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Corporate Stakeholders Department-SME Office

Report on the European Medicines Agency roundtable meeting with stakeholders - 10th anniversary of the SME initiative

27 November 2015

1. Introduction

To mark the 10th anniversary of the implementation of Commission Regulation (EC) No 2049/2005 ("SME Regulation"), the Agency held a meeting with representatives of stakeholder organisations on 27 November 2015. The aim of the meeting was to provide an update on the SME initiative 10 years after its inception, to present the results of a follow-up SME survey conducted by the Agency in September 2015, and to share experience and enable exchange of views on achievements, challenges and future opportunities for SMEs.

2. Review of experience with SME initiative

The meeting started with keynote speeches from the European Commission (DG SANTE, DG Research and Innovation and DG Growth).

- **DG SANTE – Andrzej Jan Rys**

Andrzej Jan Rys presented the background for introducing a European framework for supporting SMEs in the pharmaceutical sector and the legal instruments introduced (the "SME Regulation", Regulation (EC) No 658/2014 on fees payable to EMA for the conduct of pharmacovigilance activities in respect of medicinal products for human use and Regulation (EC) No 1394/2007 on advanced therapy medicinal products). The overall objective is to provide tailor-made provisions to support innovation emerging from smaller enterprises and provide financial and administrative assistance for SMEs throughout the medicinal product development lifecycle. Upcoming changes to the legal framework were highlighted, in particular the proposed revision of the regulation on veterinary medicinal products, which includes proposals to establish national helpdesks dedicated to SMEs.

- **DG Research and Innovation – Antoine Mialhe**

The changes of the EU Research and Innovation programmes available for SMEs over the years were presented, underlining the importance of European public funding in addressing research on societal and public health themes. Compared with the Seventh Framework Programme (FP7; 2007-2013), the EU budget allocated for SMEs has increased under the Horizon 2020 programme together with changes to targeted applicants. Whereas EU funding used to be mainly dedicated to support early research and

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development projects, the projects supported under the Horizon 2020 programme now concern all stages of development, targeting technology push and market pull perspectives. An overview of the EU support available for SMEs through Horizon 2020 programme was also presented, underlining the major barriers which were eased for SMEs applying to research calls. One of the major landscape changes of Horizon 2020 programme was the introduction of a dedicated SME instrument that addresses the financing needs of European SMEs developing innovative projects with high potential. A study on EU funded SMEs showed encouraging signs of an increasing number of SMEs supported by EU funding, which are being listed on European markets. The report also highlighted that a significant number of EU funded SMEs are being registered with the EMA with a view to engage in a dialogue with regulators.

- **DG Growth – Krista De Spiegeleer**

Krista De Spiegeleer provided an overview of EU policies supporting SMEs. The principles behind the Small Business Act for Europe (SBA) to promote the "Think Small First" principles in law and policy making were explained, which aim to strengthen the competitiveness of SMEs and to promote entrepreneurship. The subsequent reviews of the SBA included new instruments such as the SME envoys and the SME Assembly, and more recently a focus on "Skills development". The Regulatory Fitness and Performance Programme (REFIT), a programme aimed to set up a simpler regulatory environment was also presented. It is part of the European Commission's "Better Regulation" programme, which aims to increase transparency and stakeholder engagement initiatives in regulation. The key actions of the "Single market strategy", which will create better opportunities for SMEs and start-ups to grow, and COSME, the EU programme for SMEs to access finance, were also outlined. Improving access to finance through equity and debt tools and access to market are key objectives of COSME. The information on the various financial instruments is now consolidated under one dedicated webpage (Link).

The SME Office of the European Medicines Agency presented the 10 year milestones of the implementation of the SME Regulation and the results of a SME survey.

- **European Medicines Agency's SME Office (EMA) – Constantinos Ziogas**

An overview of the achievements of the SME Office since its launch in 2005 was presented. The SME Office detailed the uptake of fee incentives, regulatory assistance and assistance for translation of product information, while highlighting the low figure of certification issued for advanced therapies. The training and workshops dedicated to SMEs were described as well as the public SME register, which is now also used by SMEs and stakeholders as a partnering and networking tool. The experience of SMEs registered at the EMA operating in the human and in the veterinary sector with the marketing authorisation process was also shared. It is encouraging to note that, there is a significant uptake of the range of scientific advice now available, including biomarker qualification and parallel advice with Health Technology Assessment (HTA) bodies, and that the success rate of SMEs in the marketing authorisation process is now approaching the average for all applicants. Areas for further developments within the SME regulation include engaging with wider stakeholders in pharmaceutical innovation, for example academia as they represent an important source of innovation, enhancing guidance and systems for SMEs to seek assistance, and developing synergies with organisations supporting SMEs.

- **European Medicines Agency's SME Office (EMA) – Angela-Christina Schmidt**

The results of the SME survey conducted by the Agency in September 2015 were presented. The aim of this follow-up survey was to evaluate the experience gained with the SME initiative at the EMA since its implementation 10 years ago. Another objective was to receive feedback from SMEs and stakeholders on the current and future challenges faced by SMEs and to identify areas for further development of the Agency's support dedicated to SMEs. It is interesting to note that access to market is a new challenge that emerged from the survey and that SMEs underlined the need to further expand procedures such as parallel scientific advice with HTA bodies. Another emerging challenge for SMEs is

the recruitment of qualified people and the need to provide training and access to relevant information to keep their knowledge base up-to-date.

