ERA for an active substance in antiseptic lozenges

Challenge

Lacked necessary expertise for Environmental Risk Assessment

- Client developed antiseptic lozenges for the treatment of sore throat.
- Support was needed for compilation of an ERA.
- Scope of required studies was unclear.
- High costs for anticipated experimental study set.
- Scientific Advice meeting at environmental agency required.
- Contract research laboratories required for experimental work.

Solution

Provision of single contact to manage and coordinate all ERA activities

- Creation of a consortium developing the same active ingredient for a different indication sharing the costs.
- Scientific Advice meetings: Waiver for several studies; stretching of timelines.
- Selection of research laboratories; Study monitoring for ERA studies (Phase I, Phase II Tier A+B).
- Single point of contact for the client:
  - Coordinates communication with authority, laboratories and other consortium members
  - Manages timelines and costs
  - Compilation of the ERA dossier.

Outcome

Environmental Risk Assessment accepted by environmental agency; costs manageable

- Benefit of working with PharmaLex:
  - Experts available with experience in Phase I and Phase II ERAs.
  - Access to know-how from many submissions.
  - Access to EU Health Agencies opinion leaders and environmental agencies via the extensive PharmaLex network.
  - Flexible contractual framework allowing quick implementation of new work orders.
- All tasks delivered within defined time frame; acceptance by environmental agency.