A comparative study of national schemes and services for “early interaction” with Regulators

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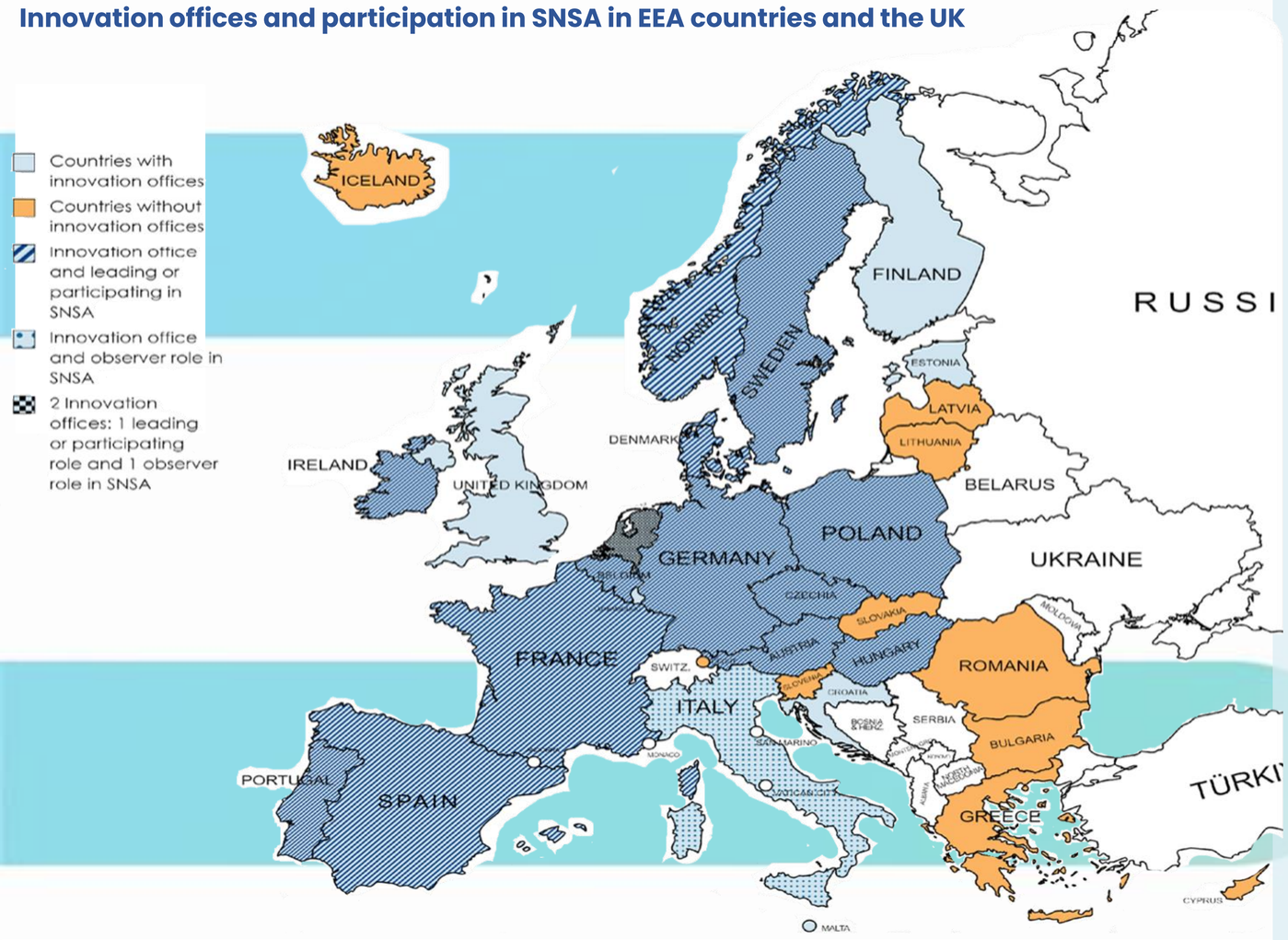
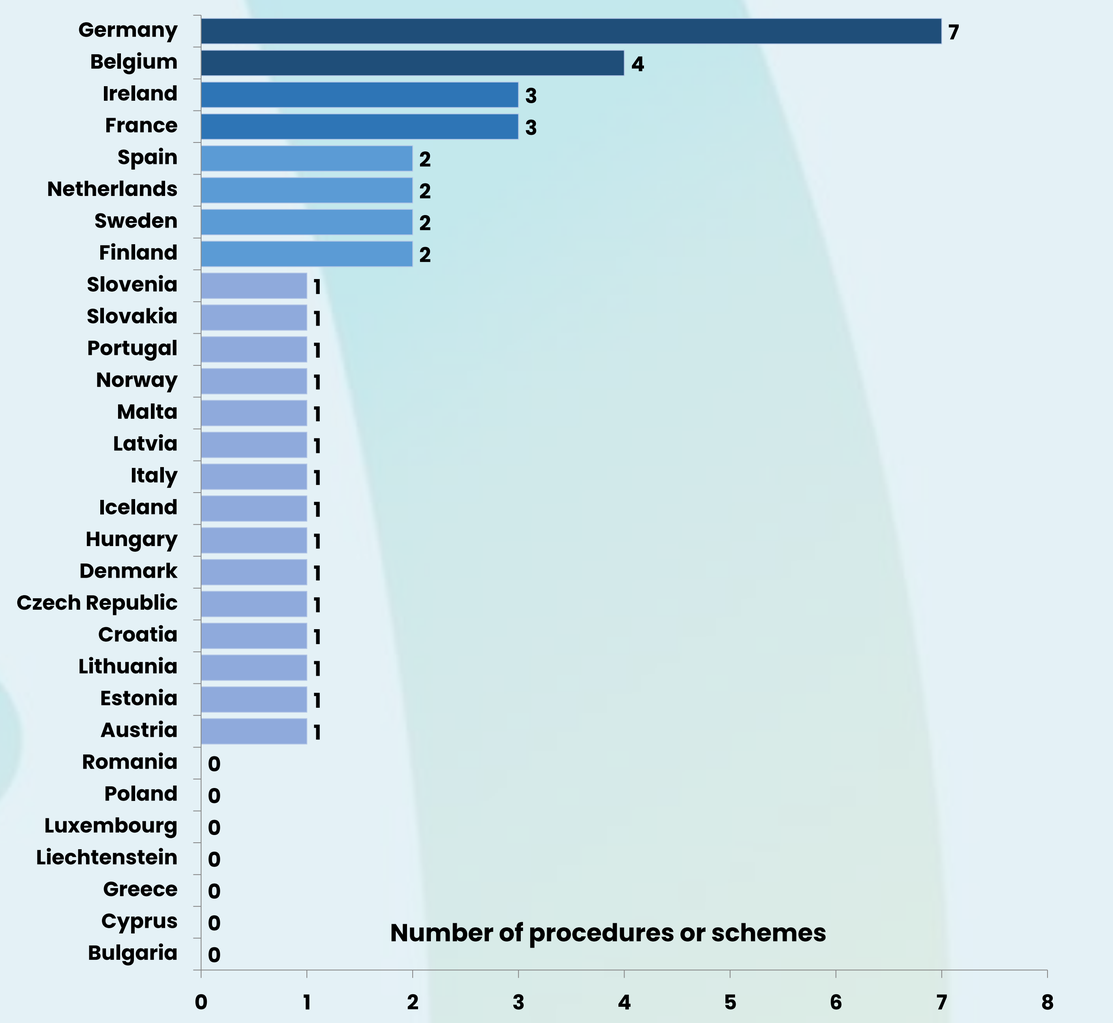
Introduction & Methodology

