BUNDESamt FÜR SICHERHEIT IM GESUNDHEITSwESEN
AUSTRIAN FEDERAL OFFICE FOR SAFETY IN HEALTH Care
Austrian Medicines and Medical Devises Agency

DECENTRALISED PROCEDURE
PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Baytril Inject –
100 mg/ml Solution for Injection for Cattle and Pigs

Date: 23.11.2012
## MODULE 1

### PRODUCT SUMMARY

<table>
<thead>
<tr>
<th>EU Procedure number</th>
<th>AT/V/0007/002/DX/001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name, strength and pharmaceutical form</td>
<td>Baytril Inject 100 mg/ml Solution for Injection for Cattle and Pigs</td>
</tr>
<tr>
<td>Applicant</td>
<td>Bayer Austria GmbH</td>
</tr>
<tr>
<td></td>
<td>Herbststrasse 6-10</td>
</tr>
<tr>
<td></td>
<td>A-1160 WIEN</td>
</tr>
<tr>
<td>Active substance</td>
<td>Enrofloxacin</td>
</tr>
<tr>
<td>ATC Vetcode</td>
<td>QJ01MA90</td>
</tr>
<tr>
<td>Target species</td>
<td>Cattle and Pigs</td>
</tr>
<tr>
<td>Indication for use</td>
<td>Cattle:</td>
</tr>
<tr>
<td></td>
<td>For the treatment of respiratory tract infections caused by enrofloxacin-sensitive <em>Histophilus somni, Mannheimia haemolytica, Pasteurella multocida</em> and <em>Mycoplasma</em> spp. For the treatment of mastitis caused by enrofloxacin-sensitive <em>E. coli</em>.</td>
</tr>
<tr>
<td></td>
<td>Pig:</td>
</tr>
<tr>
<td></td>
<td>For the treatment of bacterial bronchopneumonia caused by enrofloxacin-sensitive <em>Actinobacillus pleuropneumoniae, Pasteurella multocida</em> and complicated by <em>Haemophilus parasuis</em> as secondary pathogen in pigs.</td>
</tr>
</tbody>
</table>
MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Agencies website (www.hma.eu).
PUBLIC ASSESSMENT REPORT

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Date of completion of the original decentralised procedure</td>
<td>20/09/2012</td>
</tr>
<tr>
<td>Date product first authorised in the Reference Member State (MRP only)</td>
<td>n.a.</td>
</tr>
<tr>
<td>Concerned Member States for procedure</td>
<td>DE, FR, IE, IT, UK</td>
</tr>
</tbody>
</table>

I. SCIENTIFIC OVERVIEW

This is an extension of the authorised generic product “Baytril 1nject 100 mg/ml – solution for injection for pigs” for a new target species (cattle). The reference VMP is “Baytril RSI 100 mg/ml – Solution for Injection for Cattle and Pigs” authorised in Austria since 23.11.1999.

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.

It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.

The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the product was demonstrated according to the claims made in the SPC. The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

This is an extension procedure for a new target animal species. Therefore, the quality part is identical to “Baytril 1nject 100 mg/ml – solution for injection for pigs” which was assessed during the initial application.

A. Composition

The product contains 100 mg enrofloxacin/ml solution and the excipients benzyl alcohol, butyl alcohol, arginine and water for injection.

The container/closure systems are 100 ml brown glass bottles, type I, with chlorobutyl rubber stopper and aluminium crimp cap.
The particulars of the containers and controls performed are provided and conform to the regulation.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

**B. Method of Preparation of the Product**

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

**C. Control of Starting Materials**

The active substance is enrofloxacin, an established active substance which is described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

All the excipients are the subject of monographs in the European Pharmacopoeia respectively USP/NF and are provided to the standard.

**D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies**

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

**E. Control on intermediate products**

Not applicable.

**F. Control Tests on the Finished Product**

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.
G. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This is an extension of the authorised generic product “Baytril 1nject 100 mg/ml – solution for injection for pigs” for a new target species (cattle). The reference VMP is “Baytril RSI 100 mg/ml – Solution for Injection for Cattle and Pigs”.

III.A Safety Testing

Pharmacological Studies

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, data on pharmacodynamics and pharmacokinetics are not required. The data submitted are in accordance with the requirements of the applicable European bioequivalence guideline.

Toxicological Studies

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, this information is not required.

User Safety

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, a detailed user safety is not required. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.
Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

### III.B Residues documentation

No residue depletion studies were conducted because, in accordance with the data requirements of the applicable European bioequivalence guideline, it was demonstrated that the product is a generic of Baytril RSI 100 mg/ml solution for injection and that the residue depletion profile will be the same.

### MRLs

Enrofloxacin is listed in Table 1 of Council Regulation 37/2010. The marker substance is the sum of enrofloxacin and ciprofloxacin.

MRLs are listed below:

<table>
<thead>
<tr>
<th></th>
<th>Pigs</th>
<th>Cattle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Muscle</td>
<td>100 µg/kg</td>
<td>100 µg/kg</td>
</tr>
<tr>
<td>Liver</td>
<td>200 µg/kg</td>
<td>300 µg/kg</td>
</tr>
<tr>
<td>Kidney</td>
<td>300 µg/kg</td>
<td>200 µg/kg</td>
</tr>
<tr>
<td>Fat</td>
<td>100 µg/kg</td>
<td>100 µg/kg</td>
</tr>
<tr>
<td>Milk</td>
<td>100 µg/kg</td>
<td>100 µg/kg</td>
</tr>
</tbody>
</table>

**Withdrawal Periods**

Based on the data provided above, for cattle withdrawal periods for meat and offal 14 days (s.c.) and 7 days (i.v.) and for milk 120 hours (s.c.) and 72 hours (i.v.) are justified.

For pigs a withdrawal period of 12 days for meat and offal was justified during procedure for the marketing authorisation of the generic product “Baytril 1nject 100 mg/ml – solution for injection for pigs”.

### IV. CLINICAL ASSESSMENT (EFFICACY)

#### IV.A Pre-Clinical Studies

**Pharmacology**

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, this information is not required as it has already been presented for the reference product.
Tolerance in the Target Species of Animals

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, this information is not required as it has already been presented for the reference product.

IV.B Clinical Studies

Laboratory Trials

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, this information is not required as it has already been presented for the reference product.

V. OVERALL CONCLUSION AND BENEFIT− RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.
MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the veterinary Heads of Agencies website (www.hma.eu).