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Understanding and Evaluating Science Engagement by Regulatory Agencies in the Health Sector

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Abstract

In the evolving health sector, regulatory agencies play an important role in managing the efficacy, quality, and safety of medicines and medical innovations. This research investigates science engagement for regulatory agencies in the health sector, with a focus on their involvement in science activities. There is insufficient understanding of what activities science engagement involves, and what motivations and contributions of science engagement are. This study addresses this gap through the development of an adapted framework based on the framework of academic engagement by Perkmann et al.'s (2021), and adjusted to the context of regulatory science and regulatory agencies in the health sector. The aim of this study is to determine key science engagement activities, motivations, barriers and contributions through an exploratory approach, and using the Dutch Medicines Evaluation Board (MEB) as a case study. The assessment method of contribution mapping by Kok and Schuit (2012) is also partly used to investigate impact.

The main findings highlight that regulatory agencies engage in activities such as research projects and exchange of expertise to keep pace with scientific advancements. The adapted framework presents a typology of science engagement activities, the main antecedents to science engagement, and insights on its impact. This study contributes to filling the literature gap on science engagement of regulatory agencies in the health sector, providing a framework for understanding the concept and improve regulatory outcomes. The framework may additionally be applicable to different sectors, such as cosmetics or agrochemical industry, and can support regulators in optimizing their engagement strategies.

Executive Summary

This study examines science engagement of regulatory agencies in the health sector. It aims to fill the literature gap on the science activities, motivations, barriers and impact of this engagement, using an exploratory approach and the Dutch Medicines Evaluation Board (MEB) as a case study. The result of this research is the development of an adapted framework based on Perkmann et al.'s (2021) framework on academic engagement.

Main Findings

- **Science Engagement Activities**: Regulatory agencies engage in activities, such as common research projects, exchange of expertise, and mutual training, to keep up with their core activities and stay up to date with scientific advancements.
- **Antecedents to Science Engagement**: As a result from this research, the main motivations and barriers to science engagement at the individual, organizational, and institutional levels are identified.
- **Impact of Science Engagement**: This study highlights the main contributions to and outside of the assessment work of regulatory agencies. Additionally, the main skills and competences developed, the ways to integrate knowledge, and the main responsible actors are also identified.

The adapted framework represents a tool for regulatory agencies to enhance their science engagement. The study helps filling the literature gap and provides insights that can aid regulators in optimizing their science engagement strategies and regulatory processes.

Recommendations

- **Embed societal impact measurements in policy measures**: By making the societal and economic impacts clear, health systems can take a stronger position in national development strategies. This would also help to shift the mindset from health systems being perceived as a cost or an obstacle, to them being seen as important components towards achieving social and economic well-being
- **Introduce measures for better communication between regulators and academia**: Since difficult communication between the two sectors is a barrier found as an outcome of this research, measures need to be implemented to allow easier communication. This way, more

transparent exchange of needs and expectations can happen and the willingness for cooperation can be more easily shared with external stakeholders.

- **Develop a system with an overview of the main fields of developments nationally/on the EU level**: One barrier to science engagement on the organizational level found in this study is the missing of an overview of what research is being conducted nationally and in which fields the most developments are expected. A system, such as a database that would include the research areas relevant nationally or on the European level, but also an overview of the main areas of research active in academia, can improve the efficiency of regulatory processes.

1. Introduction

In the complex and interconnected health sector, regulatory agencies play a primary role in formal oversight, accountability, and regulation of healthcare systems (Furnival et al., 2018). Their core activities include the assessment of new medical and healthcare innovations before and after their introduction on the market, in terms of quality, safety, and efficacy (EMA, 2023c; European Commission, n.d.). Regulatory agencies are also responsible for the creation of regulatory guidelines and standards reflecting the latest developments in science. These guidelines and standards exist to lead the development process of healthcare innovations for medicine developers in the EU, as well as to ensure its consistency and quality (EMA, 2023b).

As these functions require that regulatory agencies stay up to date with the latest science, they can be involved in science activities to innovate and improve the process of assessment of medical and healthcare innovations, to facilitate the development of medicines and, in general, to improve and keep up with the abovementioned core activities (EMA, 2023a, EMA, 2023b). This comprises a multitude of activities such as conducting research and, on a wider level, establishment of collaborations, development of expertise and staying up to date on research advancing (Bansal et al., 2019; EMA, 2023a; EMA, 2023b; Feldon, 2016; Pontis et al., 2017). In this thesis we refer to these activities as science engagement activities, and, more generally, we refer to science engagement to indicate the participating in science engagement activities for regulatory agencies.

From a scientific perspective, regulatory science (RS) has emerged as a multidisciplinary and heterogenous field, in which these activities are embedded (Irwin et al., 1997). RS is concerned with the assessment of technologies and their risks and the interpretation of results in diverse environments – namely industrial, regulatory, and academic – to legitimize the adoption of policy measures (Demortain, 2017). It includes innovation activities such as the creation of new standards and tools to assess medicines, as well as the evaluation of the regulatory system for the improvement of public health (Leufkens & Eichler, 2011). Thus, regulatory agencies participate in science engagement activities to keep up with the advancements in RS.

Investigating how regulatory agencies keep up with the latest science and what the impacts of these activities are is relevant to better understand the role of regulatory agencies in the health sector and in relation to RS. In this context, the concept of academic engagement is of relevance, since it encompasses the interactions between academic scientists and external organizations, including regulatory agencies (Perkmann et al., 2021). Specifically, the framework developed by Perkmann et al. (2021) is concerned with the evaluation of engagement activities, motivations and drivers, and

impact of academic engagement. In the current literature landscape, considerable research has focused on some engagement activities, such as conducting research and establishment of collaborations (Archibald et al., 2023; Ashley et al., 2014; Bansal et al., 2019; Feldon, 2016; Pontis et al., 2017). Moreover, significant literature has focused on motivations and drivers for science engagement (Arora et al., 2017; Leten et al., 2022; Perkmann et al., 2013, 2021; Rosenberg, 1990; Rotolo et al., 2022). Finally, previous studies examined partly the consequences of science engagement, in terms of impact of joint research with academia as one form of engagement (Clancy et al., 2012; Hanney et al., 2003; Liu, 2015; Robbiano, 2022; Valero & Van Reenen, 2019). However, the study of academic engagement, and most of the current literature, focus on the academic context and partly on the private sector. Moreover, Perkmann et al.'s (2021) framework has been used to study how academics interact with other societal actors and mainly companies. Emphasis on how academic actors interact specifically with governmental actors, including regulatory agencies, is lacking in the current research literature. Additionally, no attention has been paid on whether Perkmann's et al. (2021) framework can also be used for studying science engagement activities of non-academic actors – such as regulators – with academics.

More specifically, knowledge is missing in the context of science engagement of regulatory agencies. As a matter of fact, engagement has mostly not yet been studied from the perspective of regulatory agencies (Saesen et al., 2023). More specifically, the motivations for regulatory agencies to participate in science engagement activities are poorly studied and mostly unknown. Furthermore, little literature can be found on the impact of science engagement for regulatory agencies, including the impact of joint research on regulation and innovation processes. Finally, no specific assessment framework for evaluating this engagement exists.

Given these gaps in the current literature, an exploratory approach is needed. Consequently, the following research question is formulated:

How can the participating in science engagement activities for regulatory agencies in the health sector be understood and evaluated?

Understanding and evaluating this includes the identification of the main activities, and antecedents – which includes motivations and barriers - for science engagement, as well as the forms of impact – also referred to as contributions in this thesis - of it. Therefore, the following sub-goals are formulated to answer the research question:

1) *To provide a typology of science engagement activities for regulatory agencies in the health sector.*

2) *To provide insight into the main motivations and barriers for science engagement by regulatory agencies.*
3) *To provide insight into the main forms of impact of science engagement by regulatory agencies.*

To answer this question, Perkmann et al.'s (2021) framework on academic engagement is used as a guide. The result of this research is the development of an adapted framework in the context of regulatory agencies in the health sector and RS, through multiple steps which are explained in section 3. This research is explorative in nature and focuses mostly on the specific case study of the Dutch Medicines Evaluation Board (MEB); the science activities considered are the ones pertaining to the Science Policy (2020-2024) adopted by the agency. A brief description of the main functions, structure, and responsibilities of the MEB can be found in Appendix 1 and 2.

Answering this research question through the development of an adapted framework is scientifically relevant since it helped fill in the literature gap on the impact of science engagement by regulatory agencies in the health sector, for example in terms of impact on assessment work, but also on a broader level. An essential value of this research is the reduction of uncertainty about the contribution that engagement of regulatory agencies in specific science activities is making. Moreover, determining the motivations on different levels – namely individual, organizational, and institutional - behind science engagement by regulatory agencies allowed to better understand interactions between academia and regulatory agencies in the broader context of RS. Therefore, this research can help the competent authorities to optimize their participating in science engagement activities to contribute to better action for health. In a broader context, the adapted framework may become relevant for other national agencies that have relatively high reliance on RS. This includes the health sector, but it is potentially extendable to different sectors, such as the food, cosmetic, or agrochemical industry. In addition, the resultant framework can be integrated in the context of agencies that deal with environmental sustainability.

2. Theoretical Framework

In this section, the main findings relevant to the scope of this study are presented. Firstly, regulatory science (RS) is defined and differentiated from academic science, and the main activities performed by regulatory agencies in the health sector pertaining to RS are described. Secondly, academic engagement is defined and Perkmann et al's (2021) framework on academic engagement is introduced. Afterwards, three sections are dedicated to outlining the current literature in the context of regulatory agencies and RS relating to the three main building blocks of Perkmann et al.'s framework. Firstly, some activities of engagement in science found in the literature are summarized. Secondly, the main drivers and motivations to science engagement for actors in the private sector are presented and related to regulatory agencies, and barriers and disablers are mentioned. Thirdly, the focus is dedicated to the impact of research on innovation and regulation processes, one of the activities pertaining to science engagement. Finally, a summary is given regarding the aim of the research to adapt the existing framework for the context of this study by using its main building blocks.

2.1 Regulatory Agencies and Regulatory Science

With the introduction of new technologies and products since the 20th century, the introduction of regulatory agencies came along, to ensure the quality, safety, efficacy, reliability, and accessibility of these technologies (Demortain, 2017). Pari passu, regulatory science (RS) research developed, especially for the promotion of public health through the assurance of food and medical products safety. Nowadays, it keeps supporting advancements of the processes contributing to regulatory policy decisions (Patel & Miller, 2012).

RS has multiple definitions. One that can be considered is the one given by FitzGerald (2011) "RS may be defined as the acquisition and analysis of data sufficient to inform decision making pertinent to (i) the approval and monitoring of safe and effective therapeutics, devices, and cosmetics; (ii) the safety and nutritional value of food; and (iii) the availability of tobacco-related products". Particularly for the health sector, RS can be seen as a bridge delivering of a medicine - with its information and knowledge - to society. In this sense, three functions of RS are fundamental: "providing the tools for data production, providing a basis for data assessment, and balancing the various factors involved in the decision" (Tominaga et al., 2011). RS makes use of tests, measurements, and quantitative information to evaluate whether a technology might or might not be authorized; examples are

toxicological risk assessments, life cycle assessments, and clinical trials (Demortain, 2017). Thus, advancements in the field of RS, including the development of new tools, standards, and approaches, can accelerate the creation of models that evaluate safety in a more efficient way (Hamburg, 2011). Regulatory agencies also conform with various definitions for regulatory science. For instance, the U.S. Food and Drug Administration (FDA) describes it as a science-based decision-making process necessary to execute the responsibilities of a public health agency (Institute of Medicine, 2011). The European Medicines Agency (EMA) adopts the term regulatory science that refers to "the 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 biomedical and social sciences and contributes to the development of regulatory standards and tools" (EMA, 2024b).

The analysis of RS in the agrochemicals sector conducted by Irwin et al. (1997) found that RS gathers:

- Scientific activity within academic, industrial, and governmental settings
- A range of specialty and disciplinary orientations and activities concerning different levels of scientific uncertainty
- Intellectual and practical activities which span the technical and the bureaucratic
- Scientific, political, and economic concerns
- Activities that involve both regulation and innovation

Hence, RS can be considered a heterogeneous and hybrid discipline, that crosses different scientific and institutional boundaries and that develops in various dimensions. For the pharmaceutical sector, three main forms can be differentiated in the regulatory network:

- Regulators investments to maintain pace with scientific and technological advances to assist in drug development and innovation
- Development of new standards and tools for the best assessment of medicines
- Evaluation and analysis of the regulatory system for the general enhancement of public health

All forms need their methods and technologies, and they require full collaboration between different disciplines and institutions, including regulatory agencies and academia (Leufkens & Eichler, 2011).

It should be stated that RS carried out by non-academic organizations, such as regulatory agencies in the health sector, presents important differences when compared to research science in the academic setting, including varying goals, output, and time constraints. For example, in research

science, uncertainty is expected and embraced, while, in RS, predictive certainty is required by the political process and by legal requirements (Callréus & Schneider, 2013). Table 2.1 shows an overview of the main differences between RS and research science elaborated by Jasanoff (1995).

Table 2.1: Main differences between regulatory science and academic science by Jasanoff (1995)

	Regulatory Science	Research Science
Goals	"Truths" relevant to policy	"Truths" of originality and significance
Institutions	Government, industry	Universities
Products	Studies and data analyses, often unpublished	Published papers
Incentives	Compliance with legal requirements	Professional recognition and advancement
Time-frame	Statutory timetables Political pressure	Open-ended
Options	Acceptance of evidence Rejection of evidence Waiting for more data	Acceptance of evidence Rejection of evidence
Accountability Institutions	Congress Courts Media	Professional peeers
Procedures	Audits and site visits Regulatory peer review Judicial review Legislative oversight	Perr review, formal and informal
Standards	Absence of fraud or misrepresentation Conformity to approved protocols and agency guidelines Legal tests of sufficiency (e.g., substantial evidence, preponderance of the evidence)	Absence of fraud or misrepresentation Conformity to methods accepted by peer scientists Statistical significance

Moreover, on the financial dimension, organizations in academia tend to grant research funds on the grounds of scientific relevance of a project, while non-academic ones tend to grant them based on the industrial or societal impact of a project (Lauto et al., 2013).

