellence
ACPC	Advisory Committee on Procurement and Contracts
ACT EU	Accelerating Clinical Trials in the EU
ADR	adverse drug reaction
ADRA	Antimicrobials Dose Review and Adjustment group
AE	Adverse event
AER	Adverse event report
AF-INS	EMA Advisory Function Information Security
Agency	European Medicines Agency
AGES	Austrian NCA
AI	Artificial intelligence
ALIMS	Medicines and Medical Devices Agency of Serbia
AM	antimicrobial
AMA	African Medicines Agency
AMEG	Antimicrobial Advice Ad Hoc Expert Group
AMR	Antimicrobial resistance
AMRH	African Medicines Regulatory Harmonization programme
ANSA	EU Agencies Network on Scientific Advice
ANVISA	Brazilian Health Regulatory Agency
API	Active pharmaceutical ingredient
ASU	Antimicrobial sales and use
ATAm	Alternative to Antimicrobials
ATD	Access to documents
ATMP	Advanced-therapy medicinal product
AUDA-NEPAD/AMRH	African Union Development Agency- New Partnership for Africa's Development-/African Medicines Regulatory Harmonization
AVS	Assisted Validation System
AWP	Annual Work Programme
BCP	Business continuity plan and public health threat plan
BDSG	Big data steering group
BI	Business Intelligence
BMJ	British Medical Journal
BPM	Business Pipeline Meeting
Brexit	Commonly used term for the United Kingdom's planned withdrawal from the European Union
CAMD	Competent Authorities for Medical Devices
CAP	Centrally authorised product
CAPA	corrective and preventive actions

Term/abbreviation	Definition
CAT	Committee for Advanced Therapies
CCI	commercially confidential information
CDISC	Clinical Data Interchange Standards Consortium
CDP	Clinical Data Publication
CDPC	EU Common Data Platform for Chemicals
CECP	clinical evaluation consultation procedure
CHMP	Committee for Medicinal Products for Human Use
CMDS	Critical Medical Devices Shortages
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
Commission	European Commission
committee(s)	Scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
Council	European Council
CR	Common Repository
CRM	Customer Relationship Management
CRP	Collaborative Registration Procedure
CT	Clinical trial
CTCG	Clinical Trials Coordination Group
CTD	common technical document
CTFG	Clinical Trials Facilitation and Coordination Group
CTIS	Clinical trial information system
CTR	Clinical Trials Regulation
CTS	Clinical Trials Systems team
CTT	Clinical Trials Transformation team
CVMP	Committee for Medicinal Products for Veterinary Use
CxMP	Scientific committees of the Agency
DADI	Digital Application Dataset Integration
DARWIN EU	Data Analytics and Real World Interrogation Network
DG	Directorate-General of the European Commission
DG INTPA	European Commission Directorate-General for International Partnerships
DG SANTE	European Commission Directorate-General for Health and Food Safety
DG ENV	Commission Directorate-General for Environment
DIA	Drug Information Association
DigiLab	EMA Digital Innovation Lab
DoI	Declaration of interests
DPC	Data Protection Coordinators
DPIA	Data Protection Impact Assessments
DPO	Data Protection Officer
DPR	Data protection Regulation for EU institutions and bodies
DQF	Data Quality Framework
EC	European Commission

Term/abbreviation	Definition
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECP	European Commission priority
eCTD	Electronic common technical document
ED	Executive Director
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEA	European Economic Area
EFSA	European Food Safety Authority
EHDS	European Health Data Space
EIT	European Institute of Innovation and Technology
EMA	European Medicines Agency
EMANS	European Medicines Agency Network Strategy
EMRN	European medicines regulatory network
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
END	Seconded national expert (Experts nationaux détachés)
Enpr-EMA	European Network of Paediatric Research at the European Medicines Agency
ENVI	European Parliament Committee on the Environment, Public Health and Food Safety
EO	Economic Operators
EORTC	European Organisation for Research and Treatment of Cancer
EP	European Parliament
EPAR	European public assessment report
ERA	Environmental risk assessment
ERAWP	Environmental Risk Assessment Working Party
ESEC	European Specialised Expert Community
ESMP	European Shortages Monitoring Platform
ESUAvet	European Sales and Use of Veterinary Antimicrobials Working Group
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EU NTC	EU Network training centre
EU SPOC	single points of contact in NCAs for shortages
EU-DPR	Data protection Regulation for EU institutions and bodies
EU-IN	EU innovation network
EU-M4all	Medicines for use outside the EU
EUnetHTA	European network for health technology assessment
EURS	European Review System for eCTDs
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EVV	Union Pharmacovigilance Database
EVVet	veterinary EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance

