

# Do you plan to expand registrations outside the US and EU?

Have you considered submitting to the Access Consortium with its five members?

Our Access Consortium procedure service offers comprehensive support for all five health authorities: Australia (TGA), Canada (HC), Singapore (HSA), Swissmedic (SMC) and UK (MHRA).

- ✓ Support with understanding the requirements of the Access Consortium and selecting the registration strategy
- ✓ Support with all local regulatory requirements for Access Consortium submission
- ✓ Expertise in managing the entire process for the registration of new active substances (NASs), a new chemical entity (NCE) or new biological entity (NBE), and for new indications
- ✓ Dossier compilation, pre-submission meetings with resp. regulatory authority to determine clinical program, especially for highly sophisticated developments, review process, national phase

**Work-sharing procedure offers streamlined processes, increased access, flexibility and predictability.**

We have the knowledge, resources, and project management skills to support you with global parallel assessments across multiple jurisdictions.



Support in navigating the complexities of international regulatory approval process



Management of the procedures and follow-up with authorities until authorization



Expertise to cover the procedure and support project management across the various territories



In-house experts and teams from all fields involved in drug development, global dossier preparation, global MA submission (including CMC, medical writing and regulatory)



We can also support with the collaborative initiative Project Orbis.

Let us be your trusted partner in navigating the complexities of international markets with confidence

25+

years of industry experience

200+

experienced local representatives support our global coverage

9/10

of the top pharmaceutical companies are our clients

50+%

of our projects are global

MA: Marketing Authorization

CMC: Chemistry, Manufacturing, and Controls

Have the right expertise by your side

[www.pharmalex.com](http://www.pharmalex.com)

Contact us