Consequently, regulatory agencies in the health sector can contribute to RS in three ways, which are explained in Table 2.2.

Table 2.2: Regulatory science activities conducted by regulatory agencies in the health sector, based on European Commission, n.d.; EMA, 2023a; EMA, 2023b; EMA, 2023c; MEB, n.d.-e

Activities	
Assessment of medicinal products	It includes: 1) The authorization of new medicinal products, following the regulation of pharmaceutical products. There are three criteria considered: quality, safety and efficacy 2) Pharmacovigilance action and benefit-risk evaluations after the introduction of the products in the market
Creation of guidelines and standards	Scientific guidelines are created in collaboration with experts, patients, and healthcare professionals, reflecting the latest developments in biomedical science. They aim to guide the process of development of medicinal products for those who wish to apply for marketing authorization. Additionally, it includes the provision of scientific advice to pharmaceutical companies for new medicines under development.
Science engagement activities	It involves several activities to improve and stay up to date with other activities. They include: 1) Conducting research 2) Collaborations 3) Development of expertise 4) Keeping up to date

These regulatory science activities found in the literature were used as foundation for the conduct of the interviews in the first stage of this research, and for the collection and operationalization of

results on the impact of science engagement. As a matter of fact, most of the forms of impact referred to the activities of assessment of medicinal products and creation of standards and guidelines, aligned with the findings in Table 2.2. Therefore, the qualitative coding concerning the impact of science engagement conducted in this research was partly deductively informed by this categorization.

2.2 Understanding Science Engagement

As outlined in section 2.1, RS proactively analyzes regulatory principles and attempts to evolve them along the continuity of scientific progress (Callréus & Schneider, 2013). Hence, to keep up with this evolving discipline, science engagement activities become essential for regulatory agencies, though this type of engagement has not been particularly studied.

However, literature can be found on academic engagement, which refers to knowledge-related interactions of academic scientists with external organizations, including government agencies (Perkmann et al., 2021). In this context, Perkmann et al. (2021) developed a framework on academic engagement (Figure 2.1) which includes three main building blocks. Firstly, the main science engagement activities are included, such as joint research, contract research, and training of personnel. Secondly, the framework focuses on the antecedents to academic engagement, consisting of motivations, drivers, barriers, and disablers, and grouped by level of analysis, namely individual, organizational, and institutional. Thirdly, the primary forms of impact of these types of engagement are identified.

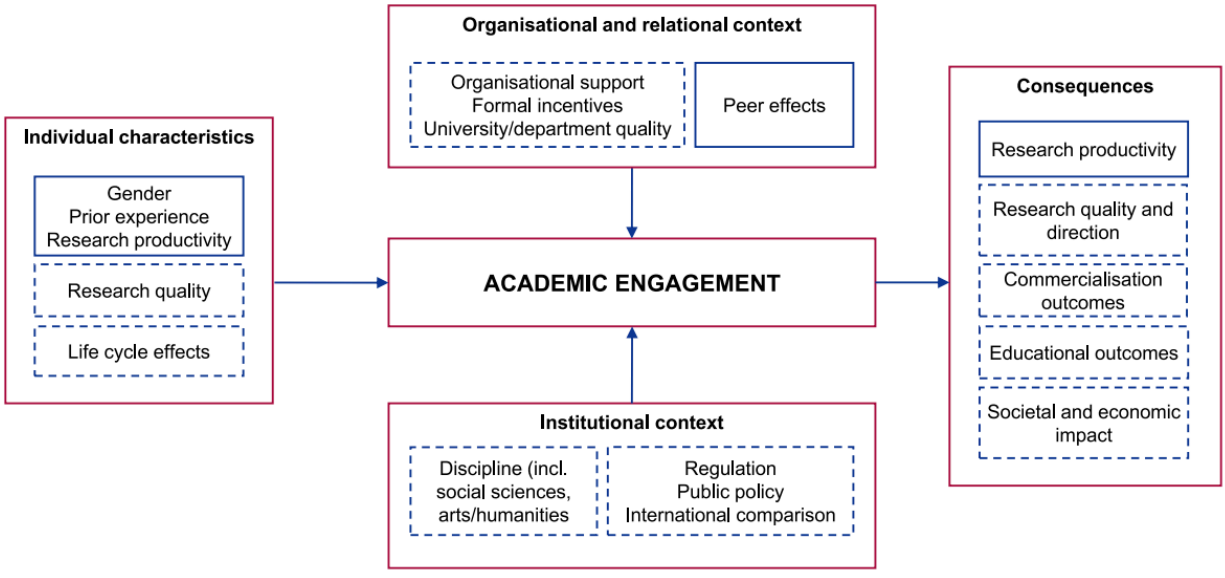

Figure 2.1: Perkmann's analytical framework of academic engagement (Perkmann et al., 2021)

Perkmann et al. (2013) found that government agencies and academics themselves have been encouraging academic engagement through the years. Moreover, academic engagement is regarded as an imperative means to render science more impactful, and several funding agencies are encouraging joint grant applications by universities and firms and facilitating or subsidizing their interactions (Perkmann et al., 2021; Upton et al., 2014). Saesen et al. (2023) conducted a study on

the involvement of EMA (European Medicines Agency) in RS research projects coordinated by external stakeholders such as academic researchers. The findings see that these projects benefitted the consortia undertaking the projects and EMA as well, in terms of new or improved medicinal products, methodological standards, research infrastructures, education tools, and increased scientific relevance of the consortia's work.

Although useful for understanding the mechanisms of academic engagement, Perkmann et al.'s (2021) framework focuses on the academic perspective, and, therefore, it does not suit the scope of this research. Hence, it needs to be adapted to capture science engagement in the context of regulatory agencies in the health sector and RS. To do so, the abovementioned three building blocks – science engagement activities, antecedents, and impact – can be used as foundation.

2.3 Science engagement Activities

There is relatively considerable literature on different science engagement activities. Some studies that focus on a few science engagement activities are found and the main findings on these activities are summarized in Table 2.3. However, this list is not necessarily exhaustive, and these studies do not mention any correlation with science activities specifically engaged with by regulatory agencies in the health sector.

Table 2.3: Value dimensions of conducting research based on

Activities	Findings
Conducting research	Academic health research is usually centered on basic mechanistic or applied studies that seek a more precise characterization of disease processes. Conducting research in the context of RS can directly inform regulatory activities. For instance, this includes studies that recognize a dose-response relationship. Goals in this area can include: 1) Stimulating innovation in clinical evaluations and personalized medicine to improve product development and patient outcomes 2) Ensuring readiness to evaluate innovative emerging technologies 3) Facilitating development of medical countermeasures to protect against threats to global health and security 4) Strengthening social and behavioral science to help consumers make informed decisions (Ashley et al., 2014)
Development of expertise	Expertise in conducting scientific research is about collecting, analyzing, interpreting data, and present conclusions in a manner that meets the standards of rigor, relevance, and novelty. Two traditions frame its current understanding: 1) Psychology of science: it characterizes the cognitive mechanisms of scientific reasoning

	2) Socialization theory: it refers to the development of research expertise as a transactional process of learning to participate as a member of a disciplinary community. In the academic setting, interaction with the environment - for instance through mentored research activities or coauthoring – are fundamental for research skill development (Feldon, 2016)
Establishment of collaborations	Collaborative research – defined as research involving coordination between researchers, institutions, organizations and/or communities – can often solve important scientific issues or innovative technologies. It can occur at five levels: 1) Disciplinary 2) Interdisciplinary 3) Multidisciplinary 4) Trans-disciplinary 5) National vs International Trans-disciplinary collaboration entails involvement of people from outside academia into the research process (Bansal et al., 2019). It is assumed to enable new perspectives and solutions otherwise not possible, and it is regarded as integral to addressing “wicked” problems (Archibald et al., 2023). Wicked problems are complex, interconnected problems that cannot be solved, but rather resolved in multiple ways (Lawrence et al., 2022). Wicked problems concern multiple fields, including the healthcare system, which has become rich with complexity (Petrie & Peters, 2020).
Keeping up to date	In the academic context, keeping up to date is a crucial part in the development of research projects, writing articles, and hiring the right researcher. The way researchers interact with information to stay updated is dependent on five interrelated dimensions involved in the information journey:

	1) Level of seniority 2) Type of information source 3) State of the project 4) Level of familiarity 5) How well-defined the relevant community is The information journey involves four phases: 1) Recognized need 2) Find information 3) Validate and interpret information 4) Use interpretation It doesn't necessarily begin when the individual recognizes a need. The information may be encountered without having previously recognized the need; the information might not be immediately used and may be kept for future use (Pontis et al., 2017).

The content of Table 2.3 was used as a starting point for the categorization of the science engagement activities in the data collection and consequent steps of the methodology. It was later integrated and adapted with the additional data accessed to during the course of the internship at the MEB and the interviews conducted as part of this thesis.

Moreover, mechanisms of university-industry linkages have been studied from an open innovation perspective (Lauto et al., 2013). Perkmann & Walsh (2007) analyzed the processes of technology transfer from the point of view of university; they identified seven specific linkages between universities and industry in an open innovation environment, as shown in Table 2.4.

Table 2.4: Linkages between universities and industry identified by Perkmann & Walsh (2007)

Research partnerships	Inter-organizational arrangements for pursuing collaborative R&D
Research services	Activities commissioned by industrial clients including contract research and consulting.
Academic entrepreneurship	Development and commercial exploitation of technologies pursued by academic inventors through a company they (partly) own.
Human resource transfer	Multi-context learning mechanisms such as training of industry employees, postgraduate training in industry, graduate trainees and secondments to industry, adjunct faculty.
Informal interaction	Formation of social relationships and networks at conferences, etc.
Commercialization of property rights	Transfer of university-generated IP (such as patents) to firms – for example, via licensing.
Scientific publications	Use of codified scientific knowledge in industry

Given this literature, it can be stated that some activities are found pertaining to regulatory science and involving engagement of multiple actors. However, more elaboration on these activities is needed, as well as an investigation of the specific science engagement activities for regulatory agencies in the health sector.

2.4 Antecedents

It is important to consider the reasons why science engagement happens in the first place, including drivers and motivations at different levels, namely individual, organizational, and institutional. In Perkmann et al.'s (2021) study of academic engagement, individual determinants (such as demographic attributes and prior career experience), organizational determinants (such as peer effect and incentives for commercialization), and institutional determinant (applied discipline) are distinguished. A brief explanation of what different levels refer to in this research can be found in Table 2.5.

Table 2.5: Explanation of three levels of antecedents of engagement

Levels	
Individual	In an organization, a person who is motivated will engage in an action or activity driven by a goal, or because it is found enjoyable or inherently interesting (Hung et al., 2011).
Organizational	Work environments often need a collective focus on motivation. Motivation on the organizational level profits from a systemic effort that sustains a unified business strategy. The culture of the organization implicitly sets boundaries for behaviours that are recognized and rewarded (Hoffman, 2015). Therefore, the motivations of the organization itself are key in influencing motivations on the individual level and, hence, they are important factors to consider for science engagement.
Institutional	An institution, broadly defined, consists of the formal and informal rules, norms, and procedures that guide and structure interactions in a specific context. These structures, that can be organizational, legal, or cultural, contribute to the foundation for individuals and groups to coordinate, collaborate, and make decisions collectively. The Institutional level investigates the way in which patterns, laws and structures within different agencies and the way in which organizational structures function to advantage some and

	disadvantage others (Silwal et al., 2024). Thus, considering the motivations on the institutional level can allow to capture an additional perspective and get a more complete overview of the main motivations for regulatory agencies in the health sector to participate in science engagement activities.

However, from the distinction made in section 2.1 between academic science and RS, it can be deduced that the drivers and motivations for regulatory agencies and academic groups to science engagement cannot be considered comparable. Therefore, even though considerable literature has been dedicated to the analysis of the main missions of universities, it is not presented here (Boulton, 2022; Compagnucci & Spigarelli, 2020; Cuthill, 2012; Engwall, 2020a; Scott, 2006).

Nevertheless, there is little literature on the motivations and drivers for regulatory agencies and regulators working in these agencies to carry out science engagement activities. Motivations found in the literature include the generation of societal legitimacy for publicly subsidized scientific research. However, the impact of academic engagement is only partially understood. Hence, the fact that academic engagement has always positive impact and should be promoted cannot be assumed (Perkmann et al., 2013). Consequently, motivations and drivers to do research in the private sector and to publish it are considered. The main reasons found in the available literature for firms to do basic research and to publish it are summarized in Table 2.6.

