AGENDA ITEM:

Chemicals 2/2: Good Laboratory Practice (GLP)

Country Session: The Republic of TURKEY
20-24 February 2006

EU DIRECTIVES ON GLP

- Council Directive 87/18/EEC of 18 December 1987 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, as adapted to technical progress by 1999/11/EC
- Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of good laboratory practice, as adapted to technical progress by 1999/12/EC
- Directive of the European Parliament and of the Council 2004/10/EC of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances
- Directive of the European Parliament and of the Council 2004/9/EC of 11 February 2004 on the inspection and verification of good laboratory practice (GLP)

CORRESPONDING NATIONAL GLP LEGISLATION

- Regulation on good laboratory practice principles and certification of test laboratories, transposing the GLP Directive 87/18/EEC as adapted to technical progress by 1999/11/EC, was published in the OG No. 24796, dated 25 June 2002.

- Regulation on the inspection and verification of good laboratory practice, transposing the GLP Directive 88/320/EEC as adapted to technical progress by 1999/12/EC, was published in the OG No. 24796, dated 25 June 2002.

RESPONSIBLE AUTHORITIES

The Ministry of Health - registration and control of pharmaceutical products, cosmetics, pesticides for household use.

The Ministry of Environment and Forestry - registration and control of dangerous chemicals within the scope of the Dangerous Chemicals Regulation.

The Ministry of Agriculture and Rural Affairs - registration and control of agricultural pesticides, veterinary drugs, food and feed additives.

NATIONAL LEGISLATION REQUIRING GLP APPLICATION- I

Regulation on licensing of medicinal products for human use
(OG No. 25705, dated 19 January 2005)

Annex 1. Documents to be submitted in license applications; Introduction and general principles:

Non-clinical (pharmacotoxicological) studies should be carried out in accordance with the “Regulation on good laboratory practice principles and certification of test laboratories” and the “Regulation on the inspection and verification of good laboratory practice”, both published in the OG No. 24796 of 25 June 2002.

NATIONAL LEGISLATION REQUIRING GLP APPLICATION- II

Regulation on licensing of medicinal products for human use (OG No. 25705, dated 19 January 2005)

Annex 1. Documents to be submitted in license applications; Section 3-2. Radiopharmaceuticals and precursors:

Results of single dose and repeated dose toxicity studies carried out in compliance with provisions of the "Regulation on good laboratory practice principles and certification of test laboratories" and the "Regulation on the inspection and verification of good laboratory practice", published in the OG No. 24796, dated 25 June 2002, are provided and verified.

NATIONAL LEGISLATION REQUIRING GLP APPLICATION - III

Regulation on cosmetics
(OG No. 25823, dated 23 May 2005)

Article 12. Principles for control and inspection:

For market surveillance and control, upon the request of the Ministry, the manufacturer will provide product information including safety evaluation of the final product regarding human health. For this evaluation, the manufacturer will take into consideration the toxicological characteristics, chemical structure and susceptibility levels of the product constituents. This evaluation will be carried out in conformance with the "Regulation on good laboratory practice principles and certification of test laboratories" published in the OG No. 24796, dated 25 June 2002.

IMPLEMENTATION STATUS - I

GLP Regulations:

Currently there are no GLP compliant and certified laboratories, however legal framework for GLP principles, certification and inspection has been established through regulations.

GLP Monitoring Authority(ies) has not been established yet. The Twinning Project "Strengthening the Ministries of Health, Environment and Forestry, and Agriculture and Rural Affairs to harmonise and implement legislation in the field of Good Laboratory Practice for Non Clinical Health and Environmental Protection" (Project No. TR 0402.03) will help to build the legal, administrative and technical infrastructure for implementation of the related legislation.

IMPLEMENTATION STATUS- II

Legislation Requiring GLP Application:

The following regulations requiring application of GLP are implemented by the MoH:

Regulation on licensing of medicinal products for human use
(OG No. 25705, dated 19 January 2005)

Regulation on cosmetics
(OG No. 25823, dated 23 May 2005)

WORKING GROUP

- Participation in GLP Working Group meeting

and

- Presentation on the situation in Turkey

(22 May 2003 Brussels)

PROJECTS RELEVANT TO ESTABLISHMENT OF THE LEGAL, ADMINISTRATIVE AND TECHNICAL INFRASTRUCTURE FOR IMPLEMENTATION OF THE GLP LEGISLATION

Twinning Project TR02/IB/AG-01
Between Turkey and Germany

Support for the Alignment of Turkey with the EU Veterinary Acquis Project No.02.03.05 (13-11-2003 / 31-10-2005)

GLP workshop; (purpose, goals and application of GLP in testing laboratories) with the Ministry of Agriculture and Rural Affairs, the Ministry of Health and the Ministry of Environment and Forestry; comments on GLP issues in Turkey.

Outcomes: Common GLP monitoring authority in Turkey does not exist. The necessity of creating a GLP monitoring authority was discussed and emphasised.

Twinning Project TR/2004/IB/EC/06
Between Turkey and Slovak Republic

Strengthening the Ministries of Health, Environment and Forestry and Agriculture and Rural Affairs to harmonise and implement legislation in the field of Good Laboratory Practice for Non Clinical Health and Environmental Protection" (Project No. TR 0402.03)

Project purpose: Strengthening the institutional and administrative capacity of the Ministries to adopt and implement the EU Directives on GLP (2004/9/EC, 2004/10/EC)

Project partners: Ministry of Health, Ministry of Environment and Forestry, Ministry of Agriculture and Rural Affairs, Slovak Office of Standards, Metrology and Testing

Twinning Project TR/2004/IB/EC/06
Between Turkey and Slovak Republic

Strengthening the Ministries of Health, Environment and Forestry and Agriculture and Rural Affairs to harmonise and implement legislation in the field of Good Laboratory Practice for Non Clinical Health and Environmental Protection" (Project No. TR 0402.03)

Project components:

- Enforcement of the EU Directives 2004/9/EC and 2004/10/EC, in accordance with the transposition of the Directives into Turkish Law
- Establishment of a Monitoring, Auditing and Inspection Body
- Establishment of an agreed framework for GLP procedures in the field of Chemicals

Twinning Project TR/2004/IB/EC/06
Between Turkey and Slovak Republic

Strengthening the Ministries of Health, Environment and Forestry and Agriculture and Rural Affairs to harmonise and implement legislation in the field of Good Laboratory Practice for Non Clinical Health and Environmental Protection (Project No.TR 0402.03)

Current Status: Final draft of Twinning Contract being prepared for comments of the Steering Committee. The project is expected to start following approval of the Commission.

End of project: 30 November 2007.

Twinning Project TR/2004/IB/EC/03
Between Turkey and Austria

Harmonisation and Implementation of Directive on Biocidal Products (23.11.2005-30.11.2007)

Strengthening the Ministry of Health to Harmonise and Implement Legislation in the Field of Biocides (Biocidal Products Directive) and Water (for Public Health Protection) (Project No. TR 0402.10)

National Regulation on Biocidal Products transposing Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market will be prepared within the scope of the Twinning Project.

Technical Assistance Project
TeACH – EUROPEAID/120220/D/SV/TR

Harmonisation of Directives in the Field of Chemicals

The Dangerous Chemicals Regulation needs to be revised and amended to achieve full transposition of the EU Chemicals Directives 67/548/EC, 99/45/EC, 93/67/EEC and 91/155/EEC. The Technical Assistance project for Turkey in the field of chemicals will help harmonise these Directives.

Completion date of the project is 2007.

THANK YOU FOR YOUR ATTENTION