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Stakeholders and Communication

EMA action plan for small and medium-sized enterprises (SMEs)

1. Background

In accordance with the EU Medicines Agencies Network Strategy to 2020[1], the EMA is reviewing whether it provides adequate support and an appropriate regulatory environment for those that drive innovation including SMEs and academia.

The 2015 report on the 10th anniversary of the SME initiative[2] reviewed the experience with EMA's initiative to support SMEs, accumulated over a decade since Commission Regulation (EC) No 2049/2005[3] was implemented.

It highlighted the experience and good practices and the many measures already put in place by EMA to support SMEs throughout the medicines development lifecycle, examined current and future challenges, and called for an action plan to be developed.

The importance of SMEs as pharmaceutical innovation operators is recognised, and the SME action plan forms part of the Agency's broader objectives of supporting innovation in the pharmaceutical sector.

2. Action plan

This action plan builds on existing measures introduced to support SMEs pursuant to Commission Regulation (EC) No 2049/2005. It has been drawn up taking into account SMEs stakeholders' feedback[4,5], as well as recent EMA initiatives designed to reinforce support to innovation e.g. PRIME[6], framework for collaboration with academia[7].

It outlines a series of objectives and actions grouped by theme, which were identified in the EMA 10-year report and the SME survey, and where support and engagement is considered important to advancing EMA's mission for SMEs over 2017-2020.

The plan aims to address the challenges identified by SMEs and their stakeholders through actions focusing on communication and cooperation.

[1] EU Medicines Agencies Network Strategy to 2020
[2] Report on the 10th anniversary of the SME initiative
[3] Commission Regulation (EC) No 2049/2005
[4] Report on the European Medicines Agency roundtable meeting with stakeholders - 10th anniversary of the SME initiative
[5] Outcome of SME office survey on the implementation of the SME regulation - Commission Regulation (EC) No 2049/2005
[6] European Medicines Agency priority medicines scheme
[7] Framework of collaboration between the European Medicines Agency and academia

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The plan includes new and enhanced actions, which capitalise on the synergies between EMA, the EU network and international stakeholders, and the achievements to date.

The actions address the following challenges identified through SMEs stakeholders' consultations:

1. awareness of the EMA SME initiative
2. training and education
3. support to innovative medicines' developments
4. engagement with SMEs, EU partners and stakeholders

The plan does not contain any action that would require changes to the Commission Regulation (EC) No 2049/2005.

It consists of a series of 16 cross-Agency actions. Implementation of the plan will be monitored through dedicated contact points across the operational divisions.

Key challenges that SMEs face in all phases of their lifecycle with regards to funding, cost of regulation and reduction of regulatory burden, identified in SMEs stakeholders' consultations are addressed through actions planned at EU level[8,9]. The measures aim to promote innovation, unlock potential investments and help small and medium-sized enterprises to grow.

Progress on the actions identified in the plan and other actions which impact SMEs will be reported in the EMA annual report, with details in the dedicated EMA Annual SME report[10].

[8] Upgrading the Single Market: more opportunities for people and business, COM(2015) 550 final
[9] Europe's next leaders: the Start-up and Scale-up Initiative, COM(2016)0733 final
[10] Implementation to consider business continuity plans and operations and relocation preparedness

3. Themes, objectives and actions

3.1. Theme: Raising awareness of the EMA SME initiative to stakeholders in the innovation lifecycle

Objective	Actions	Stakeholder/Partner	Timelines
Expand outreach to newly created innovative pharmaceutical companies by collaborating with public and private organisations and networks.	1. Engage with stakeholders such as biotech incubators, universities, innovation clusters, biobanks, the Europe Enterprise Network, public and private investors to raise awareness of the SME initiative among their stakeholders, members and innovating enterprises. *Enhanced* e.g. participation in events or conferences that raise awareness of SME programmes available at EU level, interaction with regional bio-clusters.	Industry stakeholders Academia EU partners[11]	2018-2020
	2. Increase awareness of EMA support services. *Enhanced* e.g. enhancing areas of the EMA corporate website of interest to SMEs (training or conferences), use of social media and professional web-based networking platforms to promote effective dialogue and public consultation.	Industry stakeholders Academia EU partners International partners	2018-2020
	3. Enhance public information on innovative SMEs. **New**	Industry stakeholders Academia	2019

[11] Includes EU institutions and Agencies

Objective	Actions	Stakeholder/Partner	Timelines
	e.g. include in the SME public register areas of emerging innovation and SMEs experience with regulatory procedures such as PRIME, orphan designations, scientific advice and marketing authorisations.		