Table 2.6: Incentives for firms to do basic research and to publish it, based on Arora et al., 2017; Leten et al., 2022; N. Rosenberg, 1990; Rotolo et al., 2022

Motivations and drivers to conduct basic research	Motivations and drivers to publish basic research
Research often generates widespread and indiscriminate benefits. If the firm can capture some of the benefits, it's convenient to do basic research. Potential benefits largely take the form of "first-mover advantages"	It implies access to external knowledge and resources. Three mechanisms are involved: 1) Sharing open science norms and values 2) Nurturing an open culture among competitors/suppliers 3) Stimulating collateral research

For firms with strong market power, basic research is encouraged because it offers a high long-term payoff	It attracts and retains researchers. It involves four mechanisms: 1) Demonstrating researchers' capabilities 2) Accumulating social capital 3) Extracting wage discounts 4) Monitoring researchers' performance
Firms that are able to use their research in their inventions produce more of it	It is a means for supporting IP strategies. Four mechanisms underlie this: 1) Extending patent races 2) Reducing expected patent value 3) Broadening patent scope 4) Preventing the privatization of inventions
Firms whose patents cite science also report greater use of science in their R&D projects	It helps build the firm's reputation. Three mechanisms are involved: 1) Signaling discoveries and competences 2) Increasing credibility to access private/public funding 3) Disseminating scientific and technical standards
It affects technology development: 1) As strengthening of the firm's absorptive capacity to build on externally conducted science 2) As a direct source of the firm's innovation	It supports commercialization strategies. Three mechanisms structure this: 1) Signaling new products and/or services and their quality 2) Supporting claims about products or services 3) Supporting regulatory approval

By extending these motivations and drivers to regulatory agencies in the health sector, some of them can be considered applicable. Particularly, building a reputation among relevant audiences is of crucial importance to effectively communicate and maintain bureaucratic power (Bach et al., 2022). Hence, building reputation can represent a useful motivation. Secondly, attracting researchers and external knowledge can be considered pertinent. As a matter of fact, the main role of medicines regulatory agencies is to encourage public health and to enable science to contribute to better healthcare, which must be done through the understanding of relevant science and the key innovation areas. Hence, European regulatory agencies engage with several stakeholders, including academia and scientific organizations and societies, to try and manage to keep pace with innovation (Hines et al., 2020). Therefore, doing research can represent a motivation for regulatory agencies to draw in resources and knowledge to conduct additional research.

On the other hand, barriers, and disablers to science engagement activities are equally relevant. The available literature mostly focuses on academics and the barriers to publish, patent, and engage in standardization, such as high academic reputation, low previous experience with commercialization, and lack of time and resources (Blind et al., 2018; Hughes et al., 2016; Lawson et al., 2016; Tartari et al., 2012). However, there is a need to study barriers and disablers for regulatory agencies in the health sector to science engagement, which is currently lacking.

To conclude, a variety of motivations to science engagement is found in the literature. However, these motivations concern a multitude of actors. More focus is needed to more clearly identify the antecedents to science engagement specifically for regulatory agencies in the health sector.

2.5 Impact of Joint Research on Innovation and Regulation

Considering the regulatory science activities conducted by regulatory agencies in the health sector found in Table 2.2, one particularly relevant activity included in the scope of this study is joint research with academia. As a matter of fact, joint research with academia represents a relevant activity contributing to the assessment of medicinal products, the creation of guidelines and standards, and to general science engagement activities. In terms of impact, extensive research has been conducted on the general impact of conducting research on innovation and regulation processes. Thus, a section is dedicated to it.

A consistent body of literature can be found on the impact of public research on innovation and economic growth. As a matter of fact, the establishment of Public Research Institutions, such as universities and public-funded research organizations, can contribute to innovation, thanks to the generation, accumulation, and transmission of knowledge. This can result in knowledge spillovers, economic agglomeration, and, in turn, long-term growth and wealth (Liu, 2015; Robbiano, 2022; Valero & Van Reenen, 2019). In the UK, the Research Excellence Framework (REF) has been founded to determine the impact beyond academia and quality of outputs (publications, performances, exhibitions) of research in higher education institutions, through the assessment of case studies (Cruz Rivera et al., 2017; Dotti & Walczyk, 2022). However, this method has been criticized for being a simplistic approach that does not discount over time or spatially (Khazragui & Hudson, 2015).

Research can fundamentally influence policymaking in at least three steps: agenda setting, policy formulation, and implementation (Hanney et al., 2003). For the health sector, according to Clancy et al. (2012), health services researchers can play a vital role in influencing policy making through their work in four areas. Firstly, they can identify key issues that need to be addressed. Secondly, they can research the advantages and disadvantages of different policy solutions. Thirdly, they can estimate the costs and outcomes of proposed policies. Finally, they can actively participate in the policy process to help decision makers make informed choices in real-time.

Regarding how this impact can be measured, specifically in academia, universities evaluate research results as a crucial means for improving reputation (Engwall, 2020b). Traditionally based on quantitative measures, such as the number of publications or citations, more modern evaluations incorporate new, complementary dimensions. An example is altmetrics, which measure web-driven scholarly interactions, such as how often research is tweeted (Daraio & Vaccari, 2022; Korhonen et al., 2001; Williams, 2017).

However, impact is broader than only output of research. In Perkmann et al.'s (2021) framework, forms of impact of academic engagement include for example research productivity, educational outcomes, and societal impact. Impact can also affect core activities of regulatory agencies such as assessment and contributing to the development of guidelines.

Additionally, considering different impact assessment methods becomes relevant when trying to understand impact. A series of impact assessment methods were researched for this study and can be found in Appendix 4. Kok and Schuit's (2012) contribution mapping assessment method is considered the most relevant for the scope of this research, because it puts the emphasis on research-related contributions and on the ways to increase the likelihood of beneficial ones. This aligns with the scope of this research, since one of the goals is to understand and evaluate the impact of science engagement for regulatory agencies in the health sector. The method consists in the creation of a three-phase process map that includes the main actors, activities, and alignment efforts. The three phases are:

- Formulate phase. In this phase, the vision supporting the project is investigated. The vision, aims, main activities and actors are identified.
- Production phase. The aim of this phase is to get an overview of the main activities, results, and alignment efforts. Alignment efforts correspond to anticipatory efforts that attempt to enhance contributions.
- Knowledge extension phase. In this phase, the goal is to identify the meaning and consequences of the main results for policy, practice, and health (Kok & Schuit, 2012).

Given these considerations, there is a need to study and identify impact of science engagement activities, specifically for the context of regulatory agencies and RS in the health sector, and to understand how joint research contributes to the core activities of regulatory agencies.

2.6 An Adapted Framework

This research is conducted to develop a framework on science engagement by regulatory agencies in the health sector: Perkmann et al.'s (2021) framework on academic engagement outlined in section 2.2 is used as a guide and adapted for the scope of this study. Specifically, three main building blocks from Perkmann et al.'s are utilized as a starting point in the context of this study to answer the research question. As described throughout the previous sections of the theoretical framework, the three building blocks are:

1) The main science engagement activities included in the scope
2) The main antecedents, including motivations and barriers. This involves three levels, namely individual, organizational, and institutional
3) The impact of the engagement in these activities

The goal of developing the framework is to explore its value and explore how it can be adapted to make it applicable to the regulatory context.

3. Methods

In this section, the main methodology choices are presented and justified, for each building block previously explained. For each one, namely science activities, antecedents and impact, the research design, sampling strategy, data collection, operationalization, and data analysis are presented. Moreover, research quality indicators and ethical considerations are explained.

3.1 Research Design

The research conducted is of qualitative nature; this fits the scope of the study since only partial theory exists about regulatory agencies engaging in science and current theories do not adequately capture its value (Islam & Aldaihani, 2021). Perkmann et al.'s (2021) theoretical framework on academic engagement was used as a guide for the conduct of this research, through an abductive approach. Perkmann's analytical framework – and its three building blocks – was used as a starting point to develop a framework applicable in the context of regulatory agencies and their science engagement activities and RS in the health sector. An abductive approach is relevant, because it allows to ground a theoretical understanding of the contexts and people perspectives that form their worldview. Therefore, it aims to come to a social scientific account of the world as seen from those perspectives (Clark et al., 2021). In this research, this aligns with the aim of understanding science engagement from the regulatory science in the health sector perspective with a clear theoretical framework as a starting point. From there, a new framework was developed to apply the existing one to the specific context of this research. The research design chosen consisted of two stages: an interview-based study and a case study.

3.2 Stage One

During stage one of the research, data was collected to gather an overview of the main plans and strategies adopted by various EU regulatory agencies in the health sectors in the context of science engagement and regulatory science. One of the goals was to obtain information on the main science activities that regulatory agencies in the health sector engage in in the context of RS. Moreover, preliminary to stage two was the identification of the main relevant science engagement activities and interactions for the MEB, which is the regulatory agency selected for the case study. This allowed to better investigate the first sub-goal of this research and, hence, to adapt Perkmann et al.'s (2021) building block regarding the main science activities involved in science engagement.

Moreover, during the first stage, information was also gathered with a focus on the second sub-goal of the study, and to adapt Perkmann et al.'s (2021) building blocks regarding the antecedents to engagement. Specifically, in an interview-based study, broader interviews were conducted with contacts from 5 regulatory agencies in the health sector in the EU to learn about motivations and barriers to science engagement on three levels: individual, organizational, and institutional. Regarding multiple regulatory agencies in the EU is relevant for this study because it allowed to better establish the circumstances of the relevant existing theory (Aberdeen, 2013; Eisenhardt, 1989). Therefore, through these interviews, it was possible to understand the perspective of regulatory agencies in the health sector, based on the existing theory on antecedents to science engagement. This is relevant since it enabled to understand motivations and barriers to science engagement which are common to multiple regulatory agencies in the health sector. Hence, it aimed to a generalization in the sector.

3.2.1 Sampling Strategy and Data Collection

Through the course of the internship at the MEB, documents were accessed and conversations with employees were carried out about the science engagement activities of the agency and the main interactions with academia. An overview of the most representative activities currently being conducted at the MEB was gathered through multiple conversations with different employees at the agency. This allowed to put more focus on what the perceived most important and representative activities engaged with by the regulatory agency are and helped in the process of choosing the type of activity to focus on for the second stage of the research.

The documents accessed include the Foster Collaboration Survey and the CBG Science Policy Booklet (Ghobreyal et al., 2021 &MEB, 2023b). The Foster Collaboration Survey is a survey conducted in 2021 to EU drug regulatory agencies to learn about interactions between regulators and academic researchers. It contains data collected about the experience to collaboration between regulatory agencies and academia, including most important aspects of collaboration, level and frequency of collaboration and forms of collaboration. The CBG Science Policy Booklet contains an overview of all the regulatory science projects currently being conducted at the agency.
Finally, the first round of interviews with the contacts from different EU regulatory agencies, as described below, also covered the science engagement activities of EU drug regulatory agencies. Therefore, additional insight was gained with respect to the science engagement activities outside of the MEB case study.

During the first stage, the interviewees were purposively sampled from employees of various agencies in the EU, from contacts of the internship supervisor. The first stage was explorative in nature since the aim was to investigate the diversity of approaches and antecedents to science engagement and regulatory science for regulatory agencies throughout the EU. Initially, it was considered to include in the boundaries of this study the FDA as well, since its intense activity in regulatory science (FDA, 2022b, 2022a). However, given the differences in regulation approach between EU and USA, possible findings from the FDA were thought to not be relatable with the rest of the collected data concerning the EU agencies (Fink & Akra, 2023; Ghadanian & Schafheutle, 2024; Kontoghiorghes, 2021; Van Norman, 2016). Moreover, the geographical distance was considered as a factor for possible delays in the data collection phase, especially considering the limited amount of time available for this research. Therefore, it was excluded from the scope of the research. The EU level was chosen since regulatory agencies in the health sector in the EU are part of a network and work not only at the national, but also European level. Therefore, it became relevant to include multiple EU agencies in the scope of this research (EMA, 2023b).
Specifically, to fit the scope of the research, the agencies chosen were the ones that have expressed an interest in regulatory science. The expression of interest was evaluated through the examination of documents that showed data about the participation of EU agencies in various activities (Ghobreyal et al., 2021; MEB, 2023a). In addition to that, conversations with contacts in the agency during the internship gave more insight on the matter (personal communication, 2024). Agencies that did not express an interest for regulatory science were therefore not considered. Eight

interviews were planned to be conducted, to allow for higher reliability and validity. All the selected contacts were contacted through email and, in some cases, contacted more than once with reminders, only five interviews were conducted due to the unavailability of some of the contacts in the limited time frame. Semi-structured interviews were useful for understanding viewpoints of key stakeholders within an agency, allowing the respondents to take part in the process of answering the research question. The semi-structured interview is useful because it gives the possibility to raise new issues and allows to explore, deepen understanding, and clarify partially known topics (Wilson, 2014). Therefore, an interview guide was developed prior to the conduct of the interviews, which can be found in Appendix 5. The questions were developed following the structure of the three building blocks from Perkmann et al.'s (2021) framework, with particular focus on the second one on the antecedents, which were investigated on the three levels of individual, organizational and institutional. Moreover, the rest of the questions investigated the main science activities conducted in the regulatory agencies and the main impact, in terms of value and impact. Additionally, after the conduct of the second round of interviews (stage two), valuable data was also later found and analyzed for the results of this section.

3.2.2 Operationalization and Data Analysis

In the first stage, for the written documents considered, qualitative content analysis was used to analyze the data. As a matter of fact, qualitative content analysis can be defined as "a research method for the subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns" (Hsieh & Shannon, 2005). This method is relevant because it allowed to identify consistencies and patterns in the classification of the data in the documents. Data was inductively coded, and the codes were adjusted throughout the analysis. In this process, through the scanning of the documents, a distinction was made into two first level codes, namely science activity and interaction. This was based on the definition of the two terms. An interaction, and more specifically human interaction, can be defined as the action that enables communication – verbal, non-verbal, or a combination of both – between people to exchange information (Aleixo et al., 2023). An activity, and more specifically human activity, can be defined as a set of human operations and actions that have real predicted goal (Romanenko & Vasil'evna, 2016). Therefore, activities can entail different interactions that likely vary according to the context. For this reason, they were considered as two separate codes. Consequently, the data

referring to the MEB in the documents was thematically coded as second level codes referring to the science activity and interaction codes. The data translated into codes had to follow two main criteria: it had to be referring to the MEB or some other European regulatory agency in the health sector and involve one or more interaction with academia, scientists, or external researchers. The codes were inductively created and contributed to describe relevant aspects of science engagement activities, including the objective of the activity, the actors involved, and the main roles and responsibilities of the regulators. Additionally, during the first round of interviews, data on a broader European level was also collected and coded in the first level codes (science activities and interactions) and second level codes. The second level codes were then integrated in one table which can be found in section 4.2, as part of the results. These codes contribute to the development of the second building block of the new adapted framework and can be seen more specifically in the codebook in Appendix 7.

