



# Office for support of INNOVATION and KNOWLEDGE of medicinal products

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Spanish Agency  
of Medicines  
and Medical Devices



GOBIERNO  
DE ESPAÑA

MINISTERIO  
DE SANIDAD, SERVICIOS SOCIALES  
E IGUALDAD



agencia española de  
medicamentos y  
productos sanitarios



The Spanish Agency of Medicines and Medical Devices has launched the **Spanish office for support of innovation and knowledge of medicinal products** in order to integrate coordinate and strengthen the different activities and initiatives supporting investigation, innovation and the obtaining of additional knowledge about new medicinal products performed by the Agency in Spain and within the Framework of the European Medicines Agencies Network.

The development, authorisation and maintenance in the market of medicinal products is a highly regulated sector, subject to specific legislation aimed at ensuring the quality, safety, efficacy and correct information of medicinal products throughout their life cycle.

Society has thereby equipped itself at a world level with a series of rules in the field of medicinal products that imply a level of guarantees much greater than that of other technologies at the cost of a regulatory procedure which may become complex. In this context, it could be very important to maximise the

possibilities of success, for example, so that certain types of innovation in the hands of academic groups or small companies have the possibility of reaching advanced stages of development, with the implications that this may have in patient benefit.

The regulation of medicines has achieved significant harmonisation in the European Union (hereinafter EU) through a network model in which the national agencies make their scientific expertise available to the European Medicines Agency (hereinafter EMA) that coordinates these resources. Innovation in the EU no longer has a merely national orientation. Potential innovation has to reach European authorisation procedures of medicinal products and be aligned with these. For this reason, the national agencies are a point of reference for early detection of this innovation and for channelling it towards the European authorisation procedures, thus maximising its possibilities of success.

Finally, it is necessary that society is able to have access to this innovation both rapidly and according to schedule, but also taking into account the knowledge available at a certain time and the «therapeutic value» and degree of innovation implied in comparison with other available alternatives.

In accordance with its Statute, the Spanish Agency of Medicines and Medical Devices (hereinafter AEMPS) «has the commitment to support research and innovation, as well as the collaboration with the public and private sectors and institutions, so that the availability of new treatments and diagnostic tools takes place rapidly and with the greatest possible level of safety for citizens.». The Agency, in fact, has been developing different activities and initiatives in this field such as the «Independent Investigation Support Office», the activities of scientific advice or as an agency of assessment of health technologies (hereinafter HTA) in the parallel scientific advice with HTA coordinated by the EMA, among others. On the other hand, the European Medicines Agencies Network has agreed that the promotion and support of innovation in the field of medicinal products is one of its strategic objectives over the next five years.<sup>(1)</sup>

1. EU Medicines Agencies Network Strategy to 2020. Working together to improve health. Available in: [http://www.hma.eu/fileadmin/dateien/HMA\\_joint/00-\\_About\\_HMA/Adopted\\_EU\\_Medicines\\_Agencies\\_Network\\_Strategy\\_to\\_2020.pdf](http://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/Adopted_EU_Medicines_Agencies_Network_Strategy_to_2020.pdf)





Office for  
support of  
**innovation and  
knowledge**  
of medicinal  
products



## Office for support of innovation and knowledge of medicinal products

The office for support of innovation and knowledge of medicinal products of the AEMPS has been created with an integrated vision of the life cycle of medicinal products. Access to medicinal products is considered from a global perspective that covers the promotion and support of investigation and development of new therapeutic alternatives which respond to the real needs of the society, the optimisation of access to these alternatives by patients according to their moment of development and available evidence as well as the promotion and support of research that improves the knowledge of already authorised medicinal products.



The services offered by office for support of innovation and knowledge of medicinal products revolve around four principal objectives:

- 01 Integration in the structure of the European Union** services provided, thus enabling the transition to the procedures of identification of innovation, advice, assessment and registration of the European Union.
- 02 Support for investigation** including services of scientific advice adapted to the needs of the applicant and the product concerned, both in the pre-authorisation phase and throughout its life cycle by means of clinical trials or observational studies with medicinal products.
- 03 Access to medicinal products prior to authorisation** in a manner adapted to the existing degree of knowledge of the same product and the different modalities of access, prevailing those studies that are capable of generating knowledge of better quality such as clinical trials, but without forgetting the framework of compassionate use schemes and the registries.
- 04 Access to medicinal products after authorisation**, by integrating at a national level, the parallel advice with HTA, the development of therapeutic positioning reports together with the Autonomous Communities or the recommendations of access under different conditions from those authorised.