3.2. Theme: Developing regulatory knowledge base of SMEs in the pharmaceutical sector

Objective	Actions	Stakeholder/Partner	Timelines
Strengthen training of SMEs to improve regulatory knowledge and facilitate the uptake of regulatory and development support tools and compliance with legislation.	4. Increase training through multiple channels. *Enhanced* e.g. e-learning modules, webinars on topics with SMEs interest (e.g. PRIME, advanced therapies, orphan medicines) or new legislation (e.g. clinical trials, medical devices, veterinary medicines).	Industry stakeholders Academia	2017-2020
	5. Expanding outreach of the EU Network Training Centre EU-NTC in relevant areas. **New**	Academia	2020

3.3. Theme: Fostering pharmaceutical innovation for human and veterinary medicines

Objectives	Actions	Stakeholder/Partner	Timelines
Implement the EMA framework for collaboration with academia in light of their role in pharmaceutical innovation and seeding SMEs creation.	6. Guide academic sponsors to seek scientific advice early in development and review opportunities for fee incentives. **New**	Academia	2018-2019
Maximise effective use by SMEs of regulatory tools to promote the development, authorisation and access of medicines for unmet medical needs (e.g. PRIME Scheme, qualification of novel methodologies for medicines' development, EMA-HTA parallel scientific advice, conditional marketing authorisation).	7. Promote the use of regulatory development support tools in early briefing meetings with SMEs and regulatory advice for PRIME qualified medicines. *Enhanced*	Industry stakeholders	2017-2020
	8. Encourage the uptake of the PRIME scheme through 'model/sample applications'. **New**	Industry stakeholders Academia	2018
Enhance cooperation with DG Research and IMI in SME activities.	9. Promote research supported by Horizon 2020 and Innovative Medicines Initiative (IMI), in particular its SME instruments. *Enhanced* e.g. participation in events or conferences.	Industry stakeholders EU partners	2017-2020
	10. Support DG Research and IMI in horizon-scanning of innovation in SMEs and academia.	EU partners	2017-2020

Objectives	Actions	Stakeholder/Partner	Timelines
	New e.g. sharing of information on emerging trends in innovation.		
Foster innovation and the use of new approaches in the development of innovative medicines for human and veterinary use.	11. Promote the Innovation Task Force as a platform for early regulatory and scientific dialogue on innovative human and veterinary medicines and projects subject to EU funding. *Enhanced*	Industry stakeholders Academia	2017-2020

3.4. Theme: Engaging with SMEs, partners and stakeholders

Objectives	Actions	Stakeholder/Partner	Timelines
Ensure SME engagement in the implementation of EMA projects.	12. Ensure clear guidance is provided to SMEs during EMA projects implementation. **New** e.g. preparation of SME friendly leaflets in the official EU languages for the ISO IDMP implementation/SPOR project[12].	Industry stakeholders	2017-2020
Engage with SMEs and stakeholders in sectors adjacent to pharmaceuticals (e.g. companion diagnostic technologies, medical technologies industries and digital health) in light of new medical device legislation, advances in pharmacogenomics and advanced therapies.	13. Encourage the registration of stakeholders in the medtech and digital health sectors with the EMA through targeted communications. **New**	Industry stakeholders	2018-2020
Strengthen existing dialogue with EU Agencies' SME support structures and DG GROW.	14. Establish regular interaction among EU Agencies' SME support structures and DG GROW to exchange best practices in the area of SME policy, including the SME definition, and contribute to EU initiatives supporting SMEs, start-ups and innovation. *Enhanced*	EU partners	2017-2020

[12] International Organization for Standardization (ISO) for the identification of medicinal products (IDMP); substance, product, organisation and referential (SPOR); Link.

Objectives	Actions	Stakeholder/Partner	Timelines
Develop cooperation with the EU Innovation Network.	15. Contribute to the development of the EU Innovation Network's support. **New** e.g. sharing of best practices, exchange of information to support to horizon-scanning of innovation, SMEs outreach and training.	EU partners	2017-2020
Foster cooperation between EMA and international regulatory authorities to increase SMEs awareness of international innovation support programmes.	16. Establish regular interactions between FDA[13] and EMA SME offices. *Enhanced* e.g. yearly meeting to increase information sharing, attendance to events, staff exchange and visits.	International partners	2018-2020

[13] Food and Drug Administration