After the conduct of the interviews in the first and second stage, data was initially operationalized according to Perkmann et al.s (2021) framework and its three main building blocks. Specifically, the categories considered for this part were:

- Antecedents to science engagement on the:
    - Individual level
    - Organizational level
    - Institutional level

These categories included:

- Motivations to science engagement
- Barriers to science engagement

Relating the content of the interviews to these categories allowed to identify the main antecedents of science engagement for the relevant selected cases.

The interviews were conducted in Microsoft Teams meetings and were recorded and live transcribed during each interview. Later, the transcriptions were coded for valuable data using Nvivo, a computer-assisted qualitative data analysis software (CAQDAS). This allowed the removal of most of the clerical tasks associated with manual coding and retrieving of data, as well as helped highlight connections between codes, and increase the rigor of the study (Clark et al., 2021). As already stated in the research design, the data was analyzed through an abductive approach, which follows an inductive and deductive analysis. This allowed to use existing theories and concepts, while also finding new insights and perspectives directly from the data (Vila-Henninger et al., 2024). Hence, the

interview data was transcribed and analyzed firstly through deductive coding and later creating new data-driven inductive codes.

This resulted in four levels of codes. The first three levels of codes were based on the categories abovementioned from Perkmann et al.'s (2021) framework. This includes:

- Antecedents
    - Motivations
        - Individual motivations
        - Organizational motivations
        - Institutional motivations
    - Barriers
        - Individual barriers
        - Organizational barriers
        - Institutional barriers

Later, new codes were created based on new findings from the data collected. Specifically, the fourth level of codes was created. These can be found in the result section. An overview of the codebook concerning the analysis of the antecedents can be found in Appendix 7. The codes on the fourth level allowed to develop the building block on antecedents on the adapted framework.

3.3 Stage Two

In stage two, a case study was conducted, as it focused on the narrower context of the MEB and its Science Policy (2020-2024). A brief explanation of the content of the Science Policy can be found in Appendix 3. Out of the activities specifically related to the MEB, combined PhD projects was the category chosen. The aim of stage two was to answer the third sub-question of this research, and to adapt Perkmann et al.'s (2021) building block regarding the impact of engagement. In this stage, in-depth interviews were conducted focusing on the determination of the impact of the previously chosen relevant activities. Multiple combined PhD projects are being conducted currently at the MEB, and 17 have been completed between 2018 and 2023 (MEB, 2023b). This choice fits the scope of the research since it is a direct form of engagement between regulators and academia and can be used as an example to develop the building block on impact in the adapted framework on science engagement for regulatory agencies. The activity was selected according to the criterion of relevance, as importance of a topic within its substantive field (Clark et al., 2021). Combined PhD projects are high in relevance since they are one of the most represented science engagement activities in the MEB. The interviewees included contacts involved in three combined PhD projects, in the context of the MEB.

3.3.1 Sampling Strategy and Data Collection

For the second stage of the research, the interviewees included a range of employees involved in combined PhD projects in the MEB. Specifically, three projects were purposively selected for this stage. This number was thought to allow enough variation, since three different departments were considered (pharmacovigilance, pharmacotherapeutic group, and pharmacology, toxicology and kinetics), while also to analyze more in depth each project. Selecting three projects falling in the same category allowed to group together several concepts that have common features denoted by the category, and, therefore, increased the likelihood to reach a higher theoretical understanding (Clark et al., 2021). During this process, Kok and Schuit's (2012) contribution mapping assessment method was considered for the data collection and analysis, which aligns with the scope of this research to understand and evaluate the impact of science engagement for regulatory agencies in the health sector. More particularly, the second stage of this research has as an objective to delineate the main contributions of combined PhD projects in the context of the MEB as an example of science engagement activity.

The method was not applied due to limited time for the creation of a process map. However, multiple elements were taken to develop the interview guide for the second stage, which can be found in Appendix 6. Specifically, the three phases of formulate, production, and knowledge extension analyzed to create the process map were considered to structure the content of the interview guide for the second stage of the research process. Therefore, during the interviews, the vision, aims, main activities and actors, and main results for policy, practice, and health were investigated. However, in the later steps of operationalization and data analysis, this categorization was not considered applicable due to time constraints, and a different categorization was utilized, as described in section 3.3.2.

For every combined PhD project, three interviews were planned with different actors, namely the PhD candidate, the supervisor, and the head of the respective department. In total, that resulted in 9 interviews. This was also thought to be sufficient to reach a theoretical understanding on the impact of science engagement during the timeframe available for this research. However, due to time constraints and availability of the interviewee, only 7 interviews were conducted. Similarly to the first stage, an interview guide was developed prior to the conduct of semi-structured interviews, with particular focus on the third building block from Perkmann et al.'s (2021) framework concerning the impact of science engagement.

3.3.2 Operationalization and Data Analysis

The second round of interviews was also conducted in Microsoft Teams meetings and coded analogously to the first stage in Nvivo. Specifically, after the collection of the data, it was analyzed through an inductive approach. Relating to the first level code of contributions, new second level data-driven codes were created as categories inspired by the contribution mapping assessment method (Kok & Schuit, 2012). From there, third level codes were also created. The second and third level codes translated into the results for the impact (section 4.3). An overview of the codebook used for this part of the research can be found in Appendix 7. The codes on the third level allowed to develop the building block on the impact on the adapted framework.

3.4 Adapted framework

After the data collection and analysis for the first and second stage of this research, the new framework was developed. The main findings for this research, which can be found in the result section (4), allowed for the development of an adapted framework based on the one from Perkmann et al. (2021) on academic engagement. The new framework is based on the main building blocks of science activities, antecedents and impact and contains all the findings, as can be seen in section 4.4.

3.5 Research Quality Indicators

In this study, validity and reliability as research quality indicators were considered. Validity is seen in terms of “appropriateness” of the tools, processes, and data. To improve the validity of this qualitative research, theory triangulation was employed as a method to improve validity: the use of different theories to analyze and interpret data can help in supporting or refuting findings (Carter et al., 2014). Secondly, reliability refers mainly to consistency for qualitative research, and to dependability, which - as a criterion of trustworthiness – entails ensuring that complete records are kept of all phases of the research process (Clark et al., 2021; Leung, 2015). Specifically, to enhance dependability, tables were used to not only increase transparency about data collection, analysis, and findings, but also to organize and analyze data effectively (Cloutier & Ravasi, 2021). Since non-response causes reduced effective sample sizes and diminish representativeness, to minimize the risk of bias, follow-up mailings can be effective at increasing response rates (Smith et al., 2019). Therefore, this type of incentive was used to increase the response rate during the phase of interviewing.

3.6 Ethical Considerations

In the process of conducting this research, some ethical considerations emerged. Hence, prior to the start of every interview conducted during the data collection process, the participants had the opportunity to be fully informed of the nature of the research and the implications of their participation at the outset (Clark et al., 2021). In accordance with the guidelines set by Utrecht University, the consent form underlined several aspects such as the voluntary nature of the interview, the possibility to quit at any time, and the confidential processing of data in accordance with data protection legislation (Utrecht University, n.d.). Additionally, since the interviews were recorded, consent on this was asked to the interviewees.

4. Results

Here, the results from the research process are presented, divided for each building block previously discussed. Preliminary, Tables 4.1 and 4.2 contain an overview of the interviews conducted, with the position of each interviewee and a number assigned to them to refer them to the quotes used in the results.

Table 4.1: Interviewees from stage one

Interviewee	Position at EU regulatory agency in the health sector
1	Scientific affairs manager
2	Head of Innovation office
3	Head of Innovation and regulatory science
4	Member of the evaluation board and University professor
5	Head of Innovation office

Table 4.2: Interviewees from stage two

Interviewee	Position in the MEB
6	PhD candidate and non-clinical assessor
7	Head of department
8	PhD candidate and pharmacovigilance assessor
9	PhD supervisor and PRAC (Pharmacovigilance Risk Assessment Committee member)
10	Head of department
11	PhD candidate and clinical assessor
12	PhD supervisor and senior clinical assessor

4.1 First building block: Science engagement activities and Interactions

Considering the total data on activities and types of interactions gathered from the sources mentioned in the method section, the second level codes are listed and explained in this section, as seen in Table 4.3. These results refer to the MEB and more broadly to the EU regulatory agencies in the health sector. These results refer to the first building block of the science engagement framework by Perkmann et al.'s (2021). In general, the main science engagement activities for regulatory agencies include the conduct of projects to advance research on multiple fields of interest that are relevant nationally or on the EU level. This is done through collaboration with external researchers that contribute to the research and the collaboration can be realized in different manners. In addition, other types of mutually beneficial types of activities can take place between regulators and external researchers, which are listed and briefly explained in Table 4.3. These activities allow to optimize processes being part of the multiple functions of regulatory agencies, such as development of new drugs or new medical devices and conduct of clinical trials.

Table 4.3: Science engagement activities in regulatory agencies in the EU (Ghobreyal et al., 2021; MEB, 2023a; personal communications, 2024)

Activities	
Carrying out of common projects	With the aim of developing common projects between regulators and academics, key topics of interest are published from the regulatory agency. This is done to catch the interest of academic researchers and to incentivize their active input. In the context of a model of collaboration, it includes: - **Research projects**: regulatory agencies take part in several research projects that follow national/EU priorities. These projects involve multiple stakeholders (such as academic research groups and pharmaceutical companies). For example, the MEB is involved in projects concerning the main 8 themes of their Science Policy (2020-2024). They include: o Publicly funded projects, such as ones funded by Horizon Europe (Directorate-General for Research and Innovation, n.d.);

	○ Public-private partnerships, such as ones involving the Regulatory Science Network Netherlands (RSNN) and the Innovative Medicines Initiative (IMI) (IMI, n.d.; RSNN, n.d.) - **Combined PhD projects**: PhD projects represent an activity being conducted in regulatory agencies. Especially for the MEB, they are covering topics concerning the 8 main themes of the agency's Science Policy (2020-2024). 17 PhD students have been involved in projects in the MEB between 2018 and 2023 (MEB, 2023b). - **Master's/Bachelor's projects**: additional activities involving students are Master and Bachelor projects being conducted in the agency. Specifically for the MEB, students intern from 1 to 9 months from different programs (mainly pharmacy, drug innovation, biomedical sciences) to conduct projects in collaboration with the agency. The number of students varies annually, but it is increasing, with a current average of 25 students per year.
Receiving of technical support	This includes engagement with different research centers or networks to gather new perspectives on the most promising applications or changes in different research sectors, such as medical devices. Key opinions from academics and clinical experts in conjunction with the work of experts in the agency can be part of official procedures in the agency.
Provision of regulatory advice	The national agencies can provide regulatory input to researchers, in terms of early advice or early guidance, free of charge. This includes provision of information, granting access to documents, consultation, and provision of advice for the early stages of product development towards licensing and marketing.

Exchange with intermediary or additional parties	Several interactions can take place between the regulatory agency and key subgroups that connect also to academic researchers. This is for instance the case of business developers that help the researchers in terms of intellectual property rights, or technology transfer offices that represent the interface between basic research and applied clinical research. It also includes linking multiple stakeholders for different procedures, such as the link between regulatory agencies, academics, and funding bodies for procedures of regulatory scientific advice. This can allow funding bodies to make more informed decisions and grant financing to projects with the highest success rates.
Mutual training scenarios	In some cases, the regulatory agency engages with researchers from specific sectors and this engagement entails a mutual beneficial training. The regulators learn about specificities on the sector – for example in terms of best application of a certain innovation – and the researchers are trained on the regulatory landscape for that context.

Additional to the codes referring to the science engagement activities presented and explained in Table 4.3, the second level codes referring to the interactions are here listed.

Supervision of students
Participation in advisory boards
Provision of specific expertise for assessment
Participation in workshops and meetings
Reimbursement for contribution
Dialogue with experts
Combining assessment work with research or work in clinical practice

Consultation of experts on specific topics
Organization of specific targeted events to educate on regulations
Information sharing sensibilization
Communication between parties to understand requirements for developments, clinical trials etc
Participation in briefing meetings

4.2 Second building block: Antecedents to science engagement

After conducting the interviews in the first stage of this research, the data collected was analysed and the results are shown in this section. Specifically, the focus is on the results on the antecedents to science engagement, referring to the second building block from Perkmann et al.'s (2021) framework. The results are separated into motivations and barriers to science engagement, which are in turn evaluated on three different levels, namely individual, organizational, and institutional. For each of these levels, the fourth level codes are presented and explained.

4.2.1 Motivations to science engagement

In this section, the motivations are categorized on different levels. The main results for each one are presented.

Motivations on the individual level

For this level, the codes explained in section 3.3.2 referring to the motivations on the individual level are presented in this section. The codes are listed and elaborated in Table 4.4. Some quotes are also added to highlight the concepts.