**Who** is able to  
benefit from  
the services  
of the office  
for support of  
**innovation and  
knowledge**  
of medicinal  
products?



## Who is able to benefit from the services of the office for **support of innovation** and knowledge of medicinal products?

The office for support of innovation and knowledge of medicinal products is created with the global objective of unifying the administration of the different lines of collaboration during the approach, development, authorisation, access to medicinal products and obtaining knowledge of these once authorised. For this reason, the addressees of the distinct activities may be different according to the service required from the office and the moment in which said service is requested.

The services of the Innovation Support Office are directed to:

PATIENTS

ACADEMIC GROUPS

INDEPENDENT INVESTIGATORS

COOPERATIVE GROUPS

HOSPITALS

RESEARCH FOUNDATIONS

SMALL AND MEDIUM-SIZED COMPANIES

PHARMACEUTICAL INDUSTRY IN GENERAL



## Services

provided by  
the office for  
**support of  
innovation**  
and knowledge  
of medicinal  
products

**01.** Coordination with  
the European Innovation  
Offices Network

**02.** Support in Investigation

**03.** Access to medicinal  
products prior to their  
authorisation

**04.** Access to medicinal  
products after their  
authorisation



**Services**  
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products

## **01.** Coordination with the **European Innovation Offices Network**



# 1. Coordination with the European Innovation Offices Network.

An innovative medicinal product may arise anywhere from an idea and the regulatory agencies should play an important role in supporting this innovation, by facilitating dialogue, knowledge and understanding of the regulatory requirements.

At the same time, networking and a collaborative approach through the European Innovation Offices Network should enable these promising products to take the necessary steps to progress to the next regulatory level regardless of its origin and in which country it has been developed.

The objective of this coordination is to act as the “key” of the system with early identification of products that could be useful for patients and taking them step-by-step through the regulatory procedure so that the possibility of success is maximised by:

- regulatory support at both a national and European level that is more visible and attractive from early stages of development
- fluid dialogue with the stakeholders that facilitates scaling of problems identified at a European Union level
- a platform to share and broaden knowledge of innovation from the initial phases that connect with those European regulatory structures responsible for its authorisation
- active integration of all the phases of development of the innovation that allows adjustment of the transition from one to the other

## ADDRESSEES

Academic groups, independent investigators, cooperative groups, hospitals, research foundations, start-ups, small and medium-sized companies

## PRODUCTS

Any type of medicinal product in initial phases of development

## INTERACTION

Face-to-face meetings or individual teleconferences, simple consultations <sup>(2)</sup>, collective sessions or courses

## EXPECTED RESULT

Identification of innovative projects, information on the regulatory tools available and appropriate for each specific project and integration in the European system for authorisation of medicinal products or other support tools at a national level.

## INFORMATION AND CONTACT POINT

INNOV@aemps.es

2. These are specific consultations that are able to be resolved in writing or during face-to-face meetings or teleconferences given that they do not reach the degree of complexity that makes a formal advice necessary.



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products

## 02. Support in **Investigation**



## 2. Support in Investigation

### 2.1. Independent Clinical Research Support Office

The Independent Clinical Research Support Office is the contact point in the AEMPS for consultations related to clinical trials with medicinal products conducted by investigators and sponsors of non-commercial clinical trials.

The Independent Clinical Research Support Office facilitates the interaction of the National Health System investigators and sponsors of non-commercial studies with medicinal products with the AEMPS and response to consultations concerning, for example:

- ◉ administrative requirements to conduct a clinical study
- ◉ classification of a study with medicinal products as a clinical trial or observational study
- ◉ documentation for the authorisation application of a clinical trial
- ◉ telematic presentations of applications concerning clinical trials
- ◉ communication of unexpected serious adverse reactions over the course of the study
- ◉ Communications of modification of the protocol once the clinical trial has started
- ◉ Manufacturing or packaging of an investigational medicinal product for the trial, including the placebos
- ◉ fulfilment of the Good Clinical Practice guidelines (GCP)
- ◉ any other regulatory query

Moreover, the Independent Clinical Research Support Office facilitates the interaction of these investigators and sponsors with the other services offered by the AEMPS as support for innovation and knowledge of medicinal products.