Term/abbreviation	Definition
EWG	Expert Working Group
EWP	Efficacy Working Party
EXB	EMA Executive Board
EXPAMED	Expert Panels on Medical Devices
FDA	United States Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
FWC	Framework contract
GCP	Good clinical practice
GDP	good-distribution-practice
GLP	Good laboratory practice
GMP	Good manufacturing practice
GVP	Good pharmacovigilance practice
GxP	Good practice (e.g., laboratory, clinical, manufacturing etc)
HCD	Healthcare Data team
HCP	Healthcare professional
HCP POG	EMA/eligible healthcare professional organisations policy officers' group
HCPWP	Healthcare Professionals Working Party
HERA	Health Emergency Preparedness and Response Authority
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HPRA	Health Products Regulatory Authority (Ireland)
HR	Human resources
HS	Horizon Scanning
HTA	Health technology assessment
ICH	International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMRA	International coalition of medicines regulatory authorities
ICSR	Individual case-safety report
IDMP	Identification of Medicinal Products standards (ISO)
IHD	Instant Health Data
IM division	Information management division
IPA	Instrument for Pre-accession Assistance
IR	Implementing Regulation (of the Clinical Trials Regulation)
IRIS	Platform facilitating the exchange of regulatory and scientific information between EMA and organisations developing medicinal research products for potential use in the European Union
ISO	International Organisation for Standardisation
iSPOC	single points of contact in industry for shortages
IT	Information technology
ITF	Innovation Task Force
IVD	In Vitro Diagnostics
IVDR	In vitro Diagnostics Regulation
IVMAB	Immunisation and Vaccine Monitoring Advisory Board

Term/abbreviation	Definition
IVMP	immunological veterinary medicinal product
IWG	Inspectors Working Group
JIACRA	Joint inter-agency antimicrobial consumption and resistance analysis
JSC	Joint Scientific Consultations
LLFG	Listen and Learn Focus Group
LLM	large language processing models
LMS	EU Network Training Centre Learning Management System
LRSM	Lifecycle Regulatory Submission Metadata
LTT	Line to take
MA	Marketing authorisation
MAA	Marketing authorisation application
MAGHP	marketing authorisation for global health products
MAH	marketing authorisation holder
MAWP	EMA multiannual work programme
MB	Management Board
MD	Medical devices
MDIG	Medical Devices Implementation Group
MDR	Medical Devices Regulation
MDR/IVDR	Medical Devices Regulation / In vitro Diagnostics Regulation
MDSSG	Medical Devices Shortages Steering Group
Member State	Member State of the European Union
MINERVA	Metadata for data discoverability and study replicability in observational studies project
MLM	Medical literature monitoring
MNAT	Multinational assessment team
MON VS	Monitoring Value Stream
MPX	Monkeypox
MRA	Mutual recognition agreement
MRL	Maximum residue limit
MS	Member State of the European Union
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
MTA VS	Managing the Agency Value Stream
MTG	Main Therapeutic Groups
MUMS	Minor use, minor species
MVP	minimum viable product
MWD	Union Manufacturers and Wholesale Distributors Database
MWP	Methodology Working Party
NAP	Nationally authorised product
NCA	National competent authority
NDB	EU Network Data Board
Network	European medicines regulatory network
NISG	Nitrosamines International Steering Group