Table 4.4: Motivations to science engagement on the individual level

Individual motivations		Quotes
Dissemination of experience	When multiple regulators participate in science engagement with actors external to the agency, such as academia, the experience can be disseminated internally and transmitted as a motivation for other regulators to engage in these types of interactions (3).	"I think I have around 35 colleagues of the agency staff who are currently in external projects engaged with academia, and this also has a ripple effect in that the experience is transmitted externally and internally. It is shared and colleagues are learning etcetera." (3)

Fair treatment	A fair treatment of all and avoiding discriminations allow to create a fair playing field for all parties. This includes creation of incentives for academia, but also internally to the regulators as a motivation to support academia and researchers (3).	
Structure and roles and responsibilities	Specific structures of the agency and roles and responsibilities assigned to various employees can provide a higher level of coordination and the creation of a work environment that supports the colleagues to work and collaborate with academia (3).	
Internal communication	Communication inside of the agency about the details of the activities engaged with by the agency as a whole and about the pertaining motivations for the agency represents a motivation for employees to engage with researchers. This includes also automized database systems to communicate between divisions of the same agency and incentivize employees to participate in specific science engagement activities (2).	
High perceived value	Given the busy nature of the various job positions in a national agency, consciousness of each one's time is a characterizing factor. Therefore, interactions with researchers are not necessarily prioritized. Hence, a high perceived value in the considered activities is	

	a key motivator for regulators to engage with researchers. This refers to the fact that these activities are not necessarily often engaged with (because of lack of time or other reasons). Hence, the ones chosen are the ones with the highest perceived value (1).	
Awareness of the relevance of the activities	Regulators can be well informed on the relevance of the academic sector, thanks to the possibility to access publications that describe the beneficial input of academia for the sector. This includes, for example, innovations that originate in academia and are taken up by small and medium-sized enterprises (SMEs) and, consequently, by larger pharmaceutical companies. Being informed on this allows to make the employees aware of the possible benefits of participating in science engagement activities. Therefore, it constitutes a motivation for individuals (3).	
Personal interest	Regulators might tend to be open to engagement with researchers for personal interest reasons. This includes engaging in projects where the topic is considered interesting or choosing to engage to have a break from the routine tasks. Additionally, the input from researchers can be considered helpful to combine research with practical work and the better inform the	"I've never encountered a situation, or I can't think of a situation where a staff member in the agency didn't want to engage." (1) "If you are assessing, after a few years, you know what you're doing, and it gets boring. So, let's say you need some sweets in

	decision making in the various responsibilities at the agency (1,6,8,12).	your work, and this is one" (12)
Gain experience	In some cases, science engagement can be motivated by the possibility of gaining experience through the projects. An example includes PhD projects where the students can alternate their work between the project and assessment work, and, therefore, train themselves in different areas as employees of the agency. (6)	

Motivations on the organizational level

For this section, the fourth level codes referring to the motivations on the organizational level are presented and elaborated in Table 4.5.

Table 4.5: Motivations to science engagement on the organizational level

Organizational motivations		Quotes
Lack of time	The lack of time for functions that are not directly essential for the agencies in the health sector can be a characterizing factor. This can act as a motivation to seek external expertise and service (4).	
Focused internal strategies and plans	Strategies and plans developed in the agency nationally or also on the European level can better motivate and enable to work with academia and participate in various science engagement activities. This includes interactions plans and multiple	

	initiatives (1,2,3). An example is the pilot for academic and non-profit developers of advanced therapy medicines promoted by the EMA (EMA, 2024a).	
National need for a mutual input	There is the need for the regulatory agencies to learn the needs and activities of researchers from a national perspective, in order to also adapt the priorities to these needs and, consequently, benefit from the science engagement activities (2).	
Seek expertise	The agency might lack expertise in certain fields, for example emerging areas. To provide for this expertise, external stakeholders are reached out to, including academic researchers (1).	
Gain new personnel	Science engagement activities with external researchers can represent an opportunity for regulatory agencies to scout for new employees with specific expertise and experience (7).	"You get to know a person who is doing the project. The fact that the person is getting knowledge of the work and is maybe a future employee is the thing for me" (7)
Keep the university-agency link	In case where the engagement already exists between university and regulatory agencies specifically, a motivation can be represented by the desire to keep the link between the parties well established. This is because it brings advantages, such as allowing to bring research to practice, that	

	agencies want to continue benefitting from (7,8).	

Motivations on the institutional level

For this section, the fourth level codes referring to the motivations on the institutional level are presented and elaborated in Table 4.6. Some quotes from the interviews are also added to highlight the concepts.

Table 4.6: Motivations on the institutional level

Institutional motivations		Quotes
Joint efforts	As a constellation of national agencies in the EU, it can be more efficient to engage with researchers to tackle scientific and technological developments. The joint effort on the institutional level, and not as single agencies, together with external actors in a joint network strategy, can represent a way to improve this efficiency. This is, in turn, a motivation to science engagement (2).	
National or EU priorities	Different countries may have different priorities set by the respective ministries of health that regulatory agencies need to adapt to. This can include a focus on fields that need the expertise from external researchers and, therefore, the close cooperation and creation of specific consortia between parties can be motivated (2).	

Missions of regulatory agencies	A general motivation for regulatory agencies in the health sector to science engagement is that it can be part of the main goals of these types of organizations. This includes the mission of having to serve citizens nationally and across the European Union and engaging with researchers to contribute to that mission. Another goal that falls under the main missions of regulatory agencies and can be facilitated by external researchers is the focus on innovative, transformative, and highly challenging developments. Additionally, the obligation to assess and take regulatory decisions that come with the agencies needs the support of external researchers to speed up certain process (3,5).	
Need for a joint interface	A motivation can be represented by the need to develop an interface between the agencies and external researchers, where a mutual benefit can be shared (2).	"It's really about how we can develop a kind of bidirectional interface, not just the old model where regulators were used to tell and show what academics should do." (2)
Gaining an outside perspective	Actors that are outside of the institution, such as academic researchers, can offer a unique perspective in tackling challenges in developing technologies and innovations. This can act as a motivation for the agencies in the health sector to seek external input (4).	

4.2.2 Barriers to science engagement

In this section, the barriers are categorized on different levels. The main results for each one are presented.

Barriers on the individual level

Similarly to motivations, the codes referring to the barriers on the individual level are presented in Table 4.7. Some quotes from the interviews are also added to highlight the concepts.

Table 4.7: Barriers to science engagement on the individual level

Individual barriers		Quotes
Time constraints	Time constraints represent a barrier to providing the right information to the employees of the agency, so that engagement with external researchers is possible. The availability of time for employees might be limited because of the tasks necessary to fulfil their main roles. On the other hand, also the availability of researchers represents a barrier, since both parties need to be available to interact (1,4,11).	"What can be a challenge is the accessibility of the scientists or experts. And that's not a lack of willingness to engage necessarily, but it's just a timing thing. You know you're asking busy people to engage in something where there's not necessarily always a direct benefit for them." (1)

Barriers on the organizational level

For this section, the fourth level codes referring to the barriers on the organizational level are presented and elaborated in Table 4.8. Quotes from the interviews are also added to emphasize the concepts.

Table 4.8: Barriers on the organizational level

Organizational barriers		Quotes
Lack of compatibility	In engaging with researchers, especially a high number of them, challenges arise concerning the compatibility between regulators and external researchers. The experts for the specific activities might be missed, or issues may arise concerning conflicts of interest (2).	
Resource constraints	The sustainability of science engagement can be hindered by a lack of resources, and particularly funding (1,3,5).	"The financing is important because we can only incentivize so much." (3) "We clearly face the resource constraints that all national agencies throughout Europe are having. This is really a hard thing for us because we want to provide as early as possible and as much support as possible. But we have those limitations." (5)
Missing of an overview	Regulatory agencies may lack a systematic analysis of what research is being conducted nationally, and what fields are relevant for the development of medicines. Additionally, information may be missing regarding insights on the researchers and their research (3).	

Barriers on the institutional level

For this section, the fourth level codes referring to the barriers on the institutional level are presented and elaborated in Table 4.9. Quotes from the interviews are also introduced to highlight the concepts.

Table 4.9: Barriers on the institutional level

Institutional level		Quotes
Differences in priorities	There can be different priorities between regulatory agencies in the health sector and academia. The main goal for academia can be only publications, whereas for the agency it goes beyond that. In other cases, researchers may engage with regulators to obtain the funds and to more easily publish their results. In general, the needs can differ because of the differences between institutions (1,2,4).	
Divergence of mindset	The mindset of researchers may be set on the idea that regulators will hinder research. The expectations can also be different, in terms of responsibilities of regulators that are unmatched with the reality (2).	"I heard it also from other colleagues from other countries that quite often they still fear even to approach the regulatory authorities. They still think in the old way of 10 years ago that they will hamper their research and delay them. Whereas the mindset has completely shifted at the regulatory authority side to really move from the kind of

		controlling mindset to the enabling mindset.” (2)
Fragmentation of the academic scientific community	The academic scientific community in Europe is not represented by a single entity. This fragmentation represents a challenge for regulatory agencies to get input through a structured and efficient way (2).	
Regulatory burden	A number of researchers currently miss knowledge on the regulatory requirements and other aspects, such as IT systems or regulatory standards. This can be referred to as a regulatory burden, and it represents a barrier for regulators to successfully interact and engage with researchers (1,2,3,4).	“They’re experts in their fields and that’s why we are approaching them. But there’s also explaining to them the regulatory approach and how the approach of regulators take the standards that are in place, which might be kind of instinctively obvious to them, but they might not fully understand it.” (1) “Scientists, some of them are very knowledgeable and have already worked together with big pharma companies. For instance, they know how to run a proper clinical trial, they know what the regulatory requirements are about, but still a large group is insufficiently aware of what they should know.” (2)

Complexity of the sector	A barrier to science engagement and to its effectiveness or positive contribution can be represented by the inherent characteristic of complexity of the health sector and of regulatory agencies. This can cause, for instance, delays in receiving information, and multiple steps needed to communicate between agencies (9).	"That's really relevant because I think they are important studies, but the information comes in very late, and part of the delay is due to how we work. I'm hoping there might be some improvements in the way we work, but it will take time, because the whole EU has to agree and you have to take all of them on board." (9)

4.3 Third building block: Impact of science engagement

After conducting the interviews in the second stage of this research, the data collected was analysed and the results are shown in this section. Specifically, the focus is on the results on the impact of science engagement, referring to the third building block from Perkmann et al.'s (2021) framework. The section includes the second and third level codes. As explained in the methodology, different elements of the contribution mapping assessment method by Kok and Schuit (2012) were considered for the second stage and, therefore, they are reflected in the results. Hence, the second and third level codes include a variety of elements concerning the impact of science engagement, namely contributions, skills and competences, ways of integrating the knowledge, and responsibilities.

4.3.1 Contribution to the assessment work

For the totality of the interviews, the majority of the contributions mentioned by the respondents referred to the assessment work of the agency.

General improvement of the assessment

All the PhD students interviewed mentioned the general improvement of the assessment as a contribution of their research (6,8,11). Specifically, the highlighted the link to practice of their projects. One interviewee described the clear effect of the PhD on the assessment, however, also highlighting the indirect component to it. Since the health sector regulatory system works on the European level, the effect of a PhD is not necessarily immediate, but needs to be integrated outside of the national level (8).

"Because my PhD is very closely linked to practice and also improving practice within the pharmacovigilance I think." (8)

"We would make the assessment for these types of products better, but also help us to present ourselves as the experts of epilepsy in Europe." (11)

When asked to specify the specifics on the improvement of the assessment work, the categories explained below were the results obtained from the interviewees.

Change in the guidelines

A contribution of the PhDs mentioned by more than half the interviewees is some type of change in the guidelines for each specific case (6,7,8,11,12). Two respondents underlined the goal of the PhD to change the European guideline for epilepsy drugs as a practical consequence of the project (11,12). They specified that the applicable contribution of the PhD is to adapt the guideline to bring antiepileptic drugs to subgroups that cannot yet benefit from it, such as children and adolescents.

"There is an epilepsy guideline in Europe. How to do trials in epilepsy? I am the writer of the thing, and I want to change some couple of things. We discuss not to change it? You have to substantiate it. You change it by arguments and arguments are in the data." (12)

Interviewee 6 also stated more than once the aim to update the current guidelines and the advantage of the PhD research of using the knowledge gain from it in a practical way. Specifically, the respondent underlined that the PhD may root from a rather simple question, such as how one can reduce the use of animals, or if the animal experiments are necessary for a company. From there, the study can provide useful information to answer these questions and possibly change the pertinent guidelines.

"Because the knowledge is accumulating more and more, but someone needs to be updating the guidelines if the guidelines are outdated. So, the guidelines are based on our scientific evidence, and I think that's the obvious result that we have impact on this regulatory guidelines or assessment."

Two interviewees, when asked about the contributions of the PhD on the assessment work, described that one result of the conduct of the research is coming up with recommendations (11,12). Specifically, the PhD research project can contribute to answering research questions connected to issues concerning the development of new drugs. Part of the epilepsy guideline concerns how to provide recommendations to pharmaceutical companies designing the clinical development for new drugs on epilepsy. Through the PhD, new data can flow, which can be translated into new recommendations on the EU level that would also lead to an update of the current guidelines (11).

Optimize clinical trials

One PhD student described optimizing the clinical trial process as a goal of the PhD (11). The research being conducted aims to generate sufficient evidence to support a change in the requirements for drug approval. Moreover, a simplification of the trial itself is sought, with the ultimate objective to make it applicable on a larger scale, outside of the scope of the PhD.

"Maybe it can actually be implemented more broadly in terms of saying, okay, if you do this modelling approach in this situation, then you don't need to do a full-blown study again." (11)

Improve regulatory instruments

A respondent, when asked to describe the type of knowledge utilized as an outcome of the PhD, brought the attention to the evaluation of risk minimization measures (9). Considering the existing gaps and uncertainties on medicinal safety, research can help address them. This includes evaluating is new measures are needed, or where research should focus in terms of product safety. Specifically, on the effectiveness of risk minimization measures the respondent said:

"And the other thing is that the effectiveness of the risk minimization measures is quite difficult to evaluate. Now we have at the level of the EMA an impact working group that specifically looks into the best research on how effective risk minimization works. And that is also coming directly from research done by PhD students."