ADDRESSEES
Academic groups, independent investigators, cooperative groups, hospitals, research foundations, start-ups
PRODUCTS
Clinical trials to be conducted with any type of medicinal product
INTERACTION
Face-to-face meetings or individual teleconferences, simple consultations <sup>(3)</sup>
EXPECTED RESULT
Regulatory or scientific support in the process of application, authorisation or classification of a clinical trial
INFORMATION AND CONTACT POINT
More information on the Office, procedure and application form available in the link: <a href="http://www.aemps.gob.es/investigacionClinica/medicamentos/oficinApoyo.htm">http://www.aemps.gob.es/investigacionClinica/medicamentos/oficinApoyo.htm</a>

3. These are specific consultations that are able to be resolved in writing or during face-to-face meetings or teleconferences given that they do not reach the degree of complexity that makes a formal advice necessary.



## 2.2 Support for the development of Advanced Therapy Medicinal Products

The early identification and designation of advanced therapy medicinal products (gene therapy, somatic cell therapy and tissue engineering) is another of the activities that is developed to support innovation. This is managed through the Independent Clinical Research Support Office but its addressees can be more extensive.

The office receives all the consultations on the consideration of products as advanced therapy medicinal products telematically and provides advice within one week from the reception of the application.

### ADDRESSEES

Academic groups, independent investigators, cooperative groups, hospitals, research foundations, start-ups, small and medium-sized companies, pharmaceutical industry in general

### PRODUCTS

Investigational therapies in which there are doubts with regard to their classification as advanced therapy medicinal products

### INTERACTION

Simple consultations <sup>(4)</sup>

### EXPECTED RESULT

Identification and classification of innovative projects related to advanced therapies, regulatory and scientific support in these developments

### INFORMATION AND CONTACT POINT

Access to the telematic application form for advice in the following link:  
[http://www.aemps.gob.es/investigacionClinica/medicamentos/form\\_solicitudAsesora\\_terapiAvanzada.htm](http://www.aemps.gob.es/investigacionClinica/medicamentos/form_solicitudAsesora_terapiAvanzada.htm)

4. These are specific consultations that are able to be resolved in writing or during face-to-face meetings or teleconferences given that they do not reach the degree of complexity that makes a formal advice necessary.



### 2.3 National scientific advice

The AEMPS has a specific scientific advice unit, which has as its objective the scientific and/or regulatory support of the Agency in the development and knowledge of the medicinal products throughout all the phases of their life cycle.

National scientific advice is focused on resolving any scientific issue regarding the general development of medicinal products or studies designed to improve knowledge of a medicinal product once authorised, which may require the opinion of the Agency. Advice can also be provided on specific aspects of products that are to be presented specifically in our country for their authorisation or a modification of their conditions for use.

Scientific advice does not constitute a pre-assessment of the documentation of the product that may be the subject of a marketing authorisation application or any change in the conditions of its authorisation. The objective is advice on its development, providing the opinion of the Agency on specific issues of development areas of medicinal products such as clinical, non clinical/toxicology, quality of chemical, biological or biotechnological products, as well as issues regarding pharmacovigilance and observational studies.

#### ADDRESSEES

Academic groups\*, independent investigators\*, cooperative groups\*, hospitals\*, research foundations\*, start-ups, small and medium-sized companies, pharmaceutical industry in general

#### PRODUCTS

Any type of medicinal product for which an application for marketing authorisation is being considered or an application for conducting observational studies aimed at improving knowledge of the medicinal product

#### INTERACTION

Formal scientific advice

#### EXPECTED RESULT

Scientific support of the Health Authorities in the investigation of medicinal products in their different phases of development

#### INFORMATION AND CONTACT POINT

More information on the procedure of scientific advice is available in the following link: <http://www.aemps.gob.es/industria/regMedicamentos/asesoriasCientificas/home.htm>

\* Scientific advice for investigators in the academic field, hospital units or non commercial bodies does not entail payment of fees



## 2.4 Scientific Advice in the EMA Scientific Advice Working Party (European advice)

The scientific advice unit also actively participates in the activity of European scientific advice through the EMA Scientific Advice Working Party (hereinafter SAWP). The Agency has three representatives in the SAWP that coordinate the participation of their experts in these European procedures.