A SME company, Cell Therapy Ltd, shared its experience with the services offered to SMEs by the Agency.

- **Cell Therapy Ltd – Ajan Reginald**

Cell Therapy Ltd described the different occasions on which it has engaged in dialogue with the EMA, and received support in the early stages of development of an advanced therapy medicinal product. These included orphan designation, the paediatric investigation plan, advanced therapies certification, regulatory advice and support from the SME Office and the Innovation Task Force. Cell Therapy Ltd is a SME, which aims to register and commercialise product, and the relevance of the advice provided to SMEs and the possibility for iterative dialogue were considered invaluable in achieving this goal. The company sought advice from international regulatory authorities and highlighted the need to engage regulators in dialogue at a global level as an area where further developments would be welcome.

3. Roundtable discussion

Following the review of experience with the SME initiative, stakeholders had the opportunity to introduce their organisation and to provide feedback on the SME initiative.

Industry stakeholder organisations acknowledged the importance and the relevance of the SME initiative and of the support provided by the SME Office. A good level of satisfaction was received in particular on the fee incentives, the regulatory support from EMA staff, and on the translation assistance provided by the EMA. Initiatives to increase awareness on the regulatory framework, such as the SME user guide, the SME newsletter and the dedicated workshops that are organised by the EMA, were also mentioned as being particularly useful for SMEs.

The following themes emerged during the discussion:

3.1. Implementation of the SME regulation

Industry stakeholder organisations highlighted areas which could be developed within the framework of the SME regulation. An interest in increased training and workshops for SMEs was mentioned. This could be addressed through additional information sessions, including webinars to facilitate participation of SMEs. It was also suggested that the EMA liaises with the Member States' National Competent Authorities to provide specific training, e.g. on Eudravigilance. For SMEs in the veterinary field, training and fee reductions for marketing authorisations were raised as specific hurdles.

Other suggestions included raising awareness of existing opportunities for more informal dialogue through e.g. SME briefing meetings to discuss regulatory aspects of development programmes and introducing the "only once principle" for data submission relating to regulatory databases.

3.2. SME definition

The thresholds used for the EU SME definition were mooted. It was highlighted that mid-sized companies can face the same difficulties as SMEs in terms of lack of regulatory experience, and would also benefit from incentives offered to SMEs. In relation to funding, the European Commission has introduced a new investment plan for SMEs and mid-cap companies. The Innovative Medicines Initiative (IMI) was also mentioned as another example of EU funding, which has been broadened to address the needs of mid-size enterprises.

3.3. National Competent Authorities Network, International regulatory cooperation

The creation of a network of EU innovation support structures in some National Competent Authorities (NCA) was mentioned as an important initiative to provide a platform for SMEs and innovators to address gaps in regulatory science. Geographical proximity, the ability to engage in dialogue in the local language, and access to assistance in particular on national requirements, were welcomed by SMEs. The network could also be a platform for providing training and workshops opportunities.

The need for enhancing regulatory dialogue between EU, USA and Japan in specific areas such as scientific advice for advanced therapies was discussed. Alignment of requirements would help SMEs to plan the development of their products in a more efficient way.

3.4. Stakeholders' engagement

Industry stakeholders indicated that they would like to be involved at an early stage when legislation is drafted by the European Commission and to be more represented in pilot programmes on new regulations. EU initiatives for enhancing stakeholders' engagement in regulation ('REFIT') were further highlighted as opportunities for dialogue.

Addressing the links between industry and academic stakeholders involved in the wider framework for pharmaceutical innovation was highlighted as an opportunity to be seized.

To enhance visibility of the SME initiative on the EMA website, it was suggested to highlight the activities of the SME Office in a dedicated area. Access to information on EU funding and research was also considered important with guidance from the Enterprise Europe Network (EEN) and National contact points for Horizon 2020 programme to be made more clearly visible and disseminated.

3.5. Market access

Early access tools, such as PRIME, were welcomed by participants. Most participants highlighted the importance of taking a broader view of pharmaceutical innovation and of looking at aspects of market access for medicinal products, in particular for advanced therapies and orphan products. It was acknowledged that the phase between marketing authorisation and patients' access needs to be addressed and that establishing dialogue between regulators and HTA bodies was an important regulatory enabler. Parallel EMA/HTA scientific advice is a priority area for the EMA and SMEs would benefit by receiving further information in this regard.

3.6. Veterinary Medicines

There has been an increase in applications for SME status by companies developing veterinary products over recent years. There is, however, still a relatively low level of awareness of the incentives on offer in the SME regulation for these companies. The new regulation on veterinary medicines including national SME offices will help to address the knowledge gap.

4. Conclusion

The roundtable discussion on the SME initiative provided a platform for stakeholders to look back at the achievements of the last 10 years, and to engage in a dialogue on future initiatives to support SMEs and innovation in the pharmaceutical sector. The importance and relevance of the SME initiative was agreed by all participants and areas for further development of the SME initiative were highlighted. The Agency will continue its cooperation with the European Commission and its engagement with SME stakeholders to support SMEs. The SME Office will publish in 2016 a report on the 10 year experience of SME initiative together with a report on the SME survey.