

# CODE OF ETHICS

Vetoquinol s.r.o., having its registered seat at Walterovo náměstí 329/3, Jinonice, 158 00 Prague 5, Corporate ID No.: 256 34 194, registered in the Commercial Register maintained by the Municipal Court in Prague, file no. C 56632 (the **"Company"**), accepts the following regulatory and ethical principles to be followed by cooperating distributors of veterinary medicinal products and cooperating veterinaries (the **"Cooperating persons"**).

### PREAMBLE

- A. The Company ensures the registration, promotion and distribution of veterinary medicinal products (the "**VMPs**"), veterinary medicinal products containing narcotic and psychotropic substances, other veterinary medicinal products and complementary supplementary feed in the Czech and Slovak Republics.
- B. In addition to the VMPs manufactured by the Vetoquinol Group, the Company also distributes the VMPs of other marketing authorisation holders.
- C. As part of its business activity, the Company enters into contractual relationships with the Cooperating persons. Since the VMPs, veterinary medicinal products containing narcotic and psychotropic substances and supplementary feed are, as goods, of a special nature, specific regulatory and ethical requirements are imposed on the Company.
- D. Therefore, the Company accepts this Code of Ethics that summarises basic regulatory and ethical obligations to be followed by the Cooperating persons.

The Company's and Cooperating person's obligations are governed, in particular, by the following:

- 1. Act No. 378/2007 Coll., on Pharmaceuticals and Amendment of Certain Related Acts, as amended (the "Act on Pharmaceuticals");
- Act No. 40/1995 Coll., on Regulation of Advertising and Amendments of Act No. 468/1991 Coll., on the Operation of Radio and Television Broadcasting, as amended (the "Act on Advertising Regulation");
- 3. Act No. 167/1998 Coll., on Addictive Substances and Amendment of Certain Related Acts, as amended (the "**Act on Addictive Substances**");
- Act No. 166/1999 Coll., on Veterinary Care and Amendment of Certain Related Acts (Veterinary Act), as amended (the "Veterinary Act");
- Decree No. 229/2008 Coll., on the Manufacture and Distribution of Pharmaceuticals, as amended (the "Decree");
- Guideline of the Institute for State Control of Veterinary Biologicals and Medicaments ÚSKVBL/REG – 01/2018, Rules for assessing the advertising of veterinary medicinal products (the "Guideline");
- Guideline of the Institute for State Control of Veterinary Biologicals and Medicaments ÚSKVBL/INS/DIS – 01/2009, Recommended procedures of applying good distribution practice (the "Recommended procedures"; (hereinafter as "Legislation").

#### 1. GENERAL PROVISIONS

1.1. The Cooperating persons undertake to always act in accordance with the Legislation and this Code, as well as in accordance with other relevant laws and guidelines issued by administrative authorities, in particular the Institute for State Control of Veterinary Biologicals and Medicaments (the "**Institute**") according to the Act on Pharmaceuticals and the Ministry of Health according to the Act on Addictive Substances.



- 1.2. The Cooperating persons undertake, as part of the business cooperation with the Company and in connection therewith, to always act with a professional care, prevent any harm on the part of the Company or third parties and prevent threats to the health of persons and animals.
- 1.3. The Cooperating persons undertake to inform the Company without an undue delay in the event of a breach or an imminent breach of the obligation stated by the Legislation or by this Code.
- 1.4. Following a prior notification, the Company is entitled to execute an inspection of the compliance with obligations set out by the Legislation and/or this Code by the Cooperating person. The Cooperating person undertakes to provide the Company with all the necessary cooperation when carrying out the inspection, in particular to submit to the Company upon request all the documentation relating to joint business activities, to enable the Company's representatives to access storage areas and other premises where individual business cooperation activities take place.

### 2. GOOD DISTRIBUTION PRACTICE PRINCIPLES

- 2.1. The Cooperating person who is also a distributor of the VMPs (the "**Distributor**") is obliged to distribute the VMPs on the basis and in accordance with the authorisation for distribution issued by the Institute, only to the extent to which it was authorised. In the event of any modification of the authorisation for distribution, its suspension or revocation, the Distributor is obliged to inform the Company without undue delay.
- 2.2. When dealing with VMPs containing narcotic and psychotropic substances, the Distributor shall always act on the basis and in accordance with the authorisation to handle the addictive substances according to the Act on Addictive Substances, only to the extent to which it was authorised. In the event of any modification of the authorisation to handle the addictive substances, its suspension or revocation, the Distributor is obliged to inform the Company without undue delay.
- 2.3. The Distributor is obliged, upon occurrence of an adverse effect of the VMP or defect in the VMP's quality, to assess their severity and, if needed, take all available measures to ensure remedy and restrict the adverse effect to the lowest possible extent, including a possible withdrawal of the VMPs from circulation. The Distributor is also obliged to immediately communicate to the Company the ascertained information on the occurrence of the adverse effect of the VMP's quality and the information of the measures taken.
- 2.4. The Distributor is obliged to follow the good distribution practice principles pursuant to the Decree within all his business activities, in particular:
  - a) constantly and systematically apply a summary of the requirements laid down in the Decree;
  - b) purchase and supply only registered VMPs or unregistered VMPs under the conditions laid down by the Act on Pharmaceuticals and the Decree;
  - c) establish and maintain an effective quality assurance system.
- 2.5. The Distributor is obliged to ensure especially that:
  - a) procedures are defined in writing and that procedures ensuring that the quality of the VMPs is not breached in any part of the distribution chain are followed,
  - b) throughout the VMPs distribution chain, the requirements of good distribution practice are followed,
  - c) VMPs are stored and transported reliably and safely, and the possibility of contamination, damage or alienation is minimised;
  - d) a system is in place allowing any batch of the VMPs to be searched, suspended and withdrawn from circulation if necessary,
  - e) in the case of the VMPs containing narcotic drugs and psychotropic substances, additional regulatory requirements laid down in the Act on Addictive Substances are followed.