ADDRESSEES
Academic groups, independent investigators, cooperative groups, hospitals, research foundations, start-ups, small and medium-sized companies, pharmaceutical industry in general
PRODUCTS
Any type of medicinal product
INTERACTION
Formal scientific advice in the EMA
EXPECTED RESULT
Scientific support of the European Health Authorities in any aspect related to the development of the medicinal product or its conditions of authorisation
INFORMATION AND CONTACT POINT
Additional information on the activity and procedures of the European scientific advice working group can be found in the following link: <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CHMP/people_listing_000022.jsp">http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CHMP/people_listing_000022.jsp</a>

## 2.5 Regulatory advice

The AEMPS provides regulatory advice so as to resolve any regulatory and/or procedure-related issue with regard to the authorisation and access to medicinal products.

This advice is mainly directed to small companies, independent investigators or those belonging to academia, who are able to receive more benefit from this regulatory support. Nevertheless, access is not limited to these stakeholders.

Among the issues that may be raised when requesting regulatory support, the following may be highlighted:

- ◉ Applicable legislation and regulatory framework
- ◉ Identification of the products that should be considered as medicinal products and fulfil the pertinent legislation. Borderline and combined products
- ◉ Type of registration procedure and eligibility of the medicinal products
- ◉ Types of European authorisation and eligibility of the medicinal products
- ◉ Legal basis, requirements and content of the dossiers
- ◉ Information of the medicinal product, packaging, labelling and names

The procedure for requesting regulatory advice is subject to the same conditions and premises as scientific advice.



## 2.6 Parallel scientific advice with HTA

The AEMPS collaborates with the European network of agencies of health technology assessment (EunetHTA) and with the European Medicines Agency (EMA), participating in parallel European advice, not only in its regulatory activity in the authorisation of medicinal products but also in its activity of health technology assessment (HTA).

ADDRESSEES
Academic groups*, independent investigators*, cooperative groups*, hospitals*, research foundations*, start-ups, small and medium-sized companies, pharmaceutical industry in general
PRODUCTS
Any type of medicinal product for which an application for marketing authorisation or a change in the conditions of authorisation is being considered
INTERACTION
Formal regulatory advice
EXPECTED RESULT
Regulatory support of the Health Authorities in the investigation of medicinal products in their different phases of development. Resolution of consultations regarding the application of current legislation and regulatory strategy
INFORMATION AND CONTACT POINT
More information on the procedure of scientific advice is available in the following link: <a href="http://www.aemps.gob.es/industria/regMedicamentos/asesoriasCientificas/home.htm">http://www.aemps.gob.es/industria/regMedicamentos/asesoriasCientificas/home.htm</a>
* Scientific advice for investigators in the academic field, hospital units or non commercial bodies does not entail payment of fees

ADDRESSEES
Academic groups*, independent investigators*, cooperative groups*, hospitals*, research foundations*, start-ups, small and medium-sized companies, pharmaceutical industry in general
PRODUCTS
Any medicinal product that can benefit from early interaction with HTA
INTERACTION
Formal advice on aspects regarding the assessment of health technologies
EXPECTED RESULT
Optimisation of the development of medicinal products as a result of the early incorporation of aspects and considerations related to the subsequent assessment of health technologies
INFORMATION AND CONTACT POINT
<a href="mailto:sa_hta@aemps.es">sa_hta@aemps.es</a>
* La asesoría científica a investigadores del ámbito académico, unidades hospitalarias o entidades sin ánimo de lucro no conlleva el pago de tasas



**Services**  
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of medicinal  
products

**03.**  
Access to  
**medicinal  
products prior  
to their  
authorisation**



### 3. Access to medicinal products prior to their authorisation

All the actions of support in the innovation and development of medicinal products that satisfy needs not covered by current treatments have, as their final objective, that patients are able to access these according to their individual needs and the extent of knowledge of each specific medicinal product. The two possibilities of access to non authorised medicinal products are the following:

#### 3.1. Clinical trials with medicinal products

The main early access route to investigational medicinal products are the clinical trials with medicinal products, regulated by Royal Decree 1090/2015, of 4 December, by which clinical trials with medicinal products, Ethics Committees for Investigation with medicinal products and the Spanish Clinical Trials Registry are regulated.

