EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

Survey report – European Medicines Agency (EMA) consultation on the proposal of a collaboration framework with academia

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1. Background and objectives of the survey

There is already a longstanding collaboration between regulators and academia as recognised in the European Medicines Agencies Network Strategy to 2020[1] that outlines joint key priorities and a high-level roadmap to achieve them. Indeed, academia is a recognised source of scientific knowledge and excellence that provides the European medicines regulatory network with expert input to ensure that medicines are evaluated and monitored to the highest scientific standards (regulatory science[2]). Moreover, a recent publication confirms that academic research is at the origin of many of the new medicines being approved in the European Union[3].

In order to ensure that scientific and technical advances efficiently contribute to address the need for patient-focused innovation, as recommended by the European Council[4], the Network Strategy to 2020 identifies key priorities which will need to be implemented in the coming years to 2020. In this context, EMA has identified the priority of strengthening the collaboration with academia and has set off the process of defining a formal framework of collaboration to support its implementation.

EMA reached out to academia to open a dialogue by launching a targeted survey with the main objective of taking a snapshot of the current interaction between academia and regulators at European level, and collect needs and expectations to inform the definition of the framework of collaboration (see Annex 2 for the document that provided background information on the aims of the survey).

The survey should be seen in the context of the preparatory activities that EMA undertook to consult with academic stakeholders. A summary of the survey data was presented during a workshop[5] hosted by the Healthcare Professionals' Organisations Working Party (HCPWP) where a number of survey respondents were invited[6] to further discuss the foundations of the framework of collaboration.

In this concise document we report and discuss the major findings of the survey; the complete survey data can be found in Annex 1.

2. Methodology

The consultation took place from 1 February 2016 to 18 April 2016 through a web-based survey (SurveyMonkey®). The survey's questionnaire consisted of 3 parts: Profiling, Interaction with Regulators and Future Developments (12 questions in total). The survey combined the following response formats, depending on the nature of the question:

- Multiple choice and multiple response
- 4-point Rating Scale (great extent – moderate extent – little extent – not at all)
- 5-point Rating Scale (always – often – sometimes – seldom – never; strongly agree – somewhat agree – neither agree nor disagree – somewhat disagree – strongly disagree).
- Free text

[1] EU Medicines Agencies Network Strategy to 2020
[2] For the purpose of this paper regulatory science is defined as a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine. It encompasses basic and applied bio-medicinal sciences, human sciences and social sciences, and contributes to the development of regulatory standards and tools.
[3] Lincker H., Ziogas C., Carr M., Porta N., Eichler, H. G. Regulatory watch: Where do new medicines originate from in the EU? Nature Reviews Drug Discovery. 2014; 13(2): 92-93.
[4] Council conclusions on innovation for the benefit of the patients, Council conclusion, Brussels, 1 December 2014
[5] Healthcare Professionals' Organisations Working Party (HCPWP) workshop with academia
[6] HCPWP Workshop with academia - list of participants

The invitation to participate to the survey was published on the EMA's website and further disseminated through the EU medicines agencies network, as well as via academic consortia, learned societies, EU biomedical infrastructures, research foundations, targeted emailing, EMA Twitter etc.

A thousand and sixteen (1016) responses were received; of those, eight hundred and seventy seven (877) responses were considered valid (respondents completed at least the basic profiling questions; double entries and for-profit affiliated respondents were cleared).

3. Major findings from the survey

3.1. Profiling

The majority of respondents, 85% (n= 749), answered the questionnaire as individuals and the remaining 15% (n=128) on behalf of their organisation. A summary of the affiliation, the area of activities, and the type of research declared by the respondents is reported in Table 1. The majority of respondents declared affiliation to public universities, university and general hospitals, followed by public and private research institutions; the main areas of activities were medicine, pharmaceutical sciences and biology; clinical research stood out as the most pursued (for more details see Annex 1, questions 2, 4 and 5).

Table 1 - Questions: What is your organisation profile? Please indicate major area(s) of activities; If you conduct research activities, please indicate which type(s).

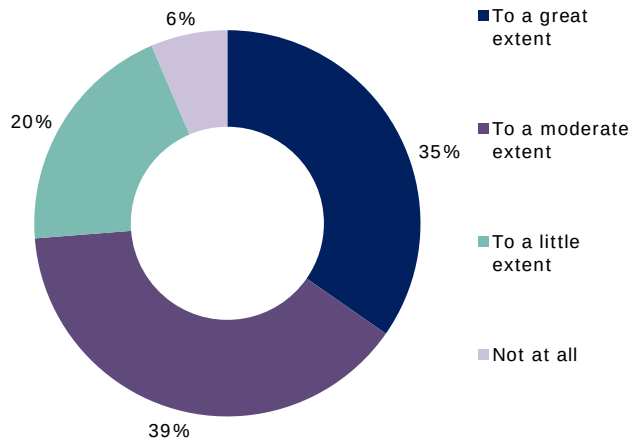
Affiliation	Area of activity	Type of research
• Public universities (n=381) • University hospitals (n=257) • General hospitals (n=133) • Public research institutes (n=114) • Private research institutes (n=51)	• Medicine (n=717) • Pharmaceutical sciences (n=283) • Biology (n=265) • Social sciences and Humanities (n=90) • Chemistry (n=65)	• Clinical research (n=569) • Basic research (n=291) • Pre-clinical research (n=289) • Real-world research (n=245)

The geographic distribution of the respondents extensively covered all of the European Economic Area countries, but it also showed interest in other continents (Asia, North and South America, Africa, Australia). The EU countries with the highest representation were Italy, United Kingdom, Spain, the Netherlands, Germany and France (for more details see Annex 1, question 3).