National regulators, here understood as National Medicines Agencies, are supporting the development of innovative medicines in the field of Gene and Cell therapy by creating dedicated schemes and services. They are the first contact point for any developer. Beyond the interest in using one’s own mother tongue, several decisions (e.g., Clinical trials authorization despite the single application via the European Union (EU) portal), rules and procedures (e.g., ATMPs under the hospital exemption) fall under the remit of each Member State. Therefore, the first intention should always be to enter into contact with the regulator of the country where the medicine is developed. However, all countries are not equal when it comes to supporting the development of medicines. The purpose of this research is to identify the opportunities, as well as differences and gaps in availability and choices for developers of innovative medicines seeking early support at the national level. The availability of national support schemes can be a piece of information allowing to complete our understanding of the different national approaches towards gene and cell therapy. If most Member States have procedures and services for developers’ early contact with, their availability and access show discrepancies between States. Between September 2023 and September 2025, research and updates have been undertaken on each European Economic Area (EEA) and EU National regulators websites. National regulators have been punctually contacted where information was not found on national websites and when appropriate contact was available. Beyond Simultaneous National Scientific Advice (SNSA) which allows interactions with multiple national regulators, the studied States have also dedicated services (often called innovation offices) and other procedures which this study aims at showing. In the remit of this study the mention N/A is indistinctly used when no services or procedures is available, if nothing has been found or if the information is not provided.