Identify and tackle issues

One PhD student, when invited to mention additional contributions, mentioned a positive contribution of the PhD on the assessment in identifying new issues and work on them (8). Once a new issue is identified, conducting research can allow to investigate it. Whereas assessment work on its own cannot offer the possibility to tackle new issues in such an immediate way.

4.3.2 Contributions outside the assessment work

Future research

The totality of the interviewees indicated future research as a major contribution of PhD projects (6,7,8,9,10,11,12). Specifically, some interviewees mentioned with certainty that the respective PhD project will stimulate follow-up research projects (6,9):

“I think for sure there will be new areas to explore and to further look into things. As far as I know, every research project has generated at least one additional question, which is good because that keeps us working, doesn’t it?” (9)

Two PhD students described their role in supervising other students as a way to contributing to future research or focus on additional aspects of their specific PhD project (6,11). Moreover, projects previous to the current ones were also mentioned to show examples on the possibilities of follow-up research (7,10). Follow-up research can allow to get deeper on the considered topics and also parallel projects can be initiated to focus on related aspects (7,8).

Societal impact

One PhD student and one supervisor mentioned the impact of the conduct of this type of projects on the societal level (11,12). This refers to the idea of bringing new anti-epileptic medications to groups of the population that cannot access them yet. This follows the general mission of regulatory agencies to have societal impact in terms bring medicines as a fundamental service to European citizens. One respondent added:

“So, it’s not only the guideline, but also changing the minds and say that this can be done easier to bring it (the medicines) to the relevant subgroups who are actually not well served at the moment.” (12)

Other contributions

A series of other contributions perceived as secondary by the interviewees but still mentioned are here presented. One contribution described was the possibility to attract more pharmaceutical companies to the agency for scientific advice or drug approvals, by showing expertise through the conduct of research with specific PhD projects (11). Moreover, keeping in contact with valuable and knowledgeable stakeholders in the field was mentioned as a positive contribution of PhDs (8). Additionally, giving the possibility to students to conduct research, can give the possibility to hire them in the agency, part-time during the project and full-time subsequently. This represents a positive contribution for the agency (7). Finally, an interviewee stated that conducting research through a PhD project can have the effect of building a better reputation of the agency itself on a broader level (11).

4.3.3 Skills and competences

All the respondents referred to skills and competences developed as a consequence of the engagement in a PhD project (6,7,8,9,10,11,12). One of the PhD students, when asked what competences and skills are being developed in the project, referred specifically to a series of soft skills, including increased confidence, improved presentation skills, better communications, and conciseness in scientific writing (6). Other respondents mentioned similar skills and additional ones that are gained during the conduct of PhDs, such as development of straight forward thinking, applying logic and learning how to focus, improved endurance and collaboration, as well as a better understanding of how research is conducted (7,8,12).

Some interviewees referred the skills and competences acquired to improve in their jobs as regulators (8,10,11). Oftentimes, the PhD students at the MEB cover also assessment roles in the agency. Therefore, two students mentioned a positive contribution of conducting research on the assessment work and vice versa. Skills including being critical, learning how to lead projects, communication with others, and summarizing were referred to as useful competences developed in the PhD that improved the skills in their role of assessor (8,11).

“Both things feed into each other. Things that I’m learning with my PhD I can actually sometimes even directly apply to my assessment work. Sometimes, something new from the assessment work pops up and I think “oh, this might actually be worthwhile”. I am also learning something about myself as a person and how I can further develop myself as a professional because I have all these things that I need to take into account, that I haven’t really thought about before.” (11)

One other interviewee referred to this exchange between student and regulator as a “fruitful collaboration” (10). Another one confirmed on this and said:

“It’s also nice that (8) has both jobs: it combines being an assessor, so they see from first-hand what kind of issues you might encounter, and, from the other hand, the research job will feed into the regulatory job” (9)

However, respondent 10 also indicated a limit in this respect, which is the lack of skill in assessing patient information, expressed during an internal audit. This resulted in setting the goal to educate employees on this.

Finally, some skills and competences were mentioned as useful for assessment tasks (9,10,11). For example, one mentioned was the adoption of a new modelling approach that could speed up the clinical trial process and potentially be implemented outside of the field of interest of the PhD (11). Other skills were mentioned as well. For example, one respondent said:

"Knowledge about databases will be improved. So, you know, sometimes marketing authorization holders are very good and they say, "we have a kind of registry, and we can do it there, and we have knowledge of what can be done or cannot be done". This is of course coming from researchers. So, I think there is a big gain." (9)

4.3.4 Ways to integrate the obtained knowledge

When asked to describe how the contribution of the PhDs is being integrated into the assessment work of the agency, a variety of answers was collected in the interviews. A PhD student referred to changes in the internal guidance as a way to do that:

"Really give guidance internally on what should be most important and what we should ask for at the end of the pharmacovigilance plan." (8)

Another interviewee mentioned the planning of presentations or meetings (also congresses nationally) where the persons doing the research present the data. By keeping a recurrent exchange of interactions, knowledge can be transferred to the assessors as a first step to integrate it into the policy documents (10). This was reiterated by another interviewee that described regulatory science meetings as an open way for students to communicate their findings (9).
Another integration of knowledge pathway arisen from this question was training of the assessors to better form them to effectively integrate the knowledge into policy (9).

"And we have training for assessors and that's also done at the level of Europe at the EMA. So, it's broader that we try to address all the assessors, create awareness of this work, try to help them, and try to make them use this kind of information as good as possible, because I think it's really helpful." (9)

4.3.5 Responsibility for the utilization of the obtained knowledge

Part of the interview guide covered the identification of the responsible actors for the utilization of the obtained knowledge from the PhDs. Four interviewees referred to a common responsibility and not to a specific stakeholder (6,8,9,11). For example, one interviewee stated:

"I think everybody should be aware and should feel at least responsible to optimize the use, because it's of course difficult with so much out there. I think we are all accountable to use the best available information and the best available evidence, but I don't think there is a real hierarchy, or a somebody who is really the responsible." (9)

Respondent 9 also stated that a big portion of the responsibility falls on the assessors, that have to look into new findings from research and use them in a meaningful way.

Another interviewee stated that the responsibility can fall on different actors depending on the type of information is being generated from the study. Consequently, the most suited person to take that information and do something with it can vary (11).

One PhD student referred to the group of stakeholders including regulators and people from private companies as responsible. Since they participate in discussions with the researchers, they are responsible for determining whether the scientific evidence collected is sufficient to have a practical implication, such as an update of the guidelines, or if there is the need to generate more evidence through research (6).

Other responsible actors mentioned were supervisors of the research as well as external experts, such as clinicians of the specific area of research (11). The respondent also alluded to the idea that responsibility shared by multiple stakeholders is translated to relevance of the results not only for regulators but to a wider audience that includes different actors.

"My external supervisors definitely have a way of utilizing this knowledge in terms using it in their clinical practice. One of my supervisors is very interested in prediction models, which is something we are trying to do right now. My other supervisor is responsible for the epilepsy guideline in the Netherlands. So, maybe information that comes from that could also feed into that." (11)

4.4 Adapted framework on science engagement

Given the results for the main science activities and interactions, antecedents, and impact, a framework on science engagement of regulatory agencies in the health sector is here developed. As seen in Figure 4.1, the framework includes the main findings for each building block. In line with the scope of this research, the framework focuses on the regulatory perspective instead of the academic one and, therefore, represents an adaptation of the original framework from Perkmann et al. (2021).

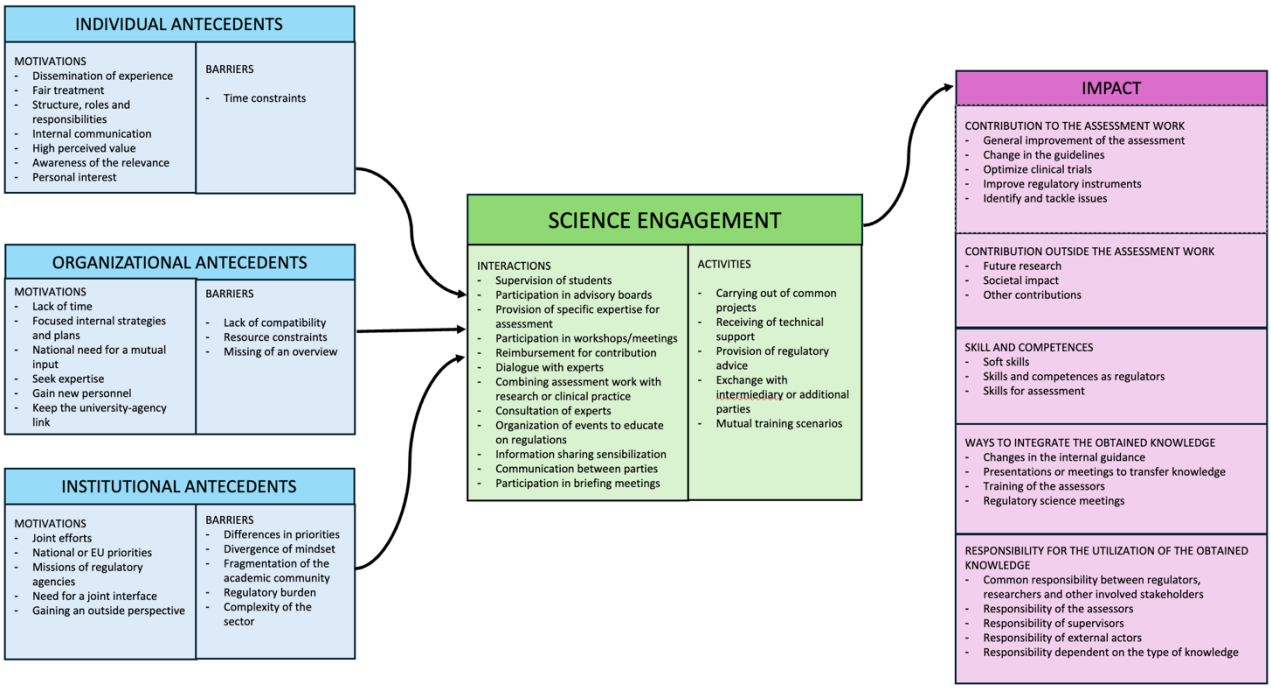

Figure 4.1: Adapted framework on science engagement

5. Discussion

This research set out to answer the research question: *How can the engagement in science activities for regulatory agencies in the health sector be understood and evaluated?*

To answer this, desk research and 12 interviews were conducted. Specifically, each sub-goal was investigated in different steps.

1: To provide a typology of science engagement activities for regulatory agencies in the health sector. To investigate this sub-goal, desk research was used to get a categorization of the main science activities engaged with by the MEB, and data on other five regulatory agencies was gathered through the interviews on the first stage of the research. The interviewees included 5 contacts from EU regulatory agencies covering different positions related to science engagement and RS. The integration of the two methods resulted in Table 4.3. Additionally, this was integrated with a list of the main interactions involved in the activities.

2: To provide insight into the main motivations and barriers for science engagement by regulatory agencies. This sub-goal was researched with the data collected mainly from the first round of interviews. Additionally, data was gathered through the second stage, where 7 interviews were conducted. This allowed to categorize the main antecedents to science engagement, in terms of motivations and barriers on the individual, organizational and institutional level.

3: To provide insight into the main forms of impact of science engagement by regulatory agencies. To explore the third sub-goal, the second stage of the research was carried out. A case study was conducted, where (3) combined PhD projects were chosen as the specific type of science activity in the context of the MEB. Therefore, the respondents included PhD students, supervisors, and heads of the respective departments. Through these interviews, data was collected using the contribution mapping assessment method by Kok and Schuit (2012) as guide to develop the interview questions. This way, information was obtained on the main forms of impact of science engagement, in terms of contributions to the assessment work, contributions outside the assessment work, skills and competences developed, ways to integrate the obtained knowledge, and main responsibilities.

In the next sub-sections, the main theoretical implications and general finding are presented, and recommendations are given to the regulatory agencies in the health sector. Finally, the limitations of this study are described.

5.1 General Findings, Theoretical Implications and Recommendations

There are multiple theoretical implications connected to this research, and from the application of Perkmann et al.'s (2021) framework to the context of science engagement of regulatory agencies in the health sector. First, the new framework was developed including a low range of actors. According to this research, regulatory agencies interact with external researchers through science engagement activities, such as carrying out of research projects and giving regulatory input to researchers. They also interact with other regulatory agencies and partly with pharmaceutical companies, for example through the development of common projects and networks that include multiple agencies on the EU level. This differs from the original framework, where the focus is on academia, but the engagement involves a higher number of actors, including industry actors (firms, companies etc.) and several governmental actors. Therefore, the application of this framework brings most of the focus on the two actors of regulatory agencies and researchers and the antecedents and impact of their engagement.

Secondly, the division between the individual, organizational and institutional levels follows Perkmann et al.'s (2021) framework on academic engagement and is useful to get a better understanding of what represents a motivation or a barrier to science engagement for employees, regulatory agencies in itself, and as part of a bigger institution. However, delineating the boundaries between different levels is partly challenging. A few antecedents are not easy to include in one specific level, and some overlapping between categories happened. One example concerns the barriers and the categories of lack of compatibility, divergence in mindset, and difference in priorities. As a matter of fact, all three have to do with challenges connected with the different nature and structure of regulatory agencies and academia. It can be argued that these barriers can concern both the organizational and institutional level, but also partly the individual one, since the employees are seen as part of an organization, and they likely function with the goals of the organization in mind. Therefore, the applicability of the adapted framework is decreased for the three levels of individual, organizational, and institutional. This can be partly considered a limitation, since the categorization of motivations and barriers took place with a personal interpretation in some instances, which partly decreased the overall internal reliability of the results. Internal reliability refers to whether there is a good match between the researcher's observations and theoretical ideas consequently developed (Clark et al., 2021) Future research should examine the three levels of individual, organizational, and institutional to draw clear boundaries between them in different contexts.