3.2. Interaction with regulators

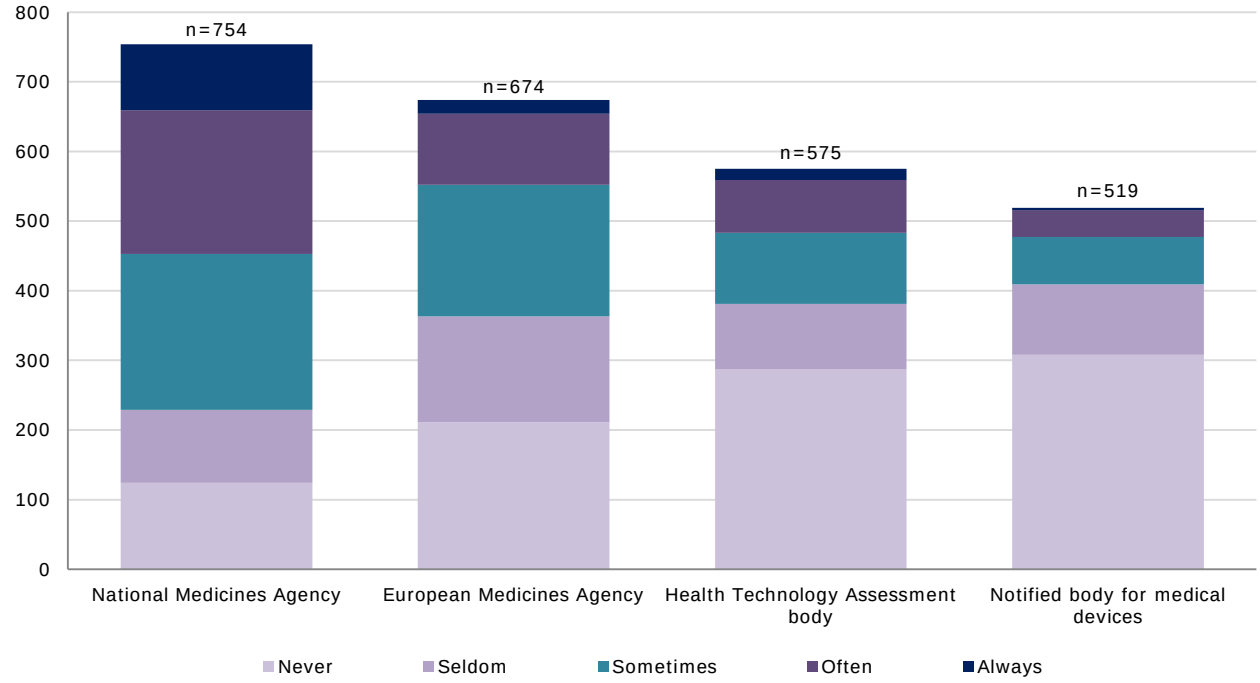
The survey aimed at capturing a snapshot of the current level of interactions between academics and regulators at European level. Overall, the level of awareness of the role and activities of regulators showed that there is space for improvement since full acknowledgement is declared by only 35% of responders (Figure 1: individuals and organisation data pulled together, see Annex 1 for separate figures, question 6). The direct interaction with regulatory bodies sees the National Competent Authorities as having a prominent role, when compared to EMA and health technology assessment (HTA) bodies (Figure 2).

Figure 1 - Question: To what extent are you aware of the role and activities of regulators?



The reasons for interactions showed that more than 50% of respondents provided their expert opinion to regulators during medicines assessment activities. The interactions largely took place via direct contact with the regulators (see Annex 1 for more details, questions 7, 8 and 9).

Figure 2 - Question: Which type of regulatory bodies do you interact with and how often?



Enquiring on the specific interactions with EMA showed that the majority of respondents provided their expertise, while only the minority took advantage of the support that the Agency makes available to medicine research and development (see Table 2).

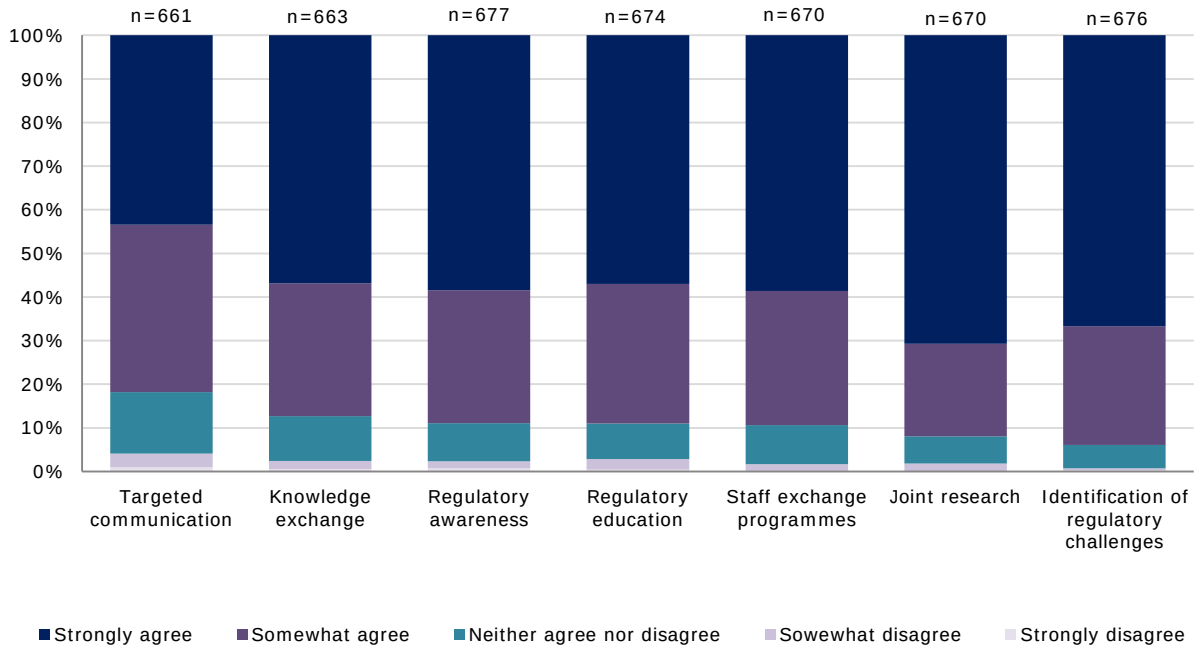
Table 2 - Question: If you have specifically interacted with EMA, what were the reasons?

Reasons for interaction with EMA	
• Provided expert opinion to EMA Scientific Committees and Working Parties (45%; n=165)	• Applied for Orphan Drug Designation (13%; n=47)
• Requested Scientific Advise (32%; n=116)	• Joint publication with EMA (12%; n=42)
• Attended an event hosted by the EMA (32%; n=116)	• Applied for qualification and advice on novel methodologies and biomarkers (8%; n=29)
• Contributed to EMA public consultations (22%; n=80)	• Invited EMA to lecture at University courses (7%; n=25)
• Invited EMA to present at conferences (21%; n=78)	• Applied for Advanced Therapy Classification (5%; n=19)
• Co-participation with EMA in advisory groups of research consortia, projects or other initiatives (21%; n=77)	• Consulted the Micro-, small- and medium-sized-enterprise (SME) Office (2%; n=8)
• Participated in EMA guideline development (16%; n=57)	• Consulted the EMA Innovation Task Force (ITF) (2%; n=8)

3.3. Future developments

The third part of the survey's questionnaire aimed at identifying proposal on how the collaboration between regulators and academia could be enhanced with mutual benefit. The respondents were asked to rate their level of agreement in the areas of education and training, support to research and communication.

Figure 3 - Question: In order to achieve an enhanced, closer collaboration between academia and regulators, what should be pursued?



All proposals received a positive reception since agreement (*strongly agree* plus *somewhat agree*, see Figure 3) scored above 80% for each of them. In particular, the identification of regulatory challenges and the support on offer and participation in research were ranked the highest.

