EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Annex 1

17 June 2019
EMA/30394/2019

EMA activities, other than the highest priority activities (category 1 activities), that will continue in 2019[1]

Theme 1: **Contributing to human health**

Objectives	Initiatives
• Focus on key public health priorities including availability of medicines and antimicrobial resistance (AMR)	• Contributing to European and international initiatives and collaborations in the area of AMR (TATFAR initiative, EC Action Plan on AMR, WHO Global Action Plan, OIE strategy) • Ensuring the needs of children are met by supporting activities related to innovation, early dialogue and research for paediatric medicines • Enhancing the ability to respond quickly to public-health emergencies by facilitating early introduction of appropriate treatments or preventive measures • Minimising the risk and impact of shortages due to manufacturing problems/quality defects by implementing a revised action plan, providing support to the EMA/HMA Task Force on availability of medicines and providing timely input on product specific issues to the European Observatory on the supply of medical radioisotopes
• Ensure timely access to new beneficial and safe medicines for patients	• Reducing time-to-patient of novel medicines through the development/enhanced collaboration with organisations such as EUnetHTA, HTAN, HTA/pricing and reimbursement bodies in the area of parallel

[1] These activities have been grouped as per the European Medicines Regulatory Network strategy to 2020 which guides the EMA multi annual work-programming

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Objectives	Initiatives
	regulatory-HTA scientific advice • Supporting effective and efficient conduct of pharmacovigilance through product related support as regards planned access to and analysis of real-world data, and conducting planned surveillance using patient registries • Capturing and incorporating patients' values and preferences into the benefit/risk evaluation of the scientific review process
• Support patient focussed innovation and contribute to a vibrant life science sector in Europe	• Facilitating the translation of innovation into medicinal products through streamlining interaction with academia • Strengthening collaboration with EUnetHTA, HTAN, HTA/pricing and reimbursement bodies to facilitate exchange between regulators and downstream decision makers • Identifying areas in need of further science and innovation support for medicines development • Providing adequate product related regulatory support to innovation stemming from SMEs and academia by taking the necessary supportive measures
• Strengthen regulatory capability and transparency	• Strengthening pharmacovigilance capability across the network in the fields of signal management and activities directly related to the EMA/HMA Big Data Task Force

Activities added in Q3-Q4 2019

Objectives	Initiatives
• Focus on key public health priorities including availability of medicines and antimicrobial resistance (AMR)	Depending on resource availability: • *Activities relating to EC/EMA Action Plan on the 10-year report on the Paediatric Regulation.*

Theme 2: Contributing to animal health and human health in relation to veterinary medicines

Objectives	Initiatives
• Increase the availability of veterinary medicines and promote the development of innovative medicines and new technologies	• Providing a clear framework to industry on the classification and incentives for the authorisation of products for MUMS/limited markets • Providing support to the EMA/HMA Task Force on availability of medicines • Developing a strategy and action plan to support retention on the market of long-used veterinary antimicrobials • Promoting access to the Agency's Innovation Task Force • Developing/implementing regulatory guidance in priority areas for new technologies
• Promote "Better Regulation"	• Providing technical support to the European Commission in drafting implementing and delegated acts specified in the new veterinary medicines legislation • Supporting efficient and effective conduct of pharmacovigilance by ensuring appropriate guidance, IT tools and data to allow effective signal detection • Providing high-quality and consistent scientific outputs through the finalisation of CVMP assessment report templates and training on their use
• Focus on key public and animal health priorities including AMR	• Contributing to minimising the risk to man/animals from the use of antibiotics in veterinary medicine by continuing data collection on antimicrobials in veterinary medicine and by providing scientific advice to the European Commission on optimising the use of antimicrobials in veterinary medicine • Supporting increased availability of veterinary medicines by working with the European Surveillance Strategy Group to review existing approaches/systems for shortage management

Activities added in Q3-Q4 2019

Objectives	Initiatives
• Promote “Better Regulation”	Depending on resource availability: • *Activities relating to the preparation for implementation of the new veterinary legislation in Q3-Q;* • *Activities relating to availability of veterinary medicines.*

Theme 3: Optimising the operation of the network

Objectives	Initiatives
• Reinforce the scientific and regulatory capacity and capability of the network	• Ensuring "fit-for-purpose" scientific capability of the network by identifying gaps in expertise and providing continuous training through the EU NTC in accordance with an agreed action plan • Ensuring optimal organisation of the available expertise in the network for EMA activities by monitoring/improving the Multi National Assessment Team approach
• Strive for operational excellence	• Optimising the current regulatory framework by ensuring efficiency of the existing regulatory operations through improvements to the EMA (support) activities
• Ensure effective communication of and within the network	• Running necessary communication initiatives to support achieving strategic goals by implementing the EMA communication strategy to 2020 and developing the new 5 year strategy
• Strengthen the link with other authorities and with stakeholders	• Involving civil society representatives more on product related aspects to further integrate clinical practice and real-life experience of disease and its management along a medicine's lifecycle

Activities added in Q3-Q4 2019

Objectives	Initiatives
• Reinforce the scientific and regulatory capacity and capability of the network	• Restart of GMDP-IWG, GCP-IWG, PhV-IWG, QWP and PAT team meetings. Depending on resource availability: • *Initiatives relating to the Regulatory Science Strategy;* • *Preparation of the EU Medicines Agencies Network Strategy to 2025.*
• Strive for operational excellence	• Initiatives relating to increasing efficiency of the processes for initial marketing authorisations for human products (e.g. IT systems); • Initiatives relating to increasing efficiency of administrative processes (increased

Objectives	Initiatives
	digitalisation). Depending on resource availability: • *Activities relating to the preparation for the implementation of the medical devices legislation;* • *Activities relating to the implementation of the General Data Protection Regulation.*
• Ensure effective communication of and within the network	Depending on resource availability: • *Activities relating to EC's report to improve product information.*
• Strengthen the link with other authorities and with stakeholders	• Restart of Patient and Consumer Working Party (PCWP) and Healthcare Professional Working Party (HCPWP) meetings.

Theme 4: Contributing to the global regulatory environment

Objectives	Initiatives
• Convergence of global standards and contribution to international fora	• Involving non-EU regulators in specific inspections to observe GCP/GMP inspections • Facilitating effective information-sharing by using international electronic standards for product specific exchanges
• Ensure best use of resources through promoting mutual reliance and work-sharing	• Expanding work-sharing and mutual-reliance initiatives by supporting the European Commission with the implementation of the MRA with the US • Increasing product-related information-sharing between regulators responsible for the conduct of clinical trials/pharmacovigilance activities • Improving existing mechanisms for sharing/exchanging information with other regulators on products throughout their lifecycle

Activities added in Q3-Q4 2019

Objectives	Initiatives
• Convergence of global standards and contribution to international fora	Depending on resource availability: • *Activities relating to the International Coalition of Medicinal Regulatory Authorities (ICMRA).*