15 December 2020
EMA/671119/2020
Regulatory Science and Innovation Task Force

Report on the European Medicines Agency roundtable with stakeholders – 15 years supporting SMEs

27 November 2020

1. Introduction

To mark the 15th anniversary of the implementation of the European Medicine Agency's (EMA's) SME regulation[1], EMA held a virtual roundtable meeting with stakeholders on 27 November 2020. The objectives of the meeting were to provide an update on the EU support to SMEs, highlight the achievements of EMA's SME initiative, present the results of an SME survey launched by the Agency in 2020 and exchange views on achievements, challenges and future opportunities to support SMEs and innovation in the pharmaceutical sector.

Representatives of the European Commission (EC), the European Investment Bank (EIB), the EU Agencies Network, industry organisations representing SMEs and service providers in the human, veterinary and medtech sectors participated to the roundtable (see list of participants in annex). Over one hundred SMEs also attended the event.

EMA's executive director Emer Cooke welcomed participants and provided introductory remarks on the emerging European Health Union[2], with the EC Pharmaceutical Strategy for Europe[3] as one of its pillars. The strategy aims to create a 'future proof' regulatory framework and support industry by promoting research and technologies that reach patients and fulfil their needs. She also presented the challenges currently faced by SMEs as reported in a recent survey conducted by SME united[4], while also pointed to the critical role that innovative SMEs are playing in addressing public health needs. SMEs and their role as a driver of innovation were highlighted as well as the importance to consider their needs in future initiatives.

2. EU policies supporting SMEs and innovation (session 1)

In Session 1, DG GROW, DG Research & Innovation (DG RTD) and the EIB, presented the EC SME strategy for SMEs[5] and the extensive range of funding opportunities available to them. Sessions 1 and 2 were chaired and moderated by Constantinos Ziogas, Head of EMA's SME Office.

[1] Commission Regulation (EC) No 2049/2005
[2] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2041
[3] https://ec.europa.eu/health/human-use/strategy_en
[4] https://smeunited.eu/
[5] https://ec.europa.eu/info/sites/info/files/communication-sme-strategy-march-2020_en.pdf

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Maarit Nyman (DG GROW) highlighted that SMEs are the engine of Europe's economy across all ecosystems and represent 99.8% of enterprises in the EU. She presented the priorities set out in the EC SME strategy for sustainable, digital and resilient industrial ecosystems in Europe. This long-term framework for SMEs' economic recovery was adopted in March 2020 and based on three pillars: taking advantage of the 'twin-transitions' digital and green, minimising administrative burdens and improving access to finance.

Stéphane Hogan (DG RTD) presented the evolution of the policy mandate of Horizon Europe (2021-2027), which aims to strengthen the EU's scientific and technological bases and to boost competitiveness. Different funding instruments are available that cover the full innovation lifecycle - technological and commercial. Horizon Europe cluster 1 on health aims to help develop *"an economy that works for people"* by supporting research to make innovative, high-quality health technologies and health care, available and affordable, to citizens. Cluster 1 on health has been allocated a budget of € 6.9 billion and the first calls are expected in spring 2021.

Yu Zhang presented the EIB support to the life science sector, focusing on the venture debt instrument targeting medtech and biotech R&D activities. This is a debt financing instrument with equity features targeting innovative SMEs and mid-caps in the life sciences sector. The instrument allows companies to increase the runway to their next milestone or funding rounds, while limiting dilution and loss of control for company founders. The EIB life science team also focuses its efforts on supporting biotech and medtech companies in vaccines, medicines and diagnostics relevant to the COVID-19.

3. Review of experience with SME initiative (session 2)

In Session 2, EMA provided an overview of the achievements of the SME regulation and the results of the 2020 EMA survey of SMEs. Support to SMEs from the EU regulatory agencies Network was presented by the co-Chair of the EU Innovation Network. SMEs shared their experience with the support and incentives received.

Leonor Enes (EMA SME office) presented the key achievements of the EMA's SME regulation over the last 5 years. She provided an overview of the profile of SME registered and the increased uptake of regulatory support and fee incentives, as well as training, communication and stakeholders' engagement activities. The high figures of registered SMEs and regulatory support, particularly during development (e.g. scientific advice, Innovation Task Force meetings, PRIME scheme) were elaborated. An overview of marketing authorisations, major objections and success rates were presented pointing to more favourable outcomes over the last couple of years. Deliverables of the EMA SME action plan were also presented as well as areas where further actions could be further developed e.g. training, early support to development, engagement with organisations supporting SMEs and innovation.

Laurence O'Dwyer (co-chair of the EU Innovation Network) presented the support available to SMEs through the network of local Innovation Offices, which act as initial contact points for innovators, and offer guidance on regulatory support available at National and European levels.