The questionnaire closed with an open text question where the respondents were asked to identify the strength and weaknesses of the current situation and the opportunities and challenges laying ahead. Hundreds of free text comments have been received, and they have been considered testimony of the interest and engagement of the survey respondents. Several key words/concept could be identified; interestingly, the same key word/concept could be ascribed to more than one of the four different categories proposed namely strengths, weaknesses, opportunities, and challenges (see Annex 1, question 12). The wealth and variety of comments captured the complexity of the field but at the same time allowed for the identification of major issues that could be pursued with high priority.

The robustness of the European regulatory framework and its transparency and independency were identified as mayor strengths of the *status quo.* The initiative of the regulators to further strengthen the collaboration with academia via a formal framework was clearly welcomed. A substantial number of comments pointed to the contribution that academia is already providing to the regulatory process and stressed that academia should benefit more from the support offered by regulators.

The major weakness of the present situation was identified as the lack of awareness of the role and activities of regulators among the academic community. Also, a substantial number of comments pointed to the complexity of the regulations and the associated bureaucracy. The dearth of financial incentives for academia and the non-optimal handling of the issue of competing interests were also considered to represent a substantial weakness. Communication was also identified as a feeble area, where many commented that regulators at present preferentially target industry stakeholders. Finally, it was questioned whether EMA would be in a position to fully implement the future framework considering that its interaction with academia was not clearly identified in its mandate.

Research, independent from industry, emerged as the area where the respondents saw the highest potential for exploiting opportunities, including adding a positive dimension to the capacity of academia to secure public research funding and be the natural environment where knowledge exchange and collaboration could thrive. As previously mentioned, communication was identified as in need of strengthening, making it an ideal priority area to invest, together with education and training opportunities. Finally, the capacity of the Agency to provide a platform at European level allowing collaborative stakeholder interactions including patients, healthcare professionals, and industry was considered a very appealing prospect.

The biggest challenges that the respondents identified were the building of an effective working model for enhancing and fostering collaboration and the creation of a space of convergence that would allow for changes in the *modus operandi* on both sides. It was pointed out that it will be a major challenge to strike a balance between the constraints of regulation and the free breathing space of research and innovation. The respondents also pointed to the fact that capacity and financial resources will represent a major challenge on the academic side. Communication emerged again as a key area, where addressing the need to enhance regulatory awareness among academia will need a strategic approach. Finally, the need for further harmonisation and cooperation at national and EU level has been highlighted as something to be addressed to ensure that the framework of collaboration delivers on its promises.

4. Conclusions

The survey provided an informative snapshot of the current interaction between academic stakeholders and EU regulatory bodies. The information gathered was further discussed at the workshop hosted by the Healthcare Professionals' Organisations Working Party (HCPWP) where a number of survey respondents were invited[5,6].

The survey results indicated the need for enhancing awareness of the role and activities of regulators as a means to increase academia's engagement in regulatory science activities and research. Education and training were also identified as crucial areas of collaborative investment, where academia in particular could potentiate its capacity to respond to funders' expectations and shape professionals profiles. Furthermore, the survey respondents strongly agreed on the need for increased regulatory support to help them translate academic research into novel methodologies and medicinal products. Finally, there was a clear indication for the strengthening of communication and knowledge exchange opportunities. This should ensure that the best scientific expertise and academic research continue to be available to support decision making in regulatory processes and that academia is offered a robust, multi-stakeholder platform for dialogue at EU level.

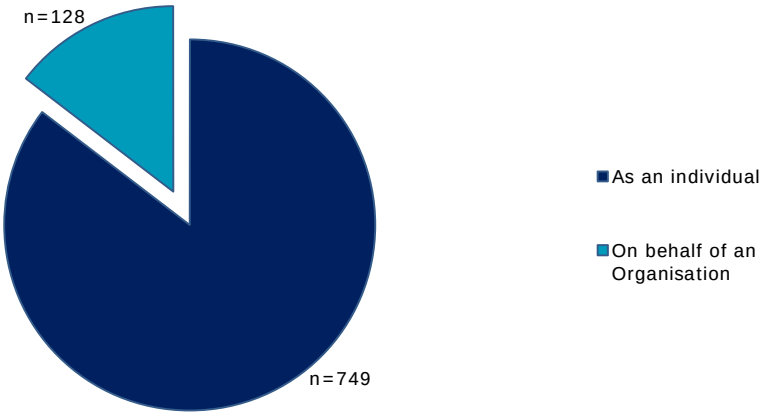
These priorities have been captured in the drafting of the framework and in the list of actions to be implemented once the framework will be formally adopted. The hundreds of written comments that highlighted strengths, weaknesses, opportunities, challenges provided further suggestions for enhancing the collaboration and will allow for the identification of specific issues where targeted action could be envisaged.

Annex 1: Survey data

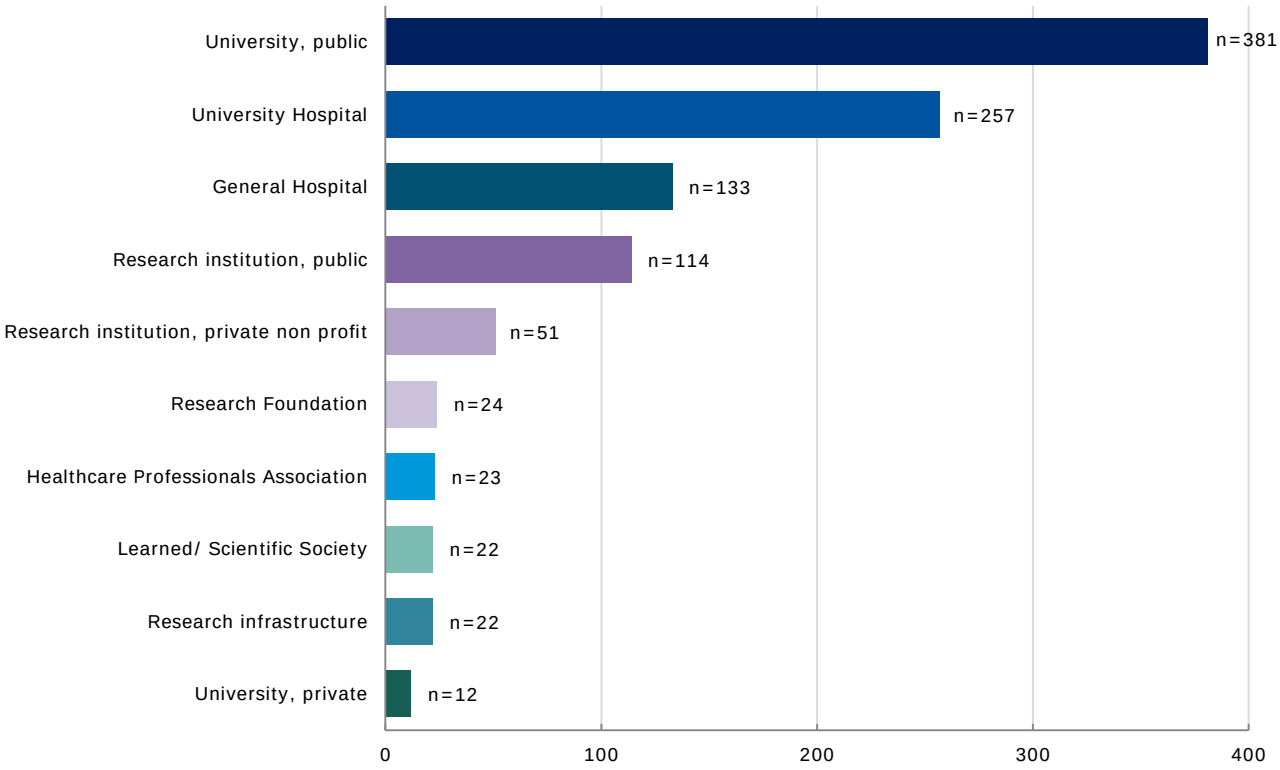
This Annex provides the data relative to all twelve questions proposed in the survey questionnaire. The survey's questionnaire consisted of 3 parts: 1. Profiling, 2. Interaction with Regulators and 3. Future Developments (12 questions in total, see section 2 on methodology).

