IV. NEW AND GLOBAL + OLD APPROACH PRODUCT LEGISLATION:

A. Standard questionnaire to be filled for each sector individually:

***Sector*: Veterinary Medicinal Products**

1. Harmonisation of laws including technical regulations

1.1. Legal basis

- **References (and copies) of the publication of acts and decrees transposing Directive(s) …….. into the national legislation of your country:**
- **Date of entry into application of the national measures transposing the Directive:**
- **If not yet transposed, please indicate the state of play, expected timing, steps to be undertaken, difficulties encountered (if any):**

The EU legislation on veterinary medicinal products includes 2001/82/EC Council Directive on medicinal products (Last amended Directive 2004/28/EC), 86/609/EEC Council Directive on experimental animals, 91/412/EEC Commission Directive on Good Manufacturing Practice (GMP), Directives of the European Parliament and of the Council 2004/10/EC and 2004/9/EC of 11 February 2004 on Good Laboratory Practice (GLP), 78/25/EEC Council Directive on colouring matters and 84/539/EEC Council Directive on electro-medical equipment used in veterinary medicine.

The national legislation transposing the EU legislation indicated above does not exist. Although the transposition of EU legislation can be completed, the implementation of the transposed legislation constitutes the main difficulty in this sector. Within this context, new administrative structuring, establishment of independent GMP and GLP authorities, and adoption of a monitoring system for GMP and GLP within the Ministry of Agriculture and Rural Affairs (MARA) are required.

The establishment of an authority and a system for market surveillance and restructuring of the existing Veterinary Control and Research Institutes are further preconditions. In view of the current EU system, the role of the State in production of veterinary vaccines also seems to be a problem. Currently, the responsibilities of the Departments of Veterinary Pharmaceuticals and Veterinary Laboratory Services regarding veterinary medicinal products include authorization, sales and distribution channels, control of manufacturing places and laboratories, follow up of complaints, imports, exports, and pricing. However alignment with the EU system requires the establishment of separate divisions for these tasks. The EU legislation on veterinary pharmaceuticals includes authorization, manufacture, test laboratories, sales, usage and controls. However, the current capacity of administrative and technical staff is not adequate for the implementation of the mentioned legislation. Alignment with the EU legislation requires these preconditions to be met.

Nevertheless, technical studies are continuing regarding alignment with EU legislation.

On the other hand, Council Regulation 90/2377 (EEC) on the Establishment of Maximum Residue Limits (MRL) was transposed by Communiqué No. 2002/30 on Maximum Residue Limits of Veterinary Pharmaceuticals in Food of Animal Origin (OG No. 24739, dated 28 April 2002).

This Communiqué is based on relevant EU legislation and is updated and subsequently re-published annually.

(Amended Communiqué No. 2005/28 – OG No. 25837 of 06.06.2005)
(Amendment in accordance with 61/2003/EC, 544/2003/EC, 665/2003/EC, 739/2003/EC, 1029/2003/EC, 1490/2003/EC, 1873/2003/EC, 2011/2003/EC, 2145/2003/EC, 324/2004/EC, 546/2004/EC, 1101/2004/EC, 1646/2004/EC, 1851/2004/EC and 1875/2004/EC).

These Communiqués are prepared pursuant to the Turkish Food Codex (OG No. 23172, dated 16/11/1997)

1.2. Responsible authority

Name and contact details of the competent authority (government, ministry, department, service) and person(s) in charge of transposing the Directive into national legislation

Ministry of Agriculture and Rural Affairs
DG for Protection and Control

Department of Animal Health Services
Division of Veterinary Laboratory Services

Department of Veterinary Pharmaceuticals, Plant Protection Products and Agricultural Equipment
Division of Veterinary Pharmaceuticals Services

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1.3. Notified bodies

Has your country the intention to notify conformity assessment bodies for the Directive? If so, could you already identify these bodies (name, and contact details) and indicate the conformity tasks (products and modules) that they will be entitled to perform

N/A

2. Implementation

2.1. Participation in Standing Committee and Experts' Group

Name, function and contact details of the representatives (and their alternates, if any) of your country's governmental authorities designated or to be designated to represent your country in the meetings of the standing committee and experts' group established under the Directive:

Until now, Turkey has participated in neither the standing committee nor the experts' group for veterinary medicinal products. However, participation and access to the related committees or experts' groups is desired

2.2. Implementing structure

Responsible authority central/local:

Name and contact details of the competent authority (government ministry, department, service) and person(s) in charge of implementing the provisions of the Directive in the territory of your country:

Ministry of Agriculture and Rural Affairs
General Directorate of Protection and Control