The AEMPS commits its support to sponsors through the support services for investigation set out in the previous point.

Furthermore, the AEMPS makes available both to patients and healthcare professionals, information related to clinical investigations permitted in Spain through the Spanish clinical trials registry (REec)<sup>(5)</sup>, clinical trials being considered as an element of early access to the medicinal products.

5. Spanish clinical trials registry (REec) <https://reec.aemps.es/reec/faces/buscador/index.xhtml>

#### ADDRESSEES

Patients and patient associations, healthcare professionals, managers of investigation

#### PRODUCTS

Any medicinal product in clinical investigation in any of its phases

#### INTERACTION

Source of direct information

#### EXPECTED RESULT

Obtaining information regarding clinical investigations authorised in Spain through the Spanish clinical trials registry (REec)

#### MORE INFORMATION

<http://www.aemps.gob.es/investigacionClinica/medicamentos/ensayosClinicos.htm>

### 3.2. Compassionate use of investigational medicinal products

Along with the clinical trials, compassionate use of the investigational medicinal products is another access route prior to authorisation which is regulated by Royal Decree 1015/2009 on the use of medicinal products in special situations.

Compassionate use is the use of a medicinal product prior to its authorisation in patients suffering from a chronic or seriously debilitating disease or that is considered as life-threatening and is unable to be treated satisfactorily with an authorised medicinal product. Said medicinal product should be subject to an application for marketing authorisation or be undergoing clinical trials.

The application process for compassionate use to the Agency is initiated by a physician when faced with a patient with an unmet medical need.. This application is conducted through the hospital centre, prior approval from the General Directorate of said centre, and should include a clinical report of the responsible physician in which the need of the medicinal product for the patient is justified, the conformity of the stakeholder or sponsor of the clinical trials to provide the medicinal product and the number of containers required. The informed consent of the patient or his/her representative does not form part of the application for authorisation to the Agency but is essential before administration of the medicinal product.

Compassionate use should not substitute clinical trials as the best standard to generate useful knowledge of medicinal products, but may complement this generation of knowledge in certain cases such as, for example, their use under real conditions from the initial stages of use of the medicinal product.



### 03. Access to medicinal products prior to their authorisation

Over and above the general information, individual patients should channel their needs for information through the healthcare professionals who are attending them, given that these are specific situations which require specific clinical care.

Likewise, the AEMPS has a specific mailbox in which the doubts or suggestions of the patient associations to whom questions can be channelled.

The applications of hospital centres are submitted through the application of medicinal products in special situations. As well, the AEMPS has a contact point for healthcare centres and professionals that also serves to channel the doubts of sponsors and stakeholders of medicinal products.

ADDRESSEES
Patients and patient associations, healthcare professionals, healthcare centres
PRODUCTS
Medicinal products not yet authorised in Spain that are under clinical investigation in any of their phases
INTERACTION
Assessment of possible access to medicinal products in the investigational phase
EXPECTED RESULT
Access to treatment with medicinal products in the investigational phase wherever appropriate
MORE GENERAL INFORMATION
<a href="https://sede.aemps.gob.es/usoHum/otros/medSituEspe.htm">https://sede.aemps.gob.es/usoHum/otros/medSituEspe.htm</a>
CONTACT POINT FOR HEALTHCARE CENTRES AND PROFESSIONALS
<a href="mailto:medicamentosospeciales@aemps.es">medicamentosospeciales@aemps.es</a>



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**04.**  
Access  
to **medicinal**  
**products after**  
**their authorisation**

## 4. Access to medicinal products after their authorisation

### 4.1. Therapeutic Positioning Reports

In collaboration with the health authorities of the Autonomous Communities and the General Directorate of the Basic Services Portfolio of the National Health and Pharmacy System, the AEMPS coordinates the preparation of therapeutic positioning reports (Informes de posicionamiento terapéutico (IPT), in Spanish) aimed at determining the therapeutic value of the new medicinal products when compared to their alternatives in the market.