1. Profiling

Question 1: Are you responding to this questionnaire: a) as an individual b) on behalf on an organisation.

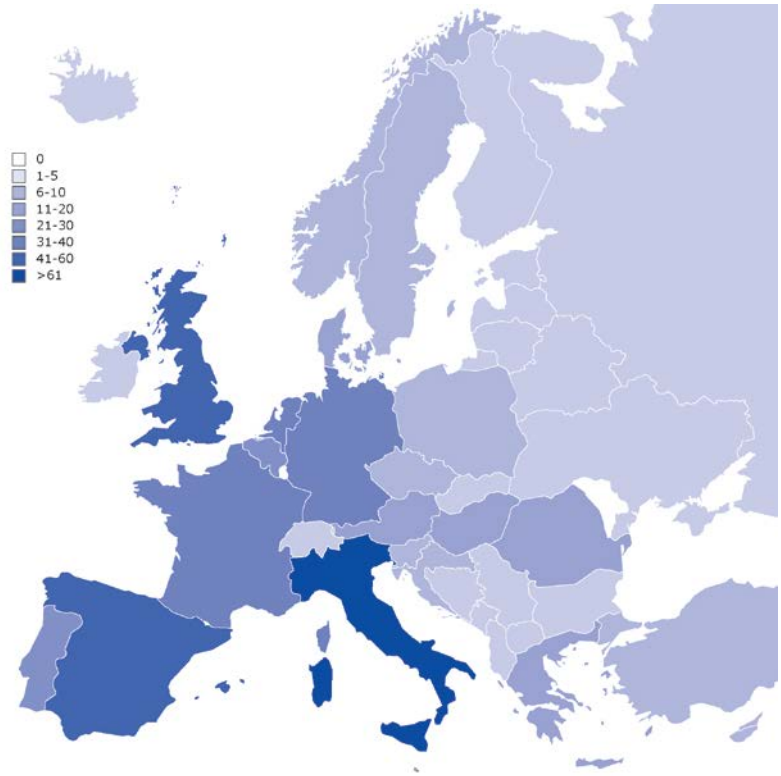


Question 2: What is your organisation's profile?

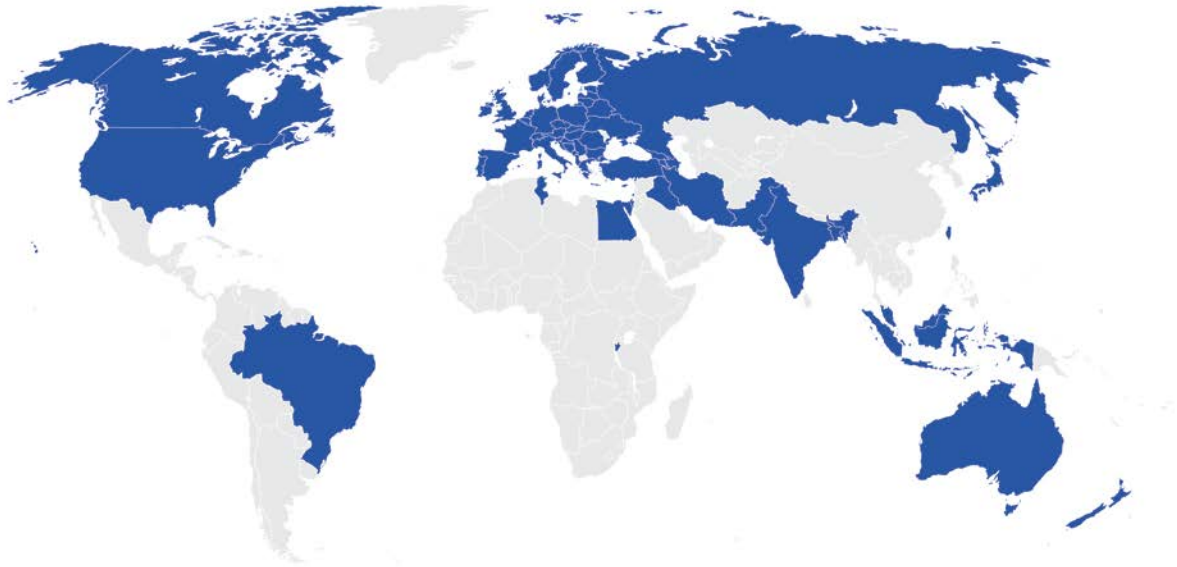


Question 3: Please select the country or countries where activities are carried out (select all that applies).