Term/abbreviation	Definition
NITAGs	National immunization technical advisory groups of WHO
NTC	EU Network training centre
NTWP	Novel Therapies and Technologies Working Party
OLAF	European Anti-Fraud Office
One Health EJP	One Health European Joint Programme
OPEN	Opening our Procedures at EMA to Non-EU authorities
OTS	off-the-shelf (studies)
PACMP	post approval change management protocols
EU PAS register	European Union electronic Register of Post-Authorisation Studies
PASS	Post-authorisation safety study
PAVM	EMA-Partnerships for African Vaccine Manufacturing
PBT	Persistent bioaccumulative and toxic substance
PCO	patients' and consumers' organisation
PCWP	Patient and consumer working party
PDCO	Paediatric Committee
PECP	performance evaluation consultation procedure
PHE	public health emergencies
PHECT	Public Health Emergency Clinical Trials
PhV	Pharmacovigilance
PhVWP	Pharmacovigilance working party
PIC/s	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PIP	Paediatric investigation plan
PK/PD	Pharmacokinetic/Pharmacodynamic
PLM	Product Lifecycle Management Value Stream
PMF	Plasma master file
PMS	Medicinal Product Management System
PO	Product Owners
POC	Point of Contact
POEG	CTIS Member State Product Owners Experts Group
PPD	protected personal data
PPHOVA	Pilot project on harmonisation of old veterinary antimicrobials
PPMT	Public Procurement Management Tool
PQKMS	Pharmaceutical Quality Knowledge Management System
PRAC	Pharmacovigilance Risk Assessment Committee
PRIME	PRIority MEdicine, a scheme to foster the development of medicines with high public health potential
PROM	CHMP's preparatory and organisational matters meeting
P-SMEG	Pilot Signal Management Expert Group
PSUR	Periodic safety-update report

Term/abbreviation	Definition
PSUSA	PSUR single assessment
Q (1, 2, 3, 4)	Quarter (1, 2, 3, 4)
QWP	Quality Working Party
R&D	Research and development
RACI	Responsible, Accountable, Consulted, Informed
RDCA-DAP	Rare Disease Cures Accelerator-Data and Analytics Platform
REA	Relative effectiveness assessment
RFI	Request for information
RMS	Referentials Management Services
RPA	Robotic Process Automation
RSS	Regulatory Science Strategy
RWD	Real world data
RWE	Real-world evidence
SA	Scientific advice
SAFe	Scaled Agile Framework
SAG	Scientific Advisory Group
SAWP	Scientific Advice Working Party
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SME	Small and medium-sized enterprise
SmPC	Summary of product characteristics
SMS	Substances Management Services
SNE	Seconded national expert
SPC	Summary of product characteristics
SPOC	Single point of contact system on availability/shortages in human and veterinary agencies in the EU
SPOR	Substances, Products, Organisations, Referentials
SRA (WHO)	Stringent Regulatory Authority
SSA	Signal and Safety Analytics
STOA	Panel for the Future of Science and Technology (European Parliament)
SUMMA	see EC SUMMA
SUSAR	Serious unexpected suspected adverse reaction
SWP-V	Committee for Veterinary Medicinal Products (CVMP) Safety Working Party
TA	Temporary agent
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TDA	EMA Data Analytics and Methods task force
TDT	EMA Digital Business Transformation task force
TF	Task force
TF AAM	EMA/HMA joint task force on availability of authorised medicines for human and veterinary use
TLM	Technology Lifecycle Management and Information Security Value Stream

Term/abbreviation	Definition
TRACES	European Commission's online platform for sanitary and phytosanitary certification required for the importation of animals, animal products, food and feed of non-animal origin and plants into the European Union, and the intra-EU trade and EU exports of animals and certain animal products
TRIP	Topic Relations Information Perspective
TRS	EMA Regulatory Science and Innovation Task Force
UAT	User Acceptance Test
UI	User interface
UPD	Union product database
UPhV	Veterinary Union pharmacovigilance
US	United States of America
UX	user experience
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VMP	EU Vaccines Monitoring Platform
VSIAG	Veterinary System Improvement Advisory Group
WG	Working group
WHO	World Health Organization
WOAH	World Organisation for Animal Health
XEVMPD	Extended EudraVigilance medicinal product dictionary