Innovation offices and participation in SNSA in EEA countries and the UK



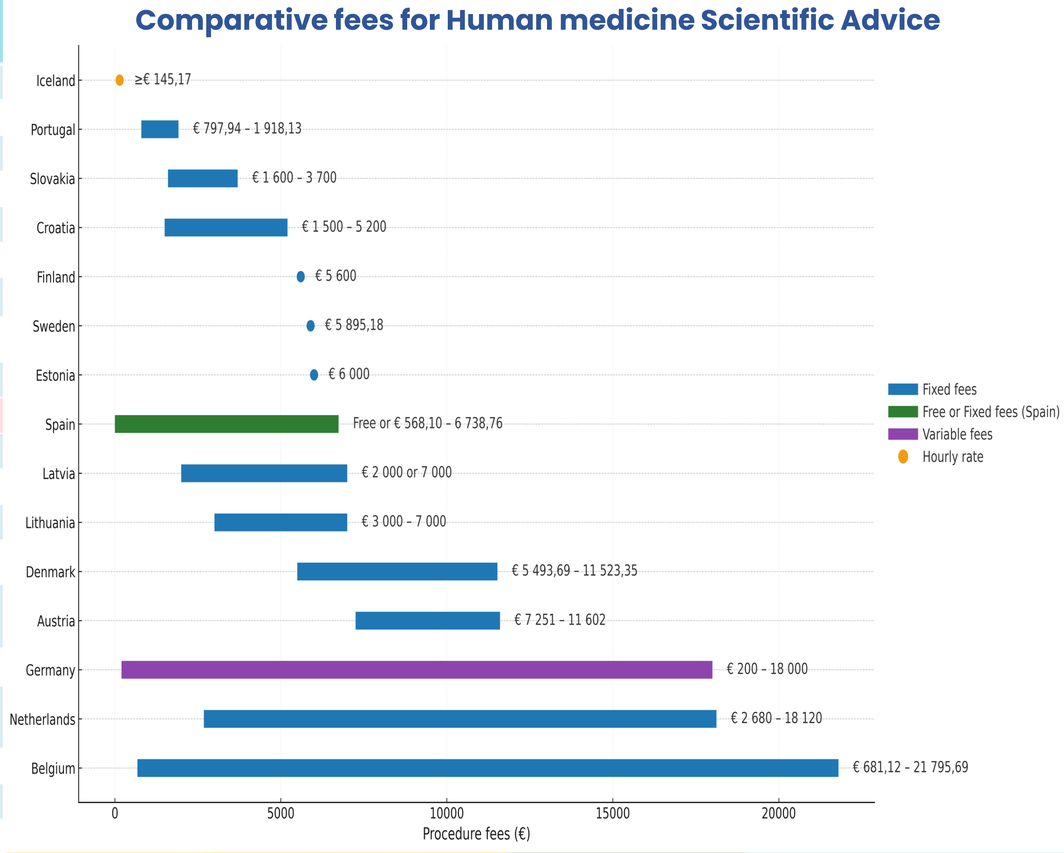
EEA countries ranked by number of found types of interaction procedures with one regulator



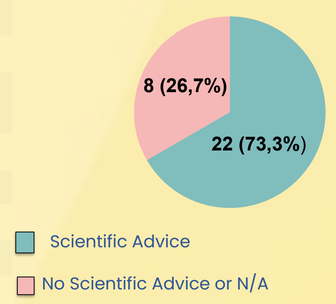
Scientific Advice procedures and linked fees for human medicines in EEA countries