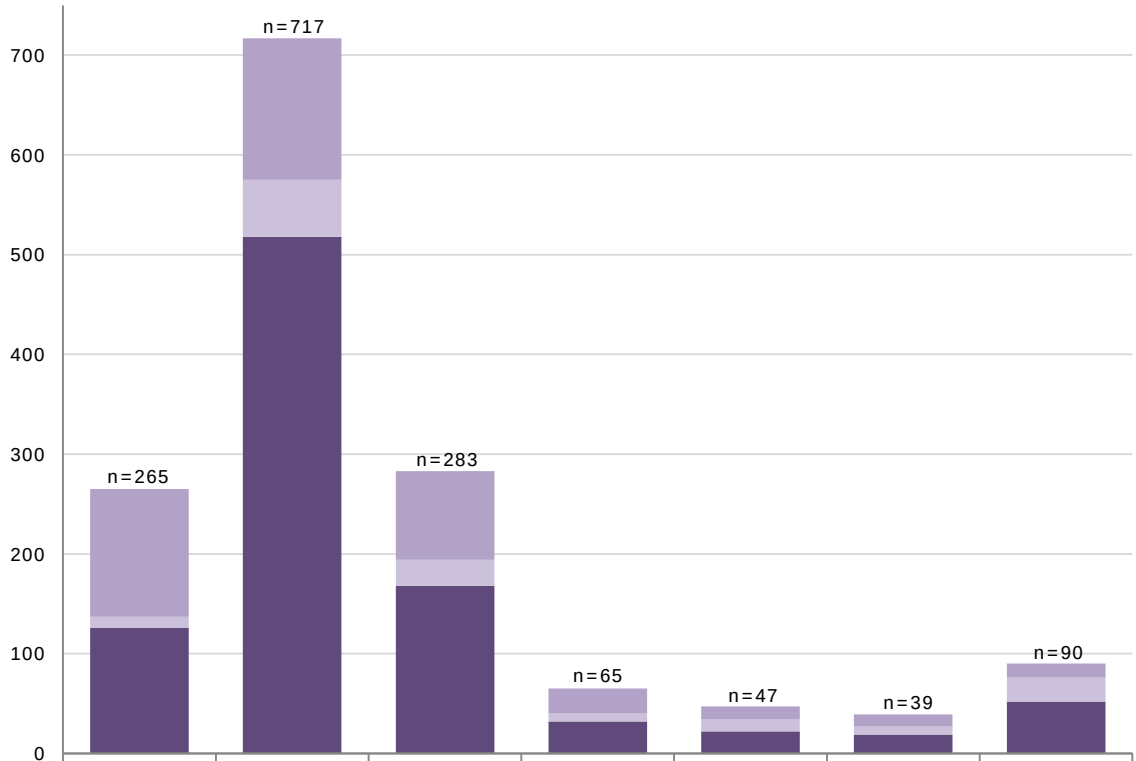
a) European overview (the intensity of the colour reflects the number of respondents, see legend).



b) Global overview (at least one respondent claimed to be active in the country).

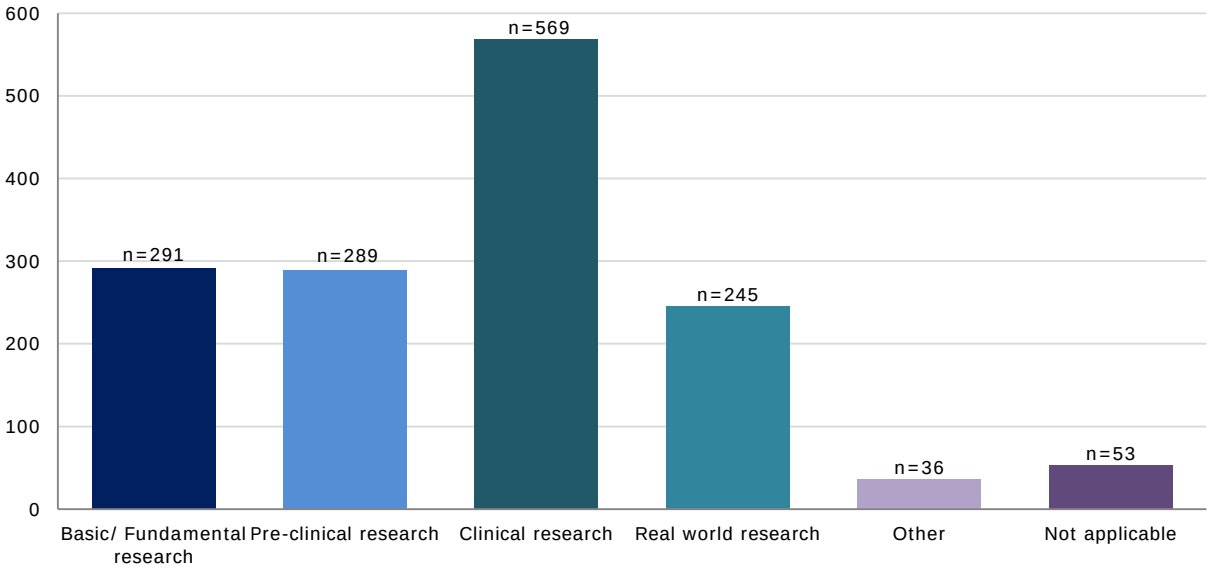


Question 4: Please indicate major area(s) of activities (select all that apply).



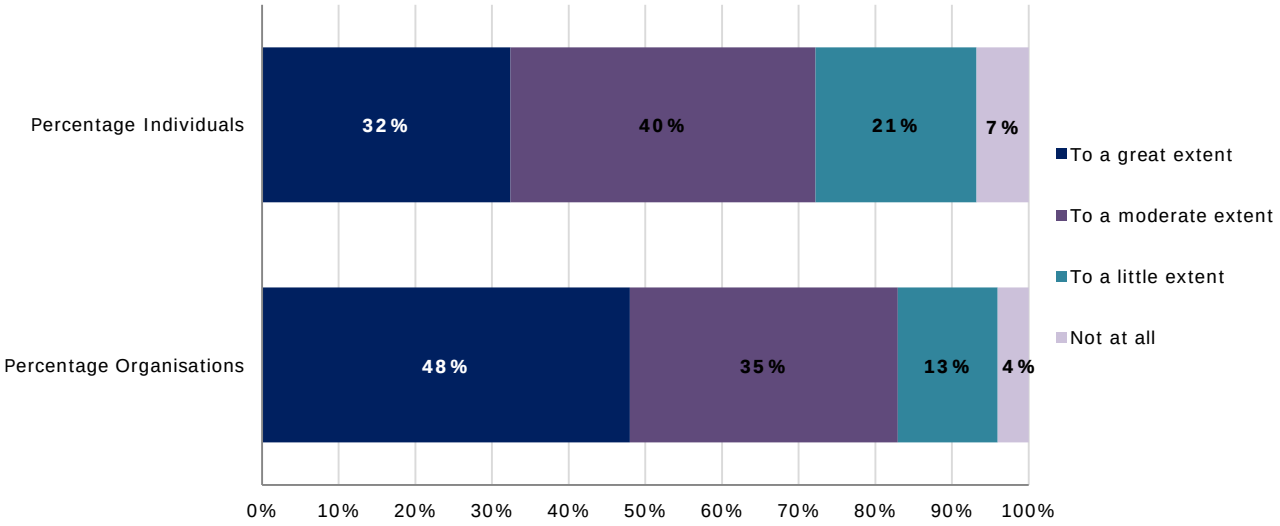
	Biology	Medicine	Pharmaceutical Sciences	Chemistry	Physics	Engineering	Social Sciences and Humanities
Research	128	142	89	25	13	12	14
Education	11	57	26	8	12	8	24
Both	126	518	168	32	22	19	52

Question 5: If you conduct research activities, please indicate which type(s) (select all that apply).

