EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 January 2010
EMA/825063/2009
Compliance and Inspection

EC – Switzerland MRA
Sectoral Annex on GMP medicinal products GMP inspection and batch certification

Update on the operation of the Annex with respect to advanced therapy medicinal products

Joint Common Statement

Background

The Mutual Recognition Agreement (MRA) between the European Community (EC) and Swiss Confederation, in its Annex on medicinal products GMP inspection and batch certification, covers all medicinal products which are industrially manufactured in Switzerland or the European Community, and to which Good Manufacturing Practice (GMP) requirements apply. Since the time of implementing the Sectoral Annex, new regulations on advanced therapy medicinal products (ATMP) entered into force in EU, applying from 30 December 2008. In Switzerland, a new law entered into force on 1 July 2007, stating that the so called transplant products (which is an equivalent term to ATMP) are equivalent to medicinal products, and are subject to numerous provisions of the Law on Therapeutic Products as if they were medicinal products.

Following the review of the EC and Swiss legislation introducing GMP requirements for ATMPs/transplant products discussion between EC and Switzerland have taken place to include ATMPs/transplant products in the operational phase under the current scope of the MRA.

Requirements for ATMP in the European Community

The scope of Regulation (EC) No 1394/2007 of the European parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and the amendments of Directive 2001/83/EC and Regulation (EC) No 726/2004, is to regulate advanced therapy medicinal products which are intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process, in accordance with the general scope of the Community pharmaceutical legislation laid down in Title II of Directive 2001/83/EC.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8595
E-mail mra@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

The manufacture of advanced therapy medicinal products should be in compliance with the principles of good manufacturing practice, as set out in Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use. Regulatory authorities in the EC will carry out GMP inspections of ATMP manufacturers in the EC and in third countries in line with Community legislation and procedures, and a manufacturing and import authorisation for ATMP manufacturers/importers is necessary.

Requirements for transplant products in Switzerland

The Swiss federal legislation for transplant products came into force in July 2007. The new Transplantation Law and the Ordinances essentially provide regulations concerning the use of human organs, tissues or cells, the allocation of human organs and xeno-transplantation.

In addition to the comprehensive provisions relating to organs, tissues and cells, the transplantation law also contains specific directives for so-called transplant products. These products are considered to be equivalent to medicinal products, and hence are subject to numerous provisions of the Law on Therapeutic Products, equivalent to medicinal products. The definition of the Swiss legal term “transplant products” is making reference to the EU definition of ATMPs. All transplant products to be placed on the market must obtain a marketing authorisation from Swissmedic, and entities manufacturing or distributing transplant products require an establishment license from Swissmedic, and their compliance with the GMP regulations is subject to regular inspection as described in the Law on Therapeutic Products (SR 812.21) and the Ordinance on Establishment Licenses (SR 812.212.1). As for all medicinal products the surveillance of these products falls under the responsibility of Swissmedic as the competent authority.

Conclusion

GMP requirements for ATMPs (EU) and transplant products (Switzerland) were deemed to be equivalent in the EC and in Switzerland. Inspections are performed on a routine basis by the competent authorities. Conclusions of such inspections by the relevant inspection services in the EC and Switzerland on their respective territories should be exchanged and mutually recognised. Such an exchange of information may take place at the request of an exporter, importer or the competent authority of the other party. Technical arrangement for the exchange of GMP certificates will be similar to those established for finished medicinal products in line with provisions of Chapter 15 of the Agreement.

In accordance with the general provisions of the Agreement, both EC and Switzerland shall continue to exchange any information necessary for the harmonisation and the mutual recognition of inspections in this new field.

This arrangement came into effect on 1 January 2010.

Further information on the EC – Switzerland MRA: http://www.ema.europa.eu/inspections/mra.html and http://www.seco.admin.ch/themen/00513/00730/01217/01887/index.html?lang=de