Access Consortium

The **Access Consortium is a collaborative initiative between five Health Authorities**: Australia´s Therapeutic Goods Administration (TGA), Health Canada (HC), Singapore's Health Sciences Authority (HSA), the Swiss Agency for Therapeutic Products (Swissmedic) and the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK. It intends to build synergies and maximize international cooperation to ensure patients' timely access to safe therapeutic products in the member countries.

The Access Consortium consist of **different working groups:**

- New Active Substances working group
- Generic Medicines working group
- COVID-19 vaccines and therapeutics working group
- Biosimilars working group
- Complementary Health Products working group
- Information Technology working group

What are the advantages?

The use of this work-sharing initiative offers some important benefits to the pharmaceutical industry, such as:

- **Coordinated review*:** the sponsor will be provided with one set of consolidated/rolling questions per module across the regulatory agencies. This will generally mean a reduced number of questions.
- **Planning:** applicant will have a common calendar for the review timeframe.
- **Global Dossier:** opportunity for the sponsor to have a global dossier and resources for a global evaluation process, enabling simultaneous market access in the different countries.

How does the Consortium work?

It is expected that the applicant submits the same data set for Modules 2-5 to all agencies participating in the procedure, considering the country specific requirements. Module 1 will continue to be different for the dossiers filed in the different Access jurisdictions (as per regional requirements).

For the evaluation, the submission will be divided into modules, each module being reviewed by a specific agency. Other participating agencies will conduct a peer review of the assessment reports for each module*.

* Variable for generic products

How can we assist?

Asphalion can provide support throughout the whole process in a variety of activities:

- Dossier adequacy and publishing
- Pre-submission meetings
- Expression of Interest
- Priority review request
- Publishing and submission of the application
- Management of the procedures and follow-up with authorities until authorization
- Others