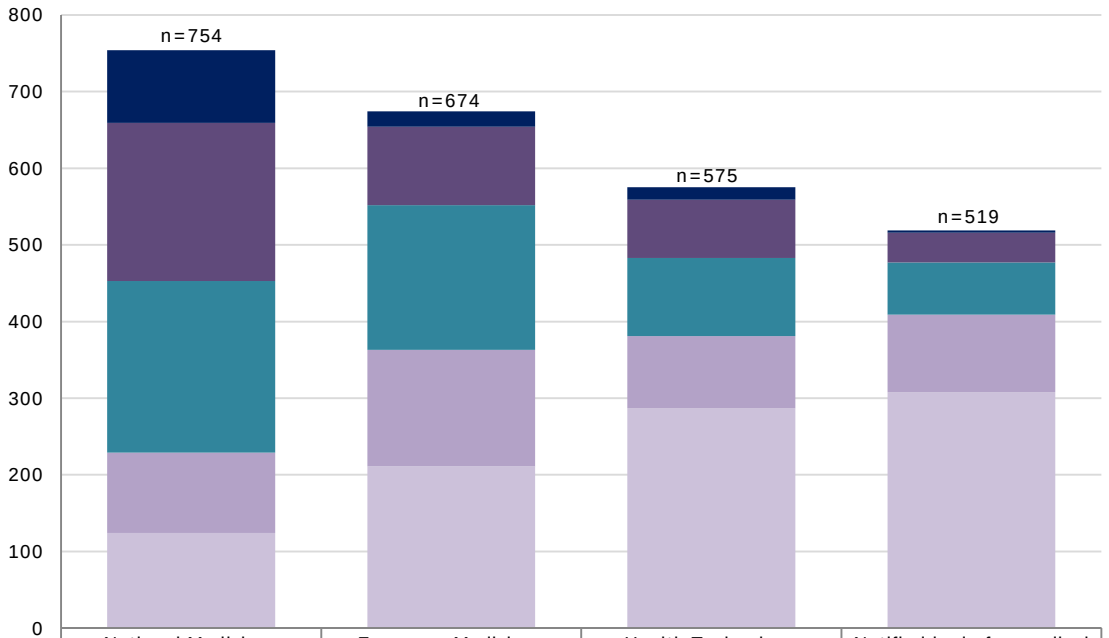


2. Interaction with Regulators

Question 6: To what extent are you aware of the role and activities of regulatory bodies?

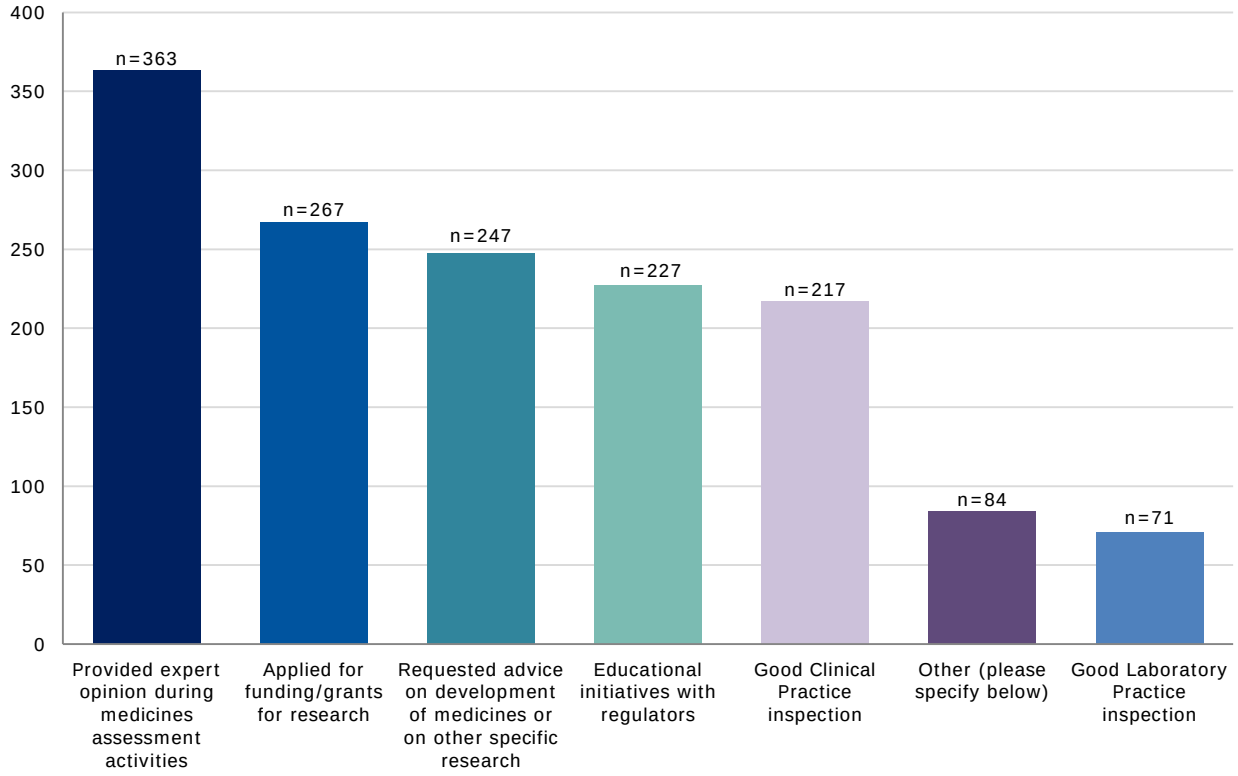


Question 7: Which type of regulatory bodies do you interact with and how often?