Clément Provansal (EMA SME office) presented the results of the SME survey launched by EMA's SME office in January 2020 to receive feedback from SMEs and stakeholder organisations on the operation of the SME Regulation. The survey showed that the SME Regulation continues to successfully deliver on its intended objectives and remains relevant to SMEs. The survey also brought up to the need to continue raising awareness of the programme and expand it particularly for regulatory assistance services, training and financial incentives. The top three challenges identified by SMEs were: the administrative and regulatory burden, access to finance and regulatory fees. Support measures to address these challenges are related to reducing the burden of regulation, facilitating access to finance and enhancing regulatory fees incentives.

Representatives from Orchard Therapeutics and Laboratorios Syva, SMEs working in the development of human and veterinary medicines respectively, shared their positive experience with the SME support and guidance received. They found particularly useful the training events organised by the SME Office. Financial incentives covering the product life-cycle and assistance with translations of the product information were also considered extremely valuable.

4. Presentations from industry organisations and discussion (session 3)

The following industry stakeholders, representing SMEs and service providers operating in human, veterinary and medtech sectors, provided feedback on the SME initiative: EuropaBio, EFPIA, Europharm SMC, Alliance for Regenerative Medicines (ARM), Medtech & Pharma Platform (MPP), EUCROF, EUCOPE and EGGVP and AnimalHealthEurope. The session was chaired and moderated by Anthony Humphreys, Head of Research and Innovation Task Force at EMA. The presentations and discussion brought up the following themes:

4.1. EMA SME incentives

The importance and relevance of the SME initiative was acknowledged by participants.

Participants suggested to increase awareness of the SME programme, enhance training, offer earlier and more rapid scientific advice, including the interface with health technology assessment and its focus on real-world-evidence, particularly for orphan medicines.

The PRIME scheme was viewed as highly valuable and the speed of scientific advice for COVID-19 medicines developers highlighted as positive. Enhancing support to the PRIME scheme was suggested in light of lower success rate experienced by SMEs.

Stakeholders proposed to consider making the incentives available to SMEs also available to entities such as universities and non-profit organisations.

Engagement with SMEs during the implementation of legislation was considered as important in addressing the needs of SMEs.

4.2. EU SME definition

Participants highlighted the potential issues of accessing incentives for small high growth European (bio)pharmaceutical companies, which cannot comply with the EU SME definition due to major venture capital investment, while also underlining the needs of (bio)pharmaceutical companies which grow over the thresholds of the SME definition, which may face hurdles experienced by SMEs.

4.3. Medical devices

Participants mentioned the need for multi-stakeholder dialogue to support the implementation of new medical device regulations, including the interface with the clinical trials regulation. Industry organisations suggested to consider SME incentives for companies operating in the medical devices sector when implementing the new regulations.

4.4. Veterinary medicines

Veterinary stakeholders presented the results of an SME survey conducted in 2020. Results showed that fee incentives and translation assistance are the most useful services. Regulatory advice by EMA

was considered relevant and communication materials highly rated. It was noted that there is a high number of SMEs amongst veterinary medicines marketing authorisation holders, with however few registered at EMA. The need to raise awareness on SME incentives through targeted communications and provide dedicated training for veterinary SMEs was suggested.

4.5. 'COVID-19' lessons

Participants welcomed the regulatory flexibilities recently introduced by regulatory authorities in the context of COVID-19 and expressed the hope that these would be continued in the post COVID-19 environment.

Industry stakeholders suggested to improve SMEs access to funding and consider measures to incentivise sourcing of active substances in the EU with a view to minimise medicines shortages and enhance competitiveness of SMEs operating in manufacturing and supply chains.

5. Conclusions

The importance and relevance of the SME initiative was acknowledged by all participants during the roundtable meeting.

Raising awareness of SME incentives and enhancing certain services such as regulatory assistance, training and fee incentives were identified. Reducing the burden of regulations and improving access to finance were also mooted. The need for early and rapid advice, and the interplay with health technology assessment, medical devices and clinical trials was underlined.

Addressing the needs of small high growth companies with major venture capital investment and those growing beyond the SME thresholds were raised. Suggestions were also made on support to universities, non-profit organisations, and companies operating in the medical devices sector and manufacturing and supply chains.

Engagement with SMEs during the implementation of new regulations was viewed as important in addressing the needs of SMEs.

EMA concluded the meeting by thanking participants for contributing to the success of the SME programme. EMA will continue to support SMEs and engage in a dialogue on future initiatives that support SMEs and innovation in the pharmaceutical sector.

A report on the 15-year experience of the SME initiative will be published in 2021. Priority actions targeting SMEs will be developed taking into account the EC pharmaceutical and SME strategies, and the EU Network and Regulatory Science strategies to 2025.