Another theoretical implication concerns motivations to science engagement. Previously, the existing literature was considered to understand antecedents to science engagement, and specifically the one referring to the private sector, because of the lack of studies concerning regulatory agencies. Two motivations for the private sector were extended and viewed as applicable for regulatory agencies, as can be found in section 2.4. However, after conducting this research, and with the creation of the new adapted framework, only one motivation was found applicable for regulatory agencies in the health sector. As a matter of fact, attracting researchers and external knowledge was found as an important motivation on the organizational and institutional levels for regulatory agencies to engage in science activities. This includes different motivations in the results, including seek expertise, gain new personnel, and gaining an outside perspective. On the other hand, building a reputation was not found as a result of this study. Therefore, applying Perkmann et al.'s (2021) framework to the context of this research allowed to show the gap in the research on motivations for regulatory agencies to science engagement and separate them from the ones pertaining to the private sector.

Additional to the theoretical implications, a set of general findings is also here described. First, the first part of the results allowed to get a better overview of the main science engagement activities. This added to the current literature, relating them directly to regulatory agencies in the health sector. As a matter of fact, the literature tends to focus on bigger categories that do not refer to specific actors (Archibald et al., 2023; Ashley et al., 2014; Bansal et al., 2019; Feldon, 2016; Lawrence et al., 2022; Petrie & Peters, 2020; Pontis et al., 2017). The categorization of activities on the European level allowed to improve the overview as well as add more details through the addition of the main interactions involved.

Another finding resulting from this research regards the results from the first stage of the research. Light was shed on the motivations for regulatory agencies to participate in science engagement activities, on three levels, namely individual, organizational, and institutional. This considerably adds on the current literature on the topic, which currently mostly focuses on the perspective of academia and the private sector (Arora et al., 2017; Boulton, 2022; Compagnucci & Spigarelli, 2020; Cuthill, 2012; Engwall, 2020a; Leten et al., 2022; Rosenberg, 1990; Rotolo et al., 2022). The findings showed that the motivations for regulatory agencies differ greatly from the ones for the private sector. As a matter of fact, the motivations and incentives for the private sector included mostly economic benefits and support of the companies' strategies. Through this study, it was found that this is not the case for regulatory agencies in the health sector, since the motivations tend to gravitate around

career benefits and, more broadly, benefits for the general role of the agencies. An example is the need for external expertise to follow European or national priorities. Moreover, consistent findings were found concerning the barriers to science engagement for regulatory agencies in the health sector. The current literature focuses on the barriers to engagement for academia, which include several commonalities, based on the survey conducted by Woitowich et al. (2022) . Firstly, time and resource constraints characterize both the academic and regulatory worlds. Secondly, one barrier found for academia consists in a communication barrier that causes more challenges in finding opportunities for engagement. Similarly, regulatory agencies encounter several barriers in terms of lack of compatibility and differences in priorities with academia. Thirdly, the regulatory burden barrier and divergence in mindset affects both academia and regulatory agencies. As a matter of fact, many members of the scientific community tend to avoid engagement since participating in politically charged activities is sometimes considered “too risky”. Findings from this research also confirm this concept, which also represents a barrier for regulatory agencies.

Another relevant finding concerns the impact of science engagement. Partly, the contribution of the PhD projects considered for this research confirms the literature on research that influences positively policymaking in multiple ways (Hanney et al., 2003). However, considering the contribution mapping assessment method allowed to additionally integrate new findings into the results. As a matter of fact, they highlighted contributions outside of the policy implications and other dimensions of the impact of engaging in science. Particularly, skills and competences developed during the process of science engagement, the way through which knowledge is integrated in the assessment work, and the main responsible stakeholders added to the literature. Whereas the current literature is mostly focused on the concept of impact of joint research (Cruz Rivera et al., 2017; Daraio & Vaccari, 2022; Dotti & Walczyk, 2022; Engwall, 2020a; Hanney et al., 2003; Korhonen et al., 2001; Liu, 2015; Robbiano, 2022; Valero & Van Reenen, 2019; Williams, 2017). Additionally, the contributions found in the results include not only the organizational level, but also consider partly a broader level. This can be seen in the finding of societal impact as a contribution of PhD projects, which allows to gain a more comprehensive overview of the impact of science engagement of regulatory agencies in the health sector. As a matter of fact, the societal impact is a fundamental dimension of the mission of regulators in the health sector. This includes a commitment to improving the health and quality of life of all citizens and encouraging healthy behaviours (Government of the Netherlands, n.d.-a).

Given these points, a series of recommendations are given to the regulatory agencies. One recommendation that stems from this research concerns the regulatory agencies as part of the health system that, through science engagement, have an impact on the societal level. There is the need for regulatory agencies to embed societal impact measurements in policy measures. As a matter of fact, by making the societal and economic impacts clear, health systems can take a stronger position in national development strategies. This would also help to shift the mindset from health systems being perceived as a cost or an obstacle, to them being seen as important components towards achieving social and economic well-being (Boyce & Brown, 2019).

A second recommendation concerns the issue of communication between regulators and academia for which goals need to be set in order to improve and increase its efficiency. As a matter of fact, during the course of this research, it was found that this barrier has also a perceived component, since regulatory agencies are highly motivated to seek collaboration. Therefore, measures need to be implemented, for example through the establishment of virtual platforms to allow easier communication between sectors. This way, more transparent exchange of needs and expectations can happen and the willingness for cooperation can be more easily shared with external stakeholders.

A third recommendation stems from this research. One barrier to science engagement on the organizational level found in this study is the missing of an overview of what research is being conducted nationally and in which fields the most developments are expected. Therefore, the creation of a database containing the main fields of development is recommended. This would include the ones relevant nationally or on the European level, but also an overview of the main areas of research active in academia. In general, several processes for regulatory agencies can be complex and challenging, and the development and automation of adequate software can improve the efficiency of these processes (Slevin et al., 2005).

5.2 Limitations and Future Research Recommendations

Pursuant to the conduct of this research, a few limitations are found and opportunities for future research are also presented here.

A first limitation concerns the first building block on science activities. Although the categorization of the science engagement activities and interactions adds to the current literature and can be considered valuable to get a better overview on the matter, it is not exhaustive. As a matter of fact, mainly due to time constraints, the data was collected considering only six out of 27 total European regulatory agencies. It was considered that data saturation was reached for stage one of this research, since the interviews brought recurring themes and, by the end of them, little new data. However, it can still be assumed that some data could have still been collected by including additional agencies to the sample. It is recommended that future research focuses on expanding the categorization considering additional EU regulatory agencies active in RS.

A second limitation has to do with the barriers to science engagement on the individual level and the external validity of this study. External validity refers to the degree to which findings can be generalized across social settings (Clark et al., 2021). As a matter of fact, only the barrier of time constraints was found in this study. Partly, this could be due to the fact that barriers to engage in these types of activities for employees are naturally quite low. This is also supported by the high number of motivations on the individual level found in the interviews conducted in this study, that confirm that science engagement is very supported by employees of regulatory agencies in the health sector. However, this could partly be limited due to the types of interviewees sampled for this research. As a matter of fact, the respondents selected for the interviews cover position in the regulatory agencies that are embedded in regulatory science and engagement with external stakeholders, such as academia. Hence, it can be assumed that the barriers perceived on the individual level are considerably lower than the motivations. This partly decreases the overall external validity of the results. Future research should examine and add to the barriers to science engagement on the individual level by involving a more various sample of interviewees, that for instance includes staff members from multiple departments.

6. Conclusions

The main research question was answered through the adaptation of the framework on academic engagement by Perkmann et al. (2021). This was done by adding up the results from the three building blocks used as foundation. Each sub-goal referred to one building block. Therefore, a new framework was obtained as a tool to understand science engagement for regulatory agencies in the health sector, as can be seen in Figure 4.1.

In conclusion, in the complexity of the health sector, and in the context of regulatory science, fully comprehending the types and ways in which interactions take place between different stakeholders can be challenging. Science engagement represents an important element of this context, and it can be present and relevant for several regulatory agencies. Understanding and evaluating science engagement becomes crucial for regulatory agencies to optimize their current practices and positively contribute to their core activities. Hence, this research allowed to develop a framework that covers the main elements of science engagement, as a first step towards enhancing regulatory agencies' science engagement to contribute to better action for health.

Appendix

Appendix 1: EU legal framework of the pharmaceutical sector and authorization process of new medicinal products

The pharmaceutical industry is responsible for the production and marketing of new medicinal products and the guarantee of their safety and validity (Poongodi et al., 2020). Pharmaceutical companies and other developers conduct research and development of medicinal products; findings and test results are subsequently submitted to the competent authorities for evaluation (EMA, 2023c). Figure 1 shows the main steps for the introduction of new medicinal products into the market.

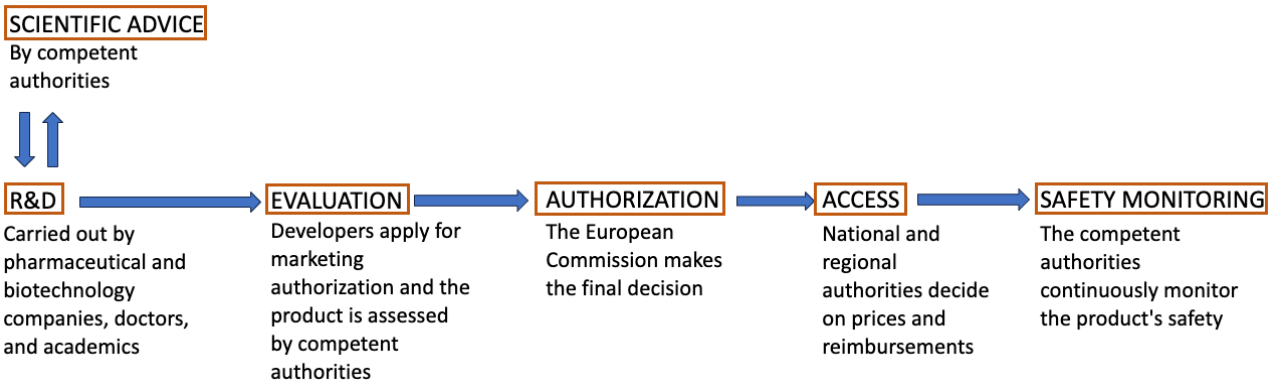

Figure 1: Main steps for the marketing of pharmaceutical products in the EU, based on EMA (2023c)

When it comes to the regulation of medicinal products, the EU legal framework consists of a large body of legislation regarding the requirements needed for placing products in the market, and for their consequent monitoring (European Commission, n.d.). This legislation was mostly developed from the 1960s, after the thalidomide tragedy, where its use as an anti-nausea treatment caused sever birth defects in thousands of children (Kim & Scialli, 2011).

The authorization of new medicinal products can take place at a European level, through a centralized procedure and with the European Commission being the authorizing body. Otherwise, on a national level, national competent authorities follow a procedure based on mutual recognition, decentralized or national procedure (European Commission, n.d.). A brief explanation of the different procedures can be found in Table 1.

Table 1: short description of the different authorization procedures (European Commission, n.d.)

Procedure Type	**Responsible authority**	**Characteristics**
Centralized	European Commission	New products can be made available to all European countries.
Decentralized	National authorities for the EU members involved	Used to obtain authorization in several EU countries, which are in this case named Concerned Member States. (CMS). One becomes the Reference Member State (RMS). This procedure also involves a mutual recognition one (MEB, n.d.-b).
Mutual recognition	National authorities for the EU members involved	In case a marketing authorization has already been issued in the RMS, other EU states can obtain it through mutual recognition (MEB, n.d.-c).
National	National authorities for the EU member involved	The authorization is only valid in the concerned state. It may also be the first step for a Mutual Recognition procedure (where it is the RMS) (MEB, n.d.-d).

The regulation of pharmaceutical products in the EU stems from three crucial criteria. First, the products need to be of suitable quality, in terms of qualitative and quantitative composition. This criterion is assessed in accordance with the EU legislation, as well as a series of guidelines (European Commission, n.d.).

The other two fundamental criteria are safety and efficacy. These are demonstrated through the results of clinical trials, which are authorized by national competent authorities through the submission of specific applications (EMA, 2023c). Specifically for new medicines, the assessment is carried out by a competent authority, which on the EU level coincides with the European Medicines Agency (EMA), which was founded in 1995. Safety and efficacy are also continually monitored after

their introduction on the market, through pharmacovigilance action and benefit-risk evaluations (European Commission, n.d.).

Appendix 2: Structure and responsibilities of the MEB

In the Netherlands, marketing authorization for human and veterinary drugs is conducted by the Medicines Evaluation Board (MEB), which falls under the Ministry of Health, Welfare and Sport (VWS) (Government of the Netherlands, n.d.-b; MEB, n.d.-f). The Board is supported by the Agency, which deals with different programs, as well as the primary assessment process and support units. The units within the primary process assess and monitor pharmaceutical products, according to a categorization in four pharmacotherapeutic groups (PT); each one of these groups is organized by medical condition. After the assessment by the Agency, the Board is responsible for the marketing authorization of the medicine for the Dutch market, as well as for the consequent monitoring of the risks. For the European market, it represents a vote out of 27 voting European countries, where the European Commission gives the final authorization (MEB, n.d.-f). The general structure of the MEB can be seen in Figure 2.