The Therapeutic Positioning Report is a scientific document that addresses the position which a certain medicinal product occupies in therapy in the light of the existing knowledge at any given time. Healthcare technicians and professionals of the collaborating institutions participate in their preparation, and the document is also subject to consultation by patient associations, scientific societies and the marketing authorisation holder himself.

The Therapeutic Positioning Reports are geared to identifying the therapeutic value of a medicinal product compared to its alternatives so that this may be used in decision-making process of price/reimbursement and, subsequently, the incorporation of the medicinal product in clinical practice.

The network assessment system coordinated from the AEMPS is centred on the so-called Therapeutic Positioning Coordination Group (Grupo de Coordinación del Posicionamiento Terapéutico (GCPT), in Spanish) of Human Use Medicinal Products. The Therapeutic Positioning Coordination Group is composed of the Head of the Department of Human Use Medicinal Products of the AEMPS, a



## 04. Access to medicinal products after their authorisation

representative of the General Directorate of the Basic Services Portfolio of the National Health and Pharmacy System, a representative of each Autonomous Community and the secretariat of the group held by the AEMPS.

The Therapeutic Positioning Coordination Group normally meets 11 times a year and, among its functions, establishes the scope of the reports, assigns their execution, ensures compliance with the established standards and time schedules, approves the reports, prioritises their execution and proposes follow-up measures for the reports undertaken.

ADDRESSEES
Health authorities, patient associations, scientific societies, marketing authorisation holders of new medicinal products
PRODUCTS
Medicinal products with new active substances and new indications of medicinal products already authorised
INTERACTION
Participation and consultation in the preparation of therapeutic positioning reports
EXPECTED RESULT
Determination of the therapeutic value of new medicinal products when compared to their alternatives in the market
MORE INFORMATION
<a href="http://www.aemps.gob.es/medicamentosUsoHumano/informesPublicos/home.htm">http://www.aemps.gob.es/medicamentosUsoHumano/informesPublicos/home.htm</a>
CONTACT POINT
<a href="mailto:gcpt@aemps.es">gcpt@aemps.es</a>



### 4.2. Recommendations of use of authorised medicinal products in conditions different from those established in their summary of product characteristics (Off-label Use)

The AEMPS is able to develop recommendations for use (or for non use) when the use of authorised medicinal products in conditions different from those established in their summary of product characteristics could reasonably be foreseen as a risk for patients, in the case of medicinal products subject to a restricted medical prescription or when the use of the medicinal product in these conditions has a significant healthcare impact.

The «Proposal of collaboration for the preparation of the therapeutic positioning reports of medicinal products» establishes as one of its specific objectives, the proposal of recommendations for the use of medicinal products in conditions different from those established in their summary of product characteristics, provided under that which is specified in Royal Decree 1015/2009, at the request of any concerned party whenever the aforementioned conditions are fulfilled.

The coordination within the Therapeutic Positioning Coordination Group of the preparation of these recommendations and their interaction with the aforementioned support systems of investigation and development of medicinal products integrates, in a coordinated manner, correct access to the medicinal products.

The collection of data in clinical practice (Real World Data/Evidence, RWD/RWE), the optimisation of the registries of use of medicinal products and the possible use of these data to complete registry dossiers of medicinal products are possibilities whose viability could be explored in this context.

#### ADDRESSEES

Healthcare professionals, healthcare centres, Autonomous Communities, patients

#### PRODUCTS

Any authorised medicinal product

#### INTERACTION

Assessment of the possible access to authorised medicinal products in conditions different from those established in their summary of product characteristics (off-label)

#### EXPECTED RESULT

Preparation of recommendations for the use of medicinal products in conditions different from those established in their summary of product characteristics

