

# WP5 Products

## About WP5

It is the remit of WP5 to develop tools for relative effectiveness assessment of pharmaceuticals. Enhanced collaboration in the development of methods and best practices for relative effectiveness assessment of pharmaceuticals across jurisdictions may save costs and reduce duplication.

For this purpose WP5 is developing a version of the HTA Core Model that aims at rapid relative effectiveness assessment of pharmaceuticals and is developing guidance for important methodological challenges that can be part of such an assessment.

In addition, as part of the work package a unique collaboration between payers and regulators is ongoing, in which the European Medicines Agency and EUnetHTA are considering how the European Public Assessment Report (EPAR) could make a better contribution to the assessment of relative effectiveness by health technology assessment bodies in the EU Member States.

## About the Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals

WP5 is developing an application of the HTA Core Model that focuses on Rapid Relative Effectiveness Assessment. It differs from other applications in its scope. Only specific assessment elements are included in that are considered relevant for a rapid relative effectiveness assessment of pharmaceuticals; it focuses mainly on the first four domain of the HTA Core Model (Health problem and current use of the technology, Description and technical characteristics of technology, Safety and Clinical Effectiveness).

## About the guidelines

The guidelines focus on methodological challenges that HTA do-ers are often confronted with when doing their job. They should provide guidance for the HTA do-ers on how to deal with these issues. In total, 9 guidelines on methodological issues are in development:

- Clinical endpoints;
- Composite endpoints;
- Surrogate endpoints;
- Safety;
- Health related quality of life;
- Choice of comparator;
- Direct and indirect comparisons;
- Internal validity;
- Applicability.

## About the Pazopanib pilot

A pilot is ongoing in which the draft version of the HTA Core Model for rapid relative effectiveness assessment and draft versions of the methodological guidelines are tested. The topic for this rapid assessment, pazopanib for the treatment of advanced renal cell cancer, was selected based on input from WP5 members, input from the SAG and the European Medicines Agency (EMA). A submission file that was provided by the marketing authorisation holder (GSK) was used as a base for the assessment.