Office for Support of **INNOVATION** and **KNOWLEDGE** of **MEDICINAL PRODUCTS**

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

SUPPORT FOR RESEARCHERS

The Innovation Office was created in 2016 with the aim of integrating, coordinating and enhancing the different activities and initiatives to support the innovation and obtain additional knowledge of authorized medicinal products.

National Scientific and/or Regulatory Advice

Support to the medicinal products research at the different stages of their development:

- For the pharmaceutical industry in general ◗ Through the National Scientific Advice Unit **(ascina@aemps.es).**
- For academic groups, independent researchers (from academia or hospitals), research foundations, startups or patient foundations) ◗ Through the Innovation Office **(innov_spain@aemps.es).**

Early guidance to independent researchers will prevent inappropriate developments, use the finding wisely and speeding up the developments. Therefore, it will allow the medicinal products to reach the patients sooner

Simultaneous National Scientific Advice (SNSA)

Carried out at the same time with more than one National Competent Authority (NCA) (ascina@aemps.es).

Centralized Scientific and/or Regulatory Advice (SAWP)

European advices, with the AEMPS participation, through the Scientific Advice Working Party (SAWP) (form).

Parallel joint scientific consultation with regulators and health technology assessment bodies

To allow medicine developers to obtain feedback from regulators and health technology assessment (HTA) bodies in European Union (EU) Member States on their evidence-generation plans to support decision-making on marketing authorisation and reimbursement of new medicines at the same time (hta@aemps.es).

Scientific, regulatory advices and parallel joint consultations are key to obtain a Marketing Authorization Application in the future

Coordination with the European Innovation Network (EU-Innovation Network, **EU-IN)**

With the objective of strengthening the collaboration between National Competent Authorities (NCA) and the EMA to address regulatory issues related to emerging therapies and technologies
(innov_spain@aemps.es).

Repurposing Pilot Project

To support **non-for-profit organisations and academia and hospital researchers to gather or generate sufficient evidence on the use of an established medicine** and used off-label, on which a future application made by a pharmaceutical company is based on. New treatment options are offered to patients.

Borderline and Classification Group (BLCG)

To discuss and share non-binding opinions on borderline classification issues. “Borderline classification” in the context of this group is understood as referring to circumstances where a product is not clearly covered by the pharmaceutical legal framework/ regulation due to the nature of the product.

Horizon Scanning

Identification of **emerging trends of innovative medicinal products and health technologies.**

STARS

STRENGTHENING REGULATORY SCIENCE

To improve the regulatory knowledge of academic and hospital researchers (www.csa-stars.eu).

It is essential to boost innovation from all fields, including the regulatory affairs point of view

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Advices carried out in 2022.

EU-IN monthly meetings and biweekly meetings on each of the projects allow an effective coordination.

50%

In **2022**, 50% of the advice received through the Innovation Office were on topics related to **Advanced Therapies** (ATMPs) and **Non-Industrially Manufactured Medicines**.

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