Country	Status	Name of advice procedure	Fee	Rate basis criteria	Fee incentives
Austria	✅	National Scientific Advice (NASA)	Yes	Novelty of active substance	N/A
Belgium	✅	Scientific-technical advice	Yes	Type of product	Yes
Bulgaria	❌	N/A	N/A	N/A	N/A
Croatia	✅	Scientific advice	Yes	Complexity of request	N/A
Cyprus	❌	N/A	N/A	N/A	N/A
Czech Republic	✅	Scientific advice	Yes	N/A	N/A
Denmark	✅	National Scientific Advice	Yes	Scope of advice	No
Estonia	✅	Scientific advice and pre-submission consultation	Yes	N/A	Yes
Finland	✅	Scientific advice	Yes	N/A	N/A
France	✅	Scientific advice	No	N/A	N/A
Germany	✅	Scientific advice	Yes	Complexity of request	N/A
Greece	❌	N/A	N/A	N/A	N/A
Hungary	✅	Scientific advice / Consultancy	Yes	N/A	N/A
Iceland	✅	Scientific advice	Yes	N/A	N/A
Ireland	✅	General Advice on regulatory requirements and general guidance on technical or scientific issue	Yes	N/A	N/A
Italy	✅	Innovation meeting incl. scientific advice	Yes	N/A	N/A
Latvia	✅	Scientific advice	Yes	Type of advice : regulatory or scientific advice	No
Liechtenstein	❌	N/A	N/A	N/A	N/A
Lithuania	✅	Scientific-Regulatory Advice (RSA)	Yes	Stage of development	No
Luxembourg	❌	N/A	N/A	N/A	N/A
Malta	❌	N/A	N/A	N/A	N/A
Netherlands	✅	Scientific advice and Joint scientific advice	Yes	Complexity of request	Yes
Norway	✅	Scientific & Regulatory Advice	Yes	N/A	N/A
Poland	❌	N/A	N/A	N/A	N/A
Portugal	✅	Regulatory & Scientific Advice (RSA)	Yes	Regulatory or scientific + fields (Clinical, pre-clinical…)	N/A
Romania	❌	N/A	N/A	N/A	N/A
Slovakia	✅	Scientific advice	Yes	Complexity and field	No
Slovenia	✅	Scientific advice	N/A	N/A	
Spain	✅	Scientific Advice	Yes	Complexity and field	Yes
Sweden	✅	Scientific advice	Yes	N/A	Yes

Comparative fees for Human medicine Scientific Advice



Proportion of EEA countries with found Scientific Advice procedures



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All contributions are credited on the EuroGCT website.

Discussion and Conclusion

1. Information accessibility

- Minor difficulties in finding information
  - Website in at least 2 languages except for Poland
  - Some information are less easy to find like the fees and their related incentives
  - Similar procedures may have different names in different countries

→ **Most countries provide accessible information on the available procedures with more or less details.**

2. Availability of services and procedures

- As of April 2025, 1/3 of countries have no innovation office and 2/3 of countries+ UK have an innovation office.
- 23% have no interaction procedure, 50% have one, 26,7% have 2 or more.
- Types of procedures are various: Scientific Advice, Pre-submission meetings, Portfolio/Innovation meetings, Informal regulatory guidance, Classification services, specific type of advice (e.g., on data protection with DiGA/DiPA in Germany)
- 2 countries have an innovation office for SNSA and no specific national procedure (Poland & Luxembourg).
- 5 countries have specific national procedures but no innovation office (Iceland, Latvia, Lithuania, Slovenia & Slovakia).
- **Combining results** :
  - Most countries have available services or procedures (83,3%).
  - Only 5 countries have no services or procedures (Bulgaria, Cyprus, Lichtenstein, Greece, Romania). These are Eastern European countries where dedicated services or procedure may not be needed to answer the demand of developers for early interaction or are not political priorities for the country. An explanation can be the resources and the national priorities of the country.

→ **In the EEA, National early interactions are generally available and accessible; they are various.**

3. The procedure of Scientific Advice

- **Scientific advice (SA) is by far the most available procedure in EEA countries:** more than 73% of EEA countries have a procedure of SA, or that can be assimilated to SA (not necessarily the exact same scope)
- SA fees vary between countries :
  - 3 countries have very large scales of prices (Germany, Netherlands & Belgium).
  - The larger the scale the more limiting it could be for developers to know what the final cost will be (e.g., Germany).
  - A higher cost or lack of fee incentives can be linked to some extent to the GDP, available resources and support policies of the country.
  - In countries where fee incentives are available, these are linked to the status of the developer: SMEs, Academia and/or Non-profit org. are targeted similarly to EMA’s SA.

→ **Scientific Advice is the main interaction procedure with or without payable fees and targeted developers' incentives**