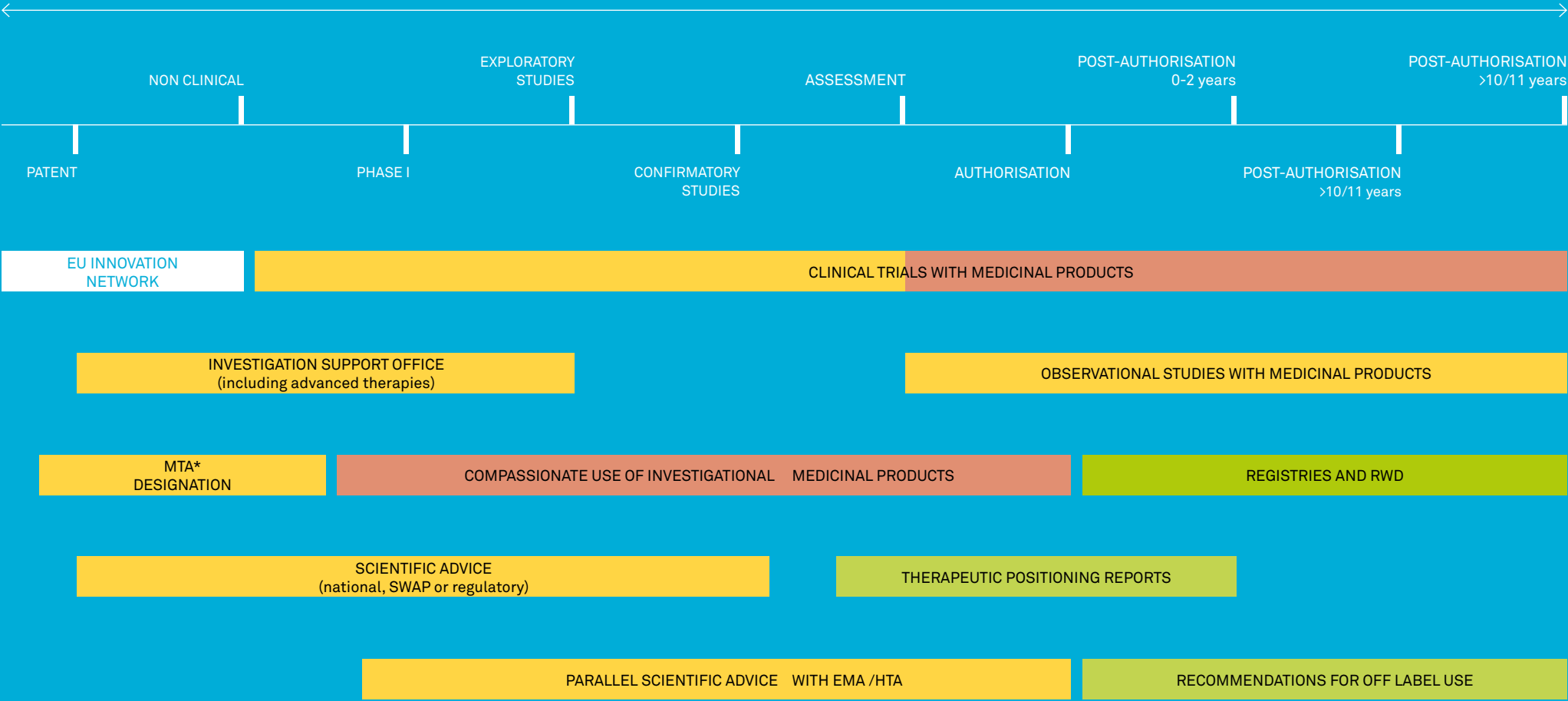
#### MORE INFORMATION

<https://sede.aemps.gob.es/usoHum/otros/medSituEspe.htm>

#### CONTACT POINT

[gcpt@aemps.es](mailto:gcpt@aemps.es)