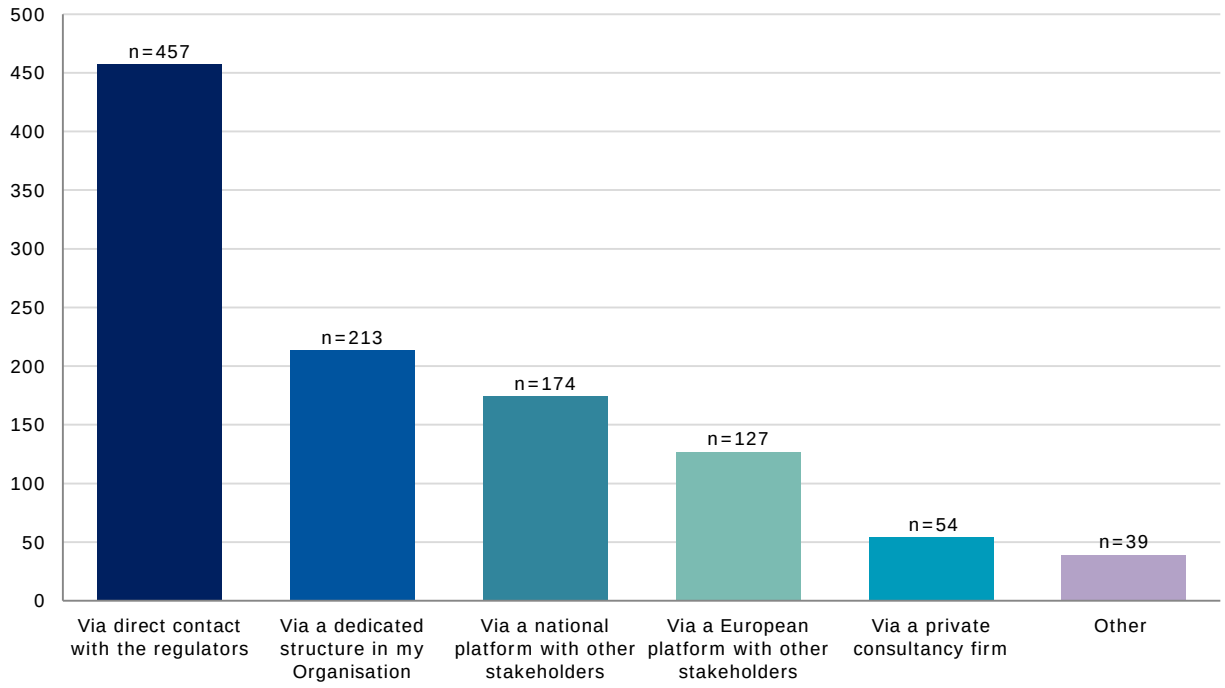


	National Medicines Agency	European Medicines Agency	Health Technology Assessment body	Notified body for medical devices
Always	95	20	16	3
Often	206	102	76	39
Sometimes	224	189	102	68
Seldom	105	152	94	101
Never	124	211	287	308

Question 8: If you have interacted with regulatory bodies, what were the reasons? (select all that apply).



Question 9: If you had interactions with regulatory bodies, how did it take place? (select all that apply).



Question 10: If you have specifically interacted with EMA, what were the reasons? (select all that apply).

Reasons for interaction with EMA	
• Provided expert opinion to EMA Scientific Committees and Working Parties (45%; n=165)	• Applied for Orphan Drug Designation (13%; n=47)
• Requested Scientific Advise (32%; n=116)	• Joint publication with EMA (12%; n=42)
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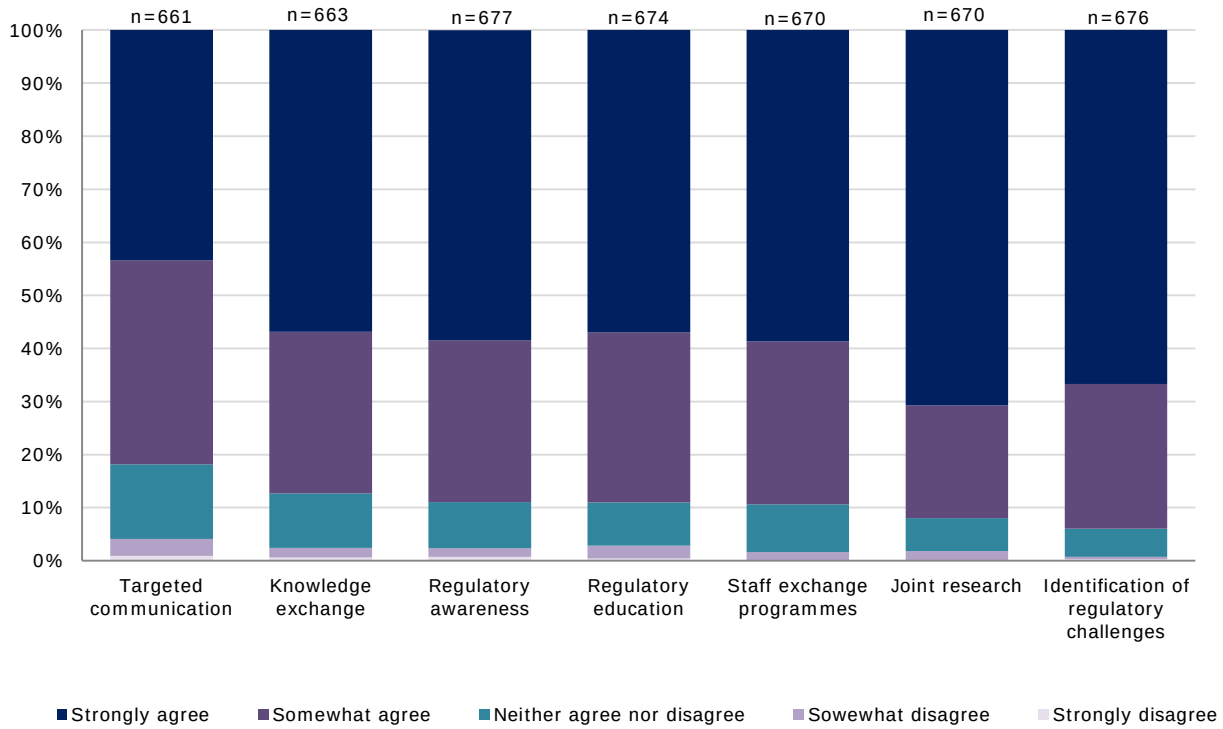
• Co-participation with EMA in advisory groups of research consortia, projects or other initiatives (21%; n=77)	• Consulted the Micro-, small- and medium-sized-enterprise (SME) Office (2%; n=8)
• Participated in EMA guideline development (16%; n=57)	• Consulted the EMA Innovation Task Force (ITF) (2%; n=8)

3. Future developments

Question 11: In order to achieve an enhanced, closer collaboration between academia and regulators, what should be pursued?



Question 12: We greatly value your opinions and ideas on how the collaboration between academia and regulators could be enhance with mutual benefit; please share your evaluation of the current situation (strengths and weaknesses) and of the opportunities and challenges lying ahead.

Strengths *key words* (*215 comments*)	**Weaknesses *key words* (*220 comments*)**
• Regulators outreach and openness • Academia contribution/gain • Knowledge/expertise • Solidity of the regulatory framework • Independency • Transparency • Commonality of goals	• Lack of awareness/interaction • Bureaucracy/complexity of regulation • Lack of incentives • Communication • Preferential relationship with industry • Conflicts of interests • EMA capacity and mandate
Opportunities *key words* (*203 comments*)	**Challenges *key words* (*192 comments*)**
• Research • Knowledge exchange/collaboration • Communication • Education/training • Multi-stakeholder platform • Funding • European dimension	• Convergence/optimisation of process • Change of modus operandi • Capacity/financial resources • Communication/education • Regulatory burden/competing interests • Independent research/scientific challenges • National vs EU dimension

Please refer to section 3.3 for extended considerations on the written comments received.