Department of Animal Health Services
Division of Veterinary Laboratory Services

Department of Veterinary Pharmaceuticals, Plant Protection Products and Agricultural Equipment
Division of Veterinary Pharmaceuticals Services

Address: Akay Caddesi, No. 3
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Responsible Persons for Veterinary Biological Products
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PROVINCIAL/DISTRICT LEVEL

81 Provincial Directorates (Animal Health Departments)

Responsible Persons for Veterinary Pharmaceuticals

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PROVINCIAL/DISTRICT LEVEL

81 Provincial Directorate (Animal Health Departments)

Implementation:

- Explain how implementation of the Directive in your country will be ensured (monitoring and control tools: market surveillance and others)

- Explain how market surveillance is carried out and on which basis

- Resources available: specify the number and qualification of personnel designated for market surveillance activities (divided in office staff/field personnel)

- Cost: What budget will be provided for market surveillance activities? How will this be financed*?*

As indicated in the part of 1.1 of this document, the current system in Turkey does not enable the implementation of the relevant EU legislation. Implementation of the EU legislation requires those previously indicated preconditions to be met.

Market surveillance of veterinary biological products is carried out pursuant to the Law No. 3285 and the "Regulation on Animal Health Control" and the "Communiqué No. 2003/40 on Storage, Transport and Marketing of Veterinary Biological Products".

The control of veterinary medicinal products includes routine control, defined as controls performed or appointed by official authorities, and notification based control that are performed based on information received regarding veterinary medicinal products. Routine control services are carried out by the Departments of Veterinary Pharmaceuticals and Veterinary Laboratories of the General Directorate of Protection and Control, at central level, and by the Animal Health Departments of Provincial Directorates at provincial/district level. Control of veterinary medicinal products includes control of the owner of authorization, manufacturing places and places of sales. Controls of pharmaceuticals are carried out by "Pendik Veterinary Control and Research Institute", and controls of veterinary biological products are carried out by "Bornova Veterinary Control and Research Institute".

The Departments of Veterinary Laboratory Services and Veterinary Pharmaceuticals, each have one person designated for market surveillance activities at central level. On the other hand, official veterinarians of the Animal Health Departments of Provincial and District Directorates carry out market surveillance activities in addition to their other tasks.

No specific budget is allocated for the market surveillance activities of veterinary medicinal products. The budget of the MARA is utilised for the supply of hardware and software, vehicles, and laboratory equipment of veterinary laboratories.

Methods of enforcement:

- **What means/methods will be available in your country for enforcing compliance with the Directive(s)?**
- **Which are the reactive methods available?**
- *Rights* **of the authority: What are the powers of the authority?**

- **Penalties: which will be the penalties applicable to violation of the national implementing measures?**

Pursuant to "Decree Law No. 441 on the Establishment and the Tasks of the Ministry of Agriculture and Rural Affairs", the rights of the responsible authority regarding veterinary medicinal products cover all provisions, excluding pharmaceutical warehouses and pharmacies which take place among wholesale and retail distribution channels. Pursuant to the "Law No. 3285 on Animal Health Control", the powers of the MARA include control of manufacturing places, control and inspection of manufactured products, permission and control of imports and exports, market surveillance, and authorization of products.

Pursuant to the "Law No. 3285 on Animal Health Control", the penalties applicable to violation of national implementing measures are as follows:

Article 52

If materials such as serum, vaccine and biologic substances which are to be used for animal health protection are found impure, or if they do not comply with the codex, if they do not fit the formula necessary to get the license, if they are found deficient of certain materials which would have increased their effect in terms of diagnosis, treatment or protection, then those who tried to manufacture or produce these substances will be fined a sum of money which should at least be five times as much as the profit they gained out of it.

If the same offence is repeated, the offender's license will be taken and the punishment will be twice as heavy.

Article 53

Those who try to produce vaccine, serum and biologic substances or any veterinary drugs to be used for animal health protection without the approval of the Ministry will be sentenced to 3 months of imprisonment and will pay a fine of various amounts.

Those involved in the marketing of these materials will be fined and the materials produced will be confiscated and destroyed by the decision of a court.

The Law No. 1918, which is against smuggling, will be imposed on those who import live or attenuated micro-organisms or other sorts of things necessary for diagnosis, treatment or the preparation of vaccine without the permission of the Ministry, when such permission is required.

Article 54

Those who produce a low quality and ineffective serum, vaccine and other veterinary drugs by imitating the original ones will be sentenced to 3 months of imprisonment, and a fine is imposed.

3. Calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance

Please provide information on the relevant regimes for the products in this sector:

- short description and
- further evolution.

Relevant regimes for vaccines, sera and biological products include sterility, safety and immunity tests. Detailed information can be presented upon request.