Office for support of innovation and knowledge of medicinal products



## Services of the AEMPS Innovation Support Office

OBJECTIVE	ACTIVITY	ADDRESSEES	USEFULNESS	INFORMATION AND CONTACT
<b>Coordination with the European Network of Innovation Offices</b>	Integration of national activities in the European Network activities and European procedures	Academic groups, independent investigators, cooperative groups, hospitals, research foundations, start-ups, small and medium-sized companies	Identification of innovative projects, information on the available regulatory tools for each specific project and integration in the European system of authorisation of medicinal products or other support tools at a national level	innov_spain@aemps.es
<b>Support in investigation</b>	Independent clinical investigation Support Office	Academic groups, independent investigators, cooperative groups, hospitals, research foundations, start-ups	Regulatory and scientific support in the process of authorisation or classification of clinical trials with any type of medicinal product	<a href="http://www.aemps.gob.es/investigacionClinica/medicamentos/oficinApoyo.htm">http://www.aemps.gob.es/investigacionClinica/medicamentos/oficinApoyo.htm</a>
<b>Support in investigation</b>	Support in the development of Advanced Therapy Medicinal Products	Academic groups, independent investigators, cooperative groups, hospitals, research foundations, start-ups, small and medium-sized companies, pharmaceutical industry in general	Identification and classification of innovative projects related to advanced therapies, regulatory and scientific support in these developments	<a href="http://www.aemps.gob.es/investigacionClinica/medicamentos/form_solicitudAsesora_terapiAvanzada.htm">http://www.aemps.gob.es/investigacionClinica/medicamentos/form_solicitudAsesora_terapiAvanzada.htm</a>
<b>Support in investigation</b>	National Scientific Advice and in the EMA Scientific Advice Working Party	Academic groups*, independent investigators*, cooperative groups*, hospitals*, research foundations*, start-ups, small and medium-sized companies, pharmaceutical industry in general	Scientific support of the Health Authorities in the investigation of medicinal products in their different phases of development	<a href="http://www.aemps.gob.es/industria/regMedicamentos/asesoriasCientificas/home.htm">http://www.aemps.gob.es/industria/regMedicamentos/asesoriasCientificas/home.htm</a> ascina@aemps.es
<b>Regulatory support</b>	Regulatory advice	Academic groups*, independent investigators*, cooperative groups*, hospitals*, research foundations*, start-ups, small and medium-sized companies, pharmaceutical industry in general	Regulatory support of the Healthcare Authorities in the investigation of medicinal products in their different phases of development. Resolution of consultations regarding the application of the current legislation and regulatory strategy	<a href="http://www.aemps.gob.es/industria/regMedicamentos/asesoriasCientificas/home.htm">http://www.aemps.gob.es/industria/regMedicamentos/asesoriasCientificas/home.htm</a> ascina@aemps.es
<b>Support in investigation/ regulatory / access</b>	Parallel scientific advice EMA/ HTA	Academic groups*, independent investigators*, cooperative groups*, hospitals*, research foundations*, start-ups, small and medium-sized companies, pharmaceutical industry in general	Optimisation of the development of medicinal products by the early incorporation of aspects and considerations related to subsequent assessment of health technologies	sa_hta@aemps.es
<b>Access to medicinal products prior to their authorisation</b>	Clinical trials with medicinal products	Patients and patient associations, healthcare professionals, managers of investigation	Obtaining information with regard to clinical investigations permitted in Spain through the Spanish clinical trials registry (REec).	<a href="http://www.aemps.gob.es/investigacionClinica/medicamentos/ensayosClinicos.htm">http://www.aemps.gob.es/investigacionClinica/medicamentos/ensayosClinicos.htm</a>
<b>Access to medicinal products prior to their authorisation</b>	Compassionate use of investigational medicinal products	Patients and patient associations, healthcare professionals, healthcare centres	Access to treatments with medicinal products in the investigational phase in appropriate cases	medicamentosEspeciales@aemps.es
<b>Access to medicinal products after their authorisation</b>	Therapeutic Positioning Reports	Healthcare authorities, patient associations, scientific societies, marketing authorisation holders of new medicinal products	Determination of the therapeutic value of the new medicinal products compared to their alternatives in the market	<a href="http://www.aemps.gob.es/medicamentosUsoHumano/informesPublicos/home.htm">http://www.aemps.gob.es/medicamentosUsoHumano/informesPublicos/home.htm</a> gcpt@aemps.es
<b>Access to medicinal products after their authorisation</b>	Recommendations of use of authorised medicinal products in conditions different from those established in their summary of product characteristics	Healthcare professionals, healthcare centres, Autonomous Communities, patients	Preparations of recommendations for the use of medicinal products in conditions different from those established in their summary of product characteristics	<a href="https://sede.aemps.gob.es/usoHum/otros/medSituEspe.htm">https://sede.aemps.gob.es/usoHum/otros/medSituEspe.htm</a> gcpt@aemps.es



# Office for support of INNOVATION and KNOWLEDGE of medicinal products

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