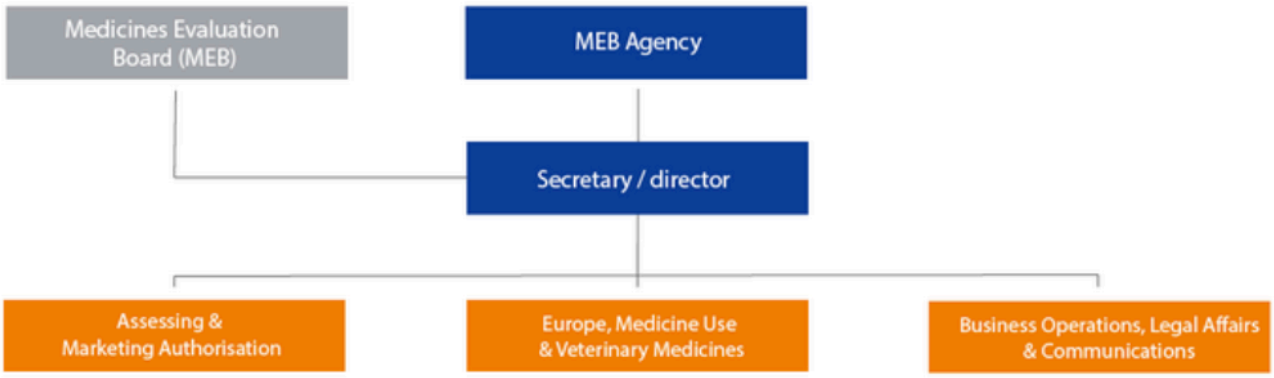

Figure 2: organizational structure of the Medicines Evaluation Board (MEB, n.d.-f)

Thus, the MEB is responsible for three main tasks. Firstly, as described more in detail in Appendix 1, the assessment of efficacy, safety and quality of the medicine is conducted through a fixed procedure: the medicine dossier provided by the pharmaceutical company is checked, the medicine is assessed in terms of overall quality and balance between the efficacy and the risks of the product, and how and where the product can be marketed is determined (MEB, n.d.-a). Secondly, an extensive monitoring system is put in place to check on adverse reactions of authorized medicines. Thirdly, the MEB is responsible for the promotion of proper use of medicines, mostly through the creation of an understandable and reliable leaflet. In addition, the MEB can also provide scientific advice to pharmaceutical companies for a new medicine under development, to contribute to the responsible

development of medicines (MEB, n.d.-e). Finally, the MEB contributes to the centralized authorization procedure with a consulting role in EMA committees, such as the Committee for Medicinal Products for Human Use (CHMP). In this context, the MEB can provide scientific opinions on quality, safety, and efficacy of medicinal products (CHMP. Rules of Procedure, 2022).

Appendix 3: MEB's Science Policy

The research design chosen is a multiple-case study in the context of a broader case of the MEB and its Science Policy (2020-2024), which is based on eight main themes for guiding scientific research. These eight themes are in line with their Strategic Business Plan (SBP) generated for the same time span and they include:

1) Replacement, reduction, and refinement of animal tests (3Rs)
2) Advanced Therapy Medicinal Products (ATMPs)
3) Data-driven assessment
4) Personalized medicine and biomarkers
5) Medical devices
6) Generics
7) Medicines used better
8) Safety and effectiveness after authorization

These activities are planned to be carried out taking into account the MEB existing as a part of an international regulatory system, where collaboration and cooperation with other national medicines authorities and the EMA exist. In addition, other activities are included in the Science Policy, in collaboration with academic groups, pharmaceutical companies, and other stakeholders (MEB, 2020).

Appendix 4: Impact assessment methods

Regarding the societal impact assessment methods, many have been developed and have become common to assure accountability as a necessary part of scientific practice at all levels (Smit & Hessels, 2021). The main approaches present in health system are considered, namely the Payback Framework, Monetization, SIAMPI, Contribution Mapping, REF, and the Research Contribution Framework (Buxton & Hanney, 1996; Health Economics Research Group (HERG) et al., 2008; Higher Education Funding Council for England et al., 2011; Kok & Schuit, 2012; Morton, 2015; Spaapen & van Drooge, 2011).

Table 2 describes what is meant by impact in each of the considered frameworks.

Table 2: Conceptualization of impact for different frameworks

Frameworks	Impact conceptualization
Payback Framework	Impact ("payback") includes five main categories of benefit from research: 1) Knowledge 2) Benefits to future research and research use 3) Benefits from informing policy and product development 4) Health and health sector benefits 5) Broader economic benefits (Donovan & Hanney, 2011)
Monetization	Impact is measured as economic returns in terms of: 1) Value of the health gains 2) GDP gains (Health Economics Research Group (HERG) et al., 2008)
SIAMPI	Societal impact is seen as a behavioral change that happen as a result new knowledge created by "productive interactions", which can be: 1) Direct 2) Indirect

	3) Financial (Spaapen & van Drooge, 2011)
Contribution Mapping	Impact is seen as "contributions", that refer to the activities which turn novel combination of knowledges into a "going concern" as a component of practices, innovations, or decisions (Kok & Schuit, 2012).
REF	Impact refers to "an effect on, change or benefit to the economy, society, culture, public policy or services, health, the environment or quality of life, beyond academia" (Higher Education Funding Council for England et al., 2011)
Research Contribution Framework	Research impact is defined as "changes in awareness, knowledge and understanding, ideas, attitudes and perceptions, and policy and practice as a result of research" (Morton, 2015)
Academic Engagement Framework	Impact is seen as a result of academic engagement, which is influenced by individual, organizational, and institutional factors. Impact is considered in terms of: 1) Scientific output 2) Educational output 3) Commercial output (Perkmann et al., 2013)

Appendix 5: Interview guide for stage one

Topic	Questions
Introduction	Can you briefly describe what your role is in the Agency? How would you define regulatory science? What types of interactions does your agency have with scientists? - *Can you give some examples?* - *Can you elaborate on these activity/activities?* - *Does your agency distinguish between different types of activities?* Does your agency have specific strategies or plans for interactions with scientists? Can you elaborate on the respective roles and responsibilities of involved regulators in these interactions? How do you incorporate the outcomes of these interactions in the day-to-day activities of the regulatory agency?
Motivations and Challenges	How is it decided by the agency to engage in specific types of interactions with scientists? *- What are the reasons/factors that weigh in when choosing to engage in a specific interaction?* *- Are there motivations to engage in these interactions for the whole agency? / How are the interactions part of the general goals of the agency? (organizational level)* *- How does the agency motivate employees to engage in these interactions? (extrinsic motivations-individual level)* *- Is the preference/wish of single individuals in the agency a factor when choosing a certain type of interaction? (intrinsic motivations-individual level)*

	What are typical challenges that are encountered when engaging in these interactions? - *Are there challenges for the agency itself? (organizational level)* - *Are there challenges for employees/specific departments to engage in these interactions? (extrinsic challenges on the individual level and intrinsic challenges on the individual level)*
Impact	What value do the interactions with scientists bring to the regulatory agency? *- How is the obtained knowledge from the interactions with scientists being used in the agency?* *- How do you ensure that the obtained knowledge from these interactions is used in the agency?* *- Could you distinguish in this respect between various forms of impact?* Do you measure the impact of the interactions with scientists? If yes, how? Do you think that your agency's interactions with scientists are valuable enough for regulatory agencies? How could the value and impact of these interactions for the regulatory agency be improved?

Appendix 6: Interview guide for stage two

Contribution phases	Questions
Production	Can you briefly describe what your role is in the Agency? Can you briefly describe what your involvement is in the activity? - *What is your role in this activity? / What are your main responsibilities?* - *Who do you interact with/who else is involved in this activity? And how?*
Formulate	What influenced your participation in the activity? - *What are the reasons/factors that weighed in when choosing to engage in this activity?* - *Are there motivations to engage in this activity for the whole MEB? / How does this activity fall into the general goals of the agency? (organizational level)* - *How are you motivated (as an employee) to engage in this activity? (extrinsic motivations-individual level)* - *Was your preference/wish a factor when choosing to engage in this activity? (intrinsic motivations-individual level)*
Knowledge extension	How would you describe the contribution of this activity to regulatory activities and practices? - *Can you describe which knowledge is being utilized as an outcome of this activity?* - *How is the obtained knowledge integrated in the assessment work of the agency? (for example, in terms of uptake in guidelines or discussions in science committees or working parties)* - *How is it ensured that the obtained knowledge from this activity is being utilized?* - *Who is responsible for the utilization/dissemination of the obtained knowledge/results of the activity?*

	- *Are new skills or competences being developed as a result of this activity? What is the importance of these new skills or competences for the assessment work?* - *Are there other contributions to the research domain and assessment work?* - *Are the results of this activity likely to initiate new projects/activities?* Are there any other aspects that you would like to mention related to the PhD trajectory?

Appendix 7: Codebooks

Here the codebook for the two rounds of interviews and the codes for the documents used to categorize the science activities and interactions are presented.

Stage one

Codes

Name	Description	Files	References
Antecedents	First level code on building block of antecedents to science engagement	11	62
Barriers	Second level code on antecedents to science engagement	7	23
Individual barriers	Third level code on antecedents to science engagement	2	3
Time constraints	“”	3	4
Institutional barriers	Third level code on antecedents to science engagement	5	12
Differences in priorities	Fourth level code on antecedents to science engagement	3	3
Divergence of mindset	“”	1	2
Fragmentation of the academic scientific community	“”	1	1
Regulatory burden	“”	4	5
Complexity of the sector	“”	1	1
Organizational barriers	Third level code on antecedents to science engagement	4	7
Lack of compatibility	Fourth level code on antecedents to science engagement	2	2

Name	Description	Files	References
Resource constraints	“”	3	3
Missing of an overview	“”	1	2
Motivations	Second level code on antecedents to science engagement	9	39
Individual motivations	Third level code on antecedents to science engagement	6	17
Dissemination of experience	Fourth level code on antecedents to science engagement	1	1
Fair treatment	“”	1	3
Structure and roles and responsibilites	“”	1	2
Internal communication	“”	1	3
High awareness of the relevance of the activities	“”	1	1
High perceived value	“”	1	1
Personal interest	“”	4	5
Gain experience	“”	1	1
Institutional motivations	Third level code on antecedents to science engagement	4	8
Joint efforts	Fourth level code on antecedents to science engagement	1	1
Mission of regulatory agencies	“”	2	3

Name	Description	Files	References
National or EU priorities	“”	1	2
Need for a joint interface	“”	1	1
Gaining an outside perspective	“”	1	1
Organizational motivations	Third level code on antecedents to science engagement	6	14
National need for a mutual input	“”	1	1
Lack of time	“”	1	1
Seek expertise	“”	1	1
Focused internal strategies and plans	“”	3	6
Gain new personnel	“”	1	2
Keep the university-agency link	“”	2	3
Interactions	First level code on building block of science activities and interactions in science engagement	3	5
Communication between parties to understand the requirements	Second level code on interactions in science engagement	1	1
Information sharing sensibilization	“”	1	1
Organization of specific targeted events to educate on regulations	“”	1	1

Name	Description	Files	References
Participation in briefing meetings	“”	1	1
Science activities	First level code on building block of science activities and interactions in science engagement	5	30
Development of common projects	Second level code on science activities in science engagement	1	1
Exchange with intermediary or additional parties	“”	1	4
Mutual training scenarios	“”	1	1
Provision of regulatory advice	“”	3	8
Receiving of technical support	“”	2	3

Stage two

Codes

Name	Description	Files	References
Contributions	First level code on building block of impact of science engagement	7	87
Contributions outside the assessment work	Second level code on impact of science engagement	7	18
Attract companies to the agency	Third level code on impact of science engagement	1	1
Build a reputation	“”	1	1
Future research	“”	6	9
Keep contact with other valuable actors	“”	1	1
New personnel	“”	1	1

Name	Description	Files	References
Societal impact	“”	2	2
Contributions to assessment work	Second level code on impact of science engagement	6	18
Change in the guidelines	Third level code on impact of science engagement	5	8
Evaluate the effectiveness of measures	“”	1	3
Identify issues	“”	1	1
Improvement in the assessment	“”	3	5
Optimize clinical trials	“”	1	2
Recommendations	“”	2	2
Integration of knowledge pathways	Second level code on impact of science engagement	3	5
Adapt guidance internally	Third level code on impact of science engagement	1	1
Presentations or meetings	“”	1	1
Regulatory science meetings	“”	1	1
Training	“”	1	2
Responsibilities	Second level code on impact of science engagement	7	22
Utilization of the obtained knowledge	Third level code on impact of science engagement	5	9
Skill and competences	Second level code on impact of science engagement	7	24

Name	Description	Files	References
Skills as a regulator	Third level code on impact of science engagement	4	9
Skills-Competences for assessment	“”	3	4
Soft skills	“”	4	10

CBG Science Policy Booklet

Name	Description
Science activities	First level code on building block of science activities and interactions in science engagement
PhD projects	Second level code on science activities in science engagement
MEB research	“”
Projects with external financing	“”
Miscellaneous	“”
Interactions	First level code on building block of science activities and interactions in science engagement
Participation in advisory board	Second level code on interactions in science engagement

Foster Collaboration Survey

Name	Description
Science activities	First level code on building block of science activities and interactions in science engagement
PhD projects	Second level code on science activities in science engagement

Master's/Bachelor's projects	""
Combining assessment work with research or clinical practice	""
Adhoc activities	""
Training	""
Interactions	Second level code on interactions in science engagement
Scientific advice	""
Supervision of students	""
Participation in meetings	""
Scientific assessment	""
Reimbursement for contribution	""
Early dialog with experts	""

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