



**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)**

**CONCEPT PAPER ON THE REVISION OF THE GUIDELINE ON  
RADIOPHARMACEUTICALS BASED ON MONOCLONAL ANTIBODIES**

<b>AGREED BY QWP</b>	June 2009
<b>AGREED BY BWP</b>	September 2009
<b>ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION</b>	24 September 2009
<b>END OF CONSULTATION (DEADLINE FOR COMMENTS)</b>	31 January 2010

Comments should be provided to [qwp@emea.europa.eu](mailto:qwp@emea.europa.eu)

<b>KEYWORDS</b>	<i>Radiopharmaceuticals; Monoclonal antibodies; Pharmaceutical and Chemical Documentation; Development; Manufacture; Quality Control; Stability</i>
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## **1. INTRODUCTION AND PROBLEM STATEMENT**

The current Note for Guidance on Radiopharmaceuticals Based on Monoclonal Antibodies (Eudralex 3AQ21a) was last revised in May 1991. An in-depth revision of this guideline is now necessary to update the guideline to the current state of the art.

## **2. DISCUSSION (ON THE PROBLEM STATEMENT)**

After the finalisation in 2008 of the revision of the guideline on Radiopharmaceuticals (CHMP/QWP/306970/2007 Rev. 1, formerly 3AQ20a) and the revision of the guideline on Development, Production, Characterisation and Specifications for Monoclonal Antibodies and Related products (CHMP/BWP/157653/2007, formerly 3AB4a), the CHMP Quality Working Party (QWP) and Biologics Working Party (BWP) agreed that a thorough revision of the guideline on Radiopharmaceuticals Based on Monoclonal Antibodies was needed to take account of scientific developments in the field.

## **3. RECOMMENDATION**

The revision of the Guideline on Radiopharmaceuticals Based on Monoclonal Antibodies will focus on quality aspects encompassing both monoclonal antibodies and radiopharmaceutical aspects and will be done so as to ensure consistency and complementarity with the above-mentioned revised guidelines on monoclonal antibodies and on radiopharmaceuticals.

For what concerns the practical arrangements for the development of the revised guideline, it is recommended that the same rapporteur and the same QWP drafting group who worked on the revision of the radiopharmaceuticals guideline also leads the revision of this guideline, with the participation in the drafting group of additional experts on monoclonal antibodies appointed by the CHMP Biologics Working Party (BWP). The BWP drafting group on monoclonal antibodies will be closely involved in the revision of this guideline.

## **4. PROPOSED TIMETABLE**

- Appointment of Rapporteur for the revision of the guideline in June 2009
- Re-installment in 3Q 2009 of the drafting group on Radiopharmaceuticals, with the involvement of additional experts on monoclonal antibodies
- Publication of the concept paper in September 2009
- Release of the revised guideline for consultation in 3Q 2010
- Publication of the finalised revised guideline in 2Q 2011.

## **5. RESOURCE REQUIREMENTS FOR PREPARATION**

The development of the revised guideline will be carried out by QWP, in close co-operation with BWP.

It is suggested that the drafting group on Radiopharmaceuticals with 1 Rapporteur and 3-5 additional group members is re-installed to revise the existing Note for Guidance on Radiopharmaceuticals Based on Monoclonal Antibodies with regards to quality aspects. The group may be supplemented with additional experts on monoclonal antibodies appointed by the BWP. It is considered that part of the work of the drafting group can be carried out by e-mail or fax with the need for 2-3 meetings to be organised at EMEA by the QWP secretariat.

## **6. IMPACT ASSESSMENT (ANTICIPATED)**

The revision of the guideline will allow reaching a uniform approach in the EU for both the development and the assessment of medicinal products containing radiopharmaceuticals based on monoclonal antibodies and will benefit industry through harmonisation of data requirements and making the acceptance by regulators of state-of-the-art approaches easier.

It will also benefit regulators by bringing the guidance up to date and easing the assessment of related applications.

## **7. INTERESTED PARTIES**

EANM (European Association of Nuclear Medicine), AIPES (Association of Imaging Producers and Equipment Suppliers) and EFPIA (European Federation of Pharmaceutical Industries and Associations) are the main industry interested parties.

BWP (Biologics Working Party) is the main regulatory interested party.

## **8. REFERENCES TO LITERATURE, GUIDELINES ETC**

- Guideline on Radiopharmaceuticals (CHMP/QWP/306970/2007 Rev. 1)
- Guideline on Development, Production, Characterisation and Specifications for Monoclonal Antibodies and Related Products (CHMP/BWP/157653/2007)