Annex 2: EMA consultation on the proposal of a collaboration framework with academia

1. Introduction

This paper provides a brief overview of the reasons underpinning the need for establishing a framework of collaboration between the European Medicine Agency (EMA) and academia. This initial consultation process is in the form of an online questionnaire that aims to gather information on the current status of interaction between the European medicines regulatory system[7] and academia, to collect its expectations and needs and to open a dialogue with academic interested parties to better structure and develop the framework.

2. Background

Horizon 2020, the biggest EU Research and Innovation programme, emphasises the need to accelerate the translation of biomedical and clinical research results to medical use, with specific areas where dialogue with regulators is either required or highly recommended (e.g. rare diseases, methodologies to reduce animal testing, in-silico trials).

One of the key priorities of the recently published EU Medicines Agency Network Strategy to 2020[8] is the need to address unmet medical needs by keeping abreast of advances in science and providing an appropriate regulatory environment for those who drive innovation, including academia. The Network Strategy also highlights the strong track record of EU regulators in supporting innovation through the National Innovation Offices and the EMA Innovation Task Force[9], providing advice and appropriate guidance. Furthermore, in the context of the current pharmaceutical legislation, initiatives such as the research networks Enpr-EMA[10] in paediatrics and ENCePP[11] in pharmacoepidemiology have been put in place and are coordinated by EMA.

3. The need for an enhanced collaboration with academia

There is already a longstanding collaboration between regulators and academia, as clearly recognised in the Network Strategy to 2020. Indeed, academia is the source that provides the European medicines regulatory system with thousands of experts that bring their expertise and knowledge to ensure that medicines are evaluated and monitored to the highest scientific standards (regulatory science[12]). Nevertheless, tremendous advances in science are leading to new medicines that are being developed, manufactured, assessed and used in completely new ways, where high degrees of complexity are often embedded. New technologies are emerging, and advanced therapies and personalised medicines will represent an increasing part of the healthcare armamentarium. Monitoring of products throughout their lifespan has never been more critical. Information is needed on the benefit-risk balance of medicines

[7] The European regulatory system for medicines is based on a Network (EU Medicines Agencies Network) of all national medicines competent authorities (NCAs) from Member States in the European Union and European Economic Area, and the European Medicines Agency (EMA), working closely together to ensure that medicines for human and veterinary use are safe, effective and of good quality.
[8] EU Medicines Agencies Network Strategy to 2020
[9] EMA Innovation Task Force (ITF)
[10] European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)
[11] European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)
[12] For the purpose of this document regulatory science can be defined as a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine. It encompasses basic and applied bio-medicinal sciences, human sciences and social sciences, and contributes to the development of regulatory standards and tools.

throughout their lifecycle, particularly where earlier access has been granted and when the need to proactively gather and analyse real world data is even more important.

In order to face these challenges and to address the need for patient-focused innovation, also recommended by the European Council[13], the Network Strategy to 2020 identifies key priorities which will need to be implemented in the next five years. Since academia is an important source of innovative medicines in the European Union (as recently shown[14], see Figure 1), one key priority is that opportunities for greater collaboration and integration with academia need to be pursued in order to translate innovation into medicinal products, to approve them through adequate and up-to-date methodologies and to monitor their use during their entire life-cycle. Notably, a recent analysis has also shown that a better dialogue with regulators has become a key positive factor in facilitating the development of safe and effective medicine to meet patients' needs[15,16].

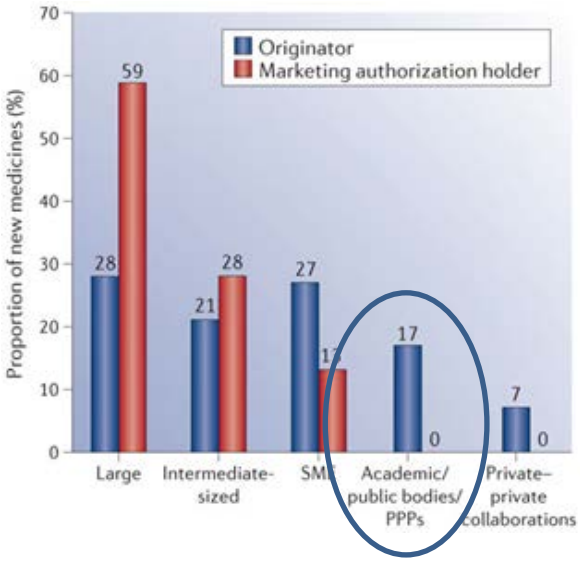


Figure 1. Originator and the marketing authorisation holder for all 94 approved products evaluated (2010-2012), divided according to organisation type. When the products were tracked back through development to their origin, academic/ Public bodies/PPPs accounted for 17%. Adapted from Nature Reviews Drug Discovery[8].

4. Academia and Regulators, a partnership that must evolve: be part of it

In view of the growing complexity with which new medicines are being developed, evaluated and monitored it has become indispensable that academia and regulators develop a partnership that will foster a proactive process to support innovation and channel it into the continuous evolution of regulatory science.

EMA in order to implement the strategic priority of establishing a greater collaboration with academia (as defined in its Work programme 2016–2017), is initiating a consultation process with the following objectives:

1. Explore opportunities for a greater collaboration in order to better support academia in generating new medicines that meet regulatory standards;
2. Channel academia's advanced knowledge into the regulatory environment;

[13] Council conclusions on innovation for the benefit of the patients, Council conclusion, Brussels, 1 December 2014
[14] Lincker H., Ziogas C., Carr M., Porta N., Eichler, H. G. Regulatory watch: Where do new medicines originate from in the EU? Nature Reviews Drug Discovery. 2014; 13(2): 92-93.
[15] Hofer MP., Jakobsson C., Zafiropoulos N., Vamvakas S., Vetter T.,Regnstrom J., Hemmings RJ. Regulatory watch: Impact of scientific advice from the European Medicines Agency. Nature Reviews Drug Discovery. 2015; 14: 302–303.
[16] Maciulaitis R., D'Apote L., Buchanan A., Pioppo L., Schneider C. K. Clinical development of advanced therapy medicinal products in Europe: evidence that regulators must be proactive. Molecular Therapy. 2012; 20(3): 479-482.

3. Assess the degree of awareness among Academics of the existing activities and incentives provided by regulators to support medicine development;
4. Refine regulators' understanding of academia's needs and expectations and develop a methodology for collaboration.

You are invited to be part in this process by answering a brief on-line questionnaire that also leaves ample space for comments and suggestions.

The deadline for completing the on-line questionnaire and, if wished, sending your separate, written contribution (Academia-consultation@ema.europa.eu) is 15 April 2016. The data and contributions collected will be analysed and the results will be communicated to the respondents who will have identified themselves during this initial consultation.