Simultaneous National Scientific Advice Pilot Project

INFARMED IP is participating in phase 2 of the Simultaneous National Scientific Advice (SNSA) Pilot, which has been launched by the <u>EU-Innovation Network</u>.

The SNSA pilot is open to applicants (including pharmaceutical companies, small and medium enterprises (SMEs) or academic researchers) who wish to obtain national scientific advice related to medicinal products from more than one National Competent Authority (NCA) at the same time.

In conjunction with the <u>Accelerating Clinical Trials in the EU (ACT EU)</u> initiative, phase 2 of the SNSA pilot will have a specific focus on scientific advice to facilitate clinical trials (CT) within Europe.

It will facilitate sponsors / developers to obtain clinical trial-related national scientific advice from NCAs in member states where they intend to perform clinical trials. The SNSA can also be used in other scenarios falling within the scope of national scientific advice, e.g. scientific advice related to a planned decentralised or mutual recognition marketing authorisation application.

Within each SNSA procedure, each participating NCA will prepare and discuss their positions on the questions raised by the applicant with a view to maximising alignment prior to a joint advice meeting with the applicant.

The outcome of each SNSA procedure will be documented in consolidated meeting minutes reflecting the position of each participating NCA.

Applying for scientific advice under the pilot scheme

Applicants wishing to apply for advice under the SNSA pilot should review the information relating to SNSA on the <u>Heads of Medicines Agencies website</u> including the following documents:

- Guidance to applicants
- Guidance on SNSA briefing book format and content
- List of participating NCAs and contact information
- Application form

For any additional information, please contact garc@infarmed.pt.