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Committee for medicinal products for human use (CHMP)

Concept paper on the need for the guidance on the clinical investigation of medicinal products to slow progression of renal insufficiency (EMA/CHMP/EWP/6054/2010)

Agreed by EWP	6 July 2010
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Comments should be provided using this template. The completed comments form should be sent to EWPSecretariat@ema.europa.eu

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1. Introduction

Renal insufficiency and end-stage renal disease has a major impact on public health and several medicinal compounds have been licensed or are under development with the aim to halt or slow renal disease progression.

2. Problem statement

Scientific Advice procedures and Marketing Authorisation Applications have highlighted the need to for a guidance document focused on methodological issues in confirmatory trials. Due to the diversity of the underlying conditions ranging from common conditions such as hypertension and diabetes to orphan diseases such as AA amyloidosis or polycystic kidney disease, the guideline is meant to serve as an adjunct to disease specific guidelines and will focus on general, but renal specific topics as detailed below.

3. Discussion (on the problem statement)

Foreseen main topics include:

- Claims/indications in relation to the kidney disorder, whether a part of a systemic disease or a renal only condition.
- Study populations: Criteria defining the kidney disorder, underlying disease and “competing risks”, e.g. cardiovascular disorder. Prognostic factors for the evolution of the kidney disorder and, when relevant, the overall morbidity and mortality of the underlying condition.
- Defining proper endpoints in relation to the objectives of treatment.
- Recommended methods to be used in relation to selected endpoints.
- Measures to undertake in order to optimise back ground therapy for the treatment complications of chronic kidney disease, such as deregulated electrolyte/phosphate/calcium homeostasis.
- Specific aspects to be considered in paediatric developments related to renal insufficiency.

4. Recommendation

It is proposed to prepare a new guidance document on the clinical investigation of medicinal products for the treatment of renal insufficiency in order to achieve a European common position.

5. Proposed timetable

It is anticipated that a draft CHMP Guideline may be available 9 months after adoption of the Concept Paper to be later released for 6 months for external consultation and, thereafter, finalized within 6 months.

6. Resource requirements for preparation

The preparation of the new Guideline will involve the EWP and as relevant PDCO. It is anticipated that at least three plenary session discussions at the EWP will be needed.

7. Impact assessment (anticipated)

This new guideline on clinical investigation of medicinal products to slow progression of renal insufficiency aims at achieving regulatory consensus on the evaluation of such products by regulatory authorities thereby also facilitating drug development.

8. Interested parties

It is envisioned to contact EDTA (European Dialysis and Transplantation Association) and KDIGO (Kidney Disease: Improving Global Outcomes).

9. References to literature, guidelines, etc.

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