



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 April 2010
EMA/CHMP/EWP/68523/2010
Committee for Medicinal Products for Human Use (CHMP)

Concept paper on the need for revision of the Note for Guidance on the Clinical Investigation of Medicinal Products for the Treatment of Urinary Incontinence (CPMP/EWP/18/01)

Agreed by Efficacy Working Party	April 2010
Adoption by CHMP for release for consultation	22 April 2010
End of consultation (deadline for comments)	31 July 2010

The proposed guideline will replace guideline (CPMP/EWP/18/01).

Comments should be provided using this [template](#). The completed comments form should be sent to EWPSecretariat@ema.europa.eu

Keywords	<i>Urinary Incontinence, Overactive bladder, Childhood Urinary Incontinence, Stress Incontinence, Tissue Engineering, Male Incontinence</i>
-----------------	---



1. Introduction

There is a need for revision of the current guideline 'Note for Guidance on the Clinical Investigation of Medicinal Products for the Treatment of Urinary Incontinence' as justified below.

2. Problem statement

There is a need to clarify the registration requirements for the ICS term "Overactive bladder" (OAB), which has been subject to the therapeutic indications of recently approved medicinal products for urinary incontinence. It is noted that this term was not used in the current guideline; hence, a more in depth discussion of the registration requirements for this claim seems appropriate.

In addition, several products for use in children with OAB are being developed. Therefore, the paediatric needs should be reflected in the revised guideline.

Other recent developments concerned the specific field of stress incontinence, which needs to be reflected in the revised guideline.

There is also an interest to develop tissue engineering products for the treatment of urinary incontinence.

Finally, there is a need to expand on the specific aspects related to male incontinence in the guideline.

3. Recommendation

The CHMP recommends revision of the guideline on 'The Clinical Investigation of Medicinal Products for the Treatment of Urinary Incontinence'.

The revision should include:

- A clarification of the terminology with regard to OAB (Overactive Bladder Syndrome) and respective registration requirements.
- A dedicated paediatric section particularly to address development for OAB.
- Outline of consideration for the development of a medicinal product for the use in stress incontinence.
- Inclusion of specific aspects on male incontinence.
- Tissue engineering.

4. Proposed timetable

It is expected that the draft of the revised version of the note for guidance will be completed to be sent out for consultation in Q4 2010.

5. Resource requirements for preparation

The preparation of the revision would involve members of the EWP as well as assessors of the regulatory network. The Paediatric Committee (PDCO) and the Committee for Advance Therapies (CAT) will particularly be involved. Additional experts for both the paediatric part and the adult part may be consulted as appropriate.

6. Impact assessment (anticipated)

The anticipated impact would be the clarification of registration requirements in this therapeutic area including further specification for specific fields thereby facilitation for industry to design appropriate development plans. This enables improving future medicines for both adults and children in this field. It is also anticipated that clear guidance will have implications on regulatory assessment and scientific advice.

7. Interested parties

ICS (International Continence Society).

ICCS (International Children's Continence Society).

EAU (European Association of Urology).

ISSAM (International Society for the Study of the Aging Male).