29 August 2013, Strasbourg, France

THE EUROPEAN PHARMACOPOEIA COMMISSION REVISES ITS STRATEGY REGARDING THE IMPLEMENTATION OF CHAPTER 5.20 "METAL CATALYST OR METAL REAGENT RESIDUES"

In their July session, the Committee for Medicinal Products for Human Use (CHMP) decided to delay the application of the current EMA *Guideline on the specification limits for residues of metal catalysts or metal reagents* (EMEA/CHMP/SWP/4446/2000) to existing marketed products until the ICH Q3D guideline for elemental impurities will have been finalised. The EMA Guideline is already applicable to new products since September 2008 and should have become applicable to existing marketed products as of 1 September 2013.

In its April 2012 session, the Ph. Eur. Commission decided to reproduce the EMA Guideline in Ph. Eur. Chapter 5.20 and to introduce a cross-reference to this Chapter in the general monograph *Substances for pharmaceutical use* (2034) at a later stage.

The reproduction of a Guideline in a Ph. Eur. Chapter does not make it legally binding as long as the Chapter is not referenced in a Ph. Eur. monograph. The revised general monograph *Substances for pharmaceutical use* (2034) that cross-references Chapter 5.20 had been adopted by the Ph. Eur. Commission at its March 2013 session for publication in Ph. Eur. Supplement 8.1. As a consequence, Chapter 5.20 would have become mandatory on the implementation date of the revised monograph, i.e. 1 April 2014, thus making the requirements of the EMA Guideline legally binding for all active pharmaceutical ingredients.

However, in view of the decision taken by the CHMP and to ensure continued consistency between the approaches of licensing authorities and the Ph. Eur., the Ph. Eur. Commission has decided to defer publication in Ph. Eur. Supplement 8.1 of the revised version of the general monograph *Substances for pharmaceutical use* (2034) that cross-references Chapter 5.20.

As a consequence, chapter 5.20 *Metal catalyst or metal reagent residues* will not now become legally binding as of 1 April 2014.

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Note for the Editor: Further information is available on the internet site **www.edqm.eu**
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[1]There are now thirty-eight members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union.* There are twenty-five observers: *the World Health Organization (WHO); 5 member states of the Council of Europe - Albania, Armenia, Georgia, Moldova and the Russian Federation; and 19 other countries in the world - Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus,*

Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, Senegal, South Africa, Syria, Tunisia, United States of America.

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