- 2.6. The Distributor is obliged to have an organisation scheme and organisation rules, which reflect the relationships, powers and responsibilities among individual units of the Distributor and hierarchy of employees' relations. The powers and responsibilities of the Distributor have to be defined unambiguously in writing and employees have to be acquainted with them in a demonstrable way.
- 2.7. The Distributor is obliged to ensure services of a qualified person meeting the requirements laid down in particular by the Act on Pharmaceuticals and, in the case of the VMPs containing narcotic and psychotropic substances, the Act on Addictive Substances, who is responsible for compliance with regulatory requirements in the context of distribution activities. The Distributor's staff must be regularly trained in good distribution practice and in assigned activities, at least to the extent necessary for the exercise of the established responsibility. The Distributor keeps records of the trainings carried out.
- 2.8. The Distributor is obliged to have premises determined for the distribution of the VMPs in accordance with the Legislation, ensuring an adequate protection of the VMPs in particular from damage, contamination and alienation. In the event of the VMPs containing addictive substances, the Distributor is obliged to observe increased regulatory requirements imposed on the storage thereof.
- 2.9. The Distributor duly maintains and keeps the documentation related to the distribution of VMPs in compliance with the Legislation.
- 2.10. The Distributor is obliged to ensure that the VMPs are supplied only to authorised buyers, especially other distributors or persons authorised to issue and serve the VMPs. When establishing cooperation with the buyers and subsequently in regular intervals, the Distributor is obliged to check whether the requirements imposed by the Legislation on the VMPs buyer are met, in particular, whether the consumer is the holder of relevant authorisations.
- 2.11. The Distributor is obliged to enhance the controlling process in case of possibility of entering of a falsified VMP into the distribution chain. If any suspicious VMPs occur, the Distributor will ensure their separate storage and will inform the Company and the Institute immediately.

### 3. ADVERTISING

- 3.1. Advertising means all information, persuasions or incentives designed to promote prescribing, supply, sales, dispensing or consumption of the VMPs. The Cooperating persons are obliged to comply with the Act on Advertising Regulation and the Guideline, not only in connection with advertising communications, but also in connection to the activities of sales representatives or to sales incentives.
- 3.2. Advertising must not be in conflict with good morals, in particular, must not contain any discrimination on grounds of race, gender or nationality or to challenge religious or national feelings, endanger, in general, morality in an unacceptable manner, reduce human dignity, include elements of pornography, violence or elements using the motive of fear. The advertising must not challenge political beliefs.
- 3.3. Advertising must not support conduct detrimental to health or threatening the security of persons and property as well as conduct detrimental to the environmental protection.
- 3.4. Advertising must not be an unfair practice within the meaning of Act No. 634/1992 Coll., on Consumer Protection, as amended.
- 3.5. The Cooperating persons must not distribute advertising of unregistered VMPs or the VMPs whose registration process is taking place.
- 3.6. The Cooperating persons must not distribute advertising aimed at wide public whose subject are the VMPs which, pursuant to a marketing authorisation, can be dispensed only upon a medical prescription or the VMPs containing narcotic or psychotropic substances.
- 3.7. All promotional materials put on the market by the Cooperating persons must be factually correct and supported by a valid version of the summary of the data on the VMPs.



- 3.8. Advertising or any form of promotion must promote the rational use of the VMPs in accordance with the valid version of the VMPs data summary. In particular, the promoted use of the VMPs must take into account the safety and health of both humans and animals.
- 3.9. <u>Advertising aimed at experts</u>
  - a) Advertising aimed at experts has to be carried out via information channels and means of communication aimed at experts such as medical journals and publications.
  - b) Comparative advertising of the VMPs in relation to experts is admissible under the conditions laid down by the Legislation.
  - c) The VMPs samples may be provided, in the context of a promotional activity, only to the expert entitled to prescribe these VMPs, exceptionally and in a limited number, i.e. the number corresponding to the use of a particular VMP in the maximum of 5 cases. The VMPs samples shall not be provided for the purpose of financial enrichment of an expert.
  - d) The provision of the VMP samples containing narcotic and psychotropic substances is forbidden.

# 4. DISCOUNTS AND BONUSES

- 4.1. As part of its business activities, the Company may provide its business partners with discounts and bonuses designed as reduced purchase prices, subsequent price compensation or bonuses in kind of individual VMPs.
- 4.2. All discounts and bonuses will be based on objective criteria and provided transparently to support the Company's business activities, not to promote a specific VMP at the expense of the substitution VMP. The rules for granting discounts and bonuses will be part of a contract governing business cooperation between the Company and the Cooperating person.
- 4.3. Discounts will never be granted for the personal benefit of a particular expert or other person. Requiring a discount or bonus for the purpose of a particular person's personal benefit is the reason for the immediate termination of the business cooperation.
- 4.4. Donations, financial advantages and any benefits of a similar kind shall not be granted, offered or promised to any expert for the purpose of incentives to prescribe, issue, sell or serve the VMP.
- 4.5. If the Cooperating person learns about breach of the rules for the discount or bonus provision laid down by this Code, it is obliged to immediately inform the Company thereof.

### 5. ANTI-BRIBERY

- 5.1. The Cooperating persons must not, as part of contractual relationships or in connection therewith, directly or indirectly provide, offer or promise financial means or any other material or non-material benefit to officials or influence these persons in any other unpermitted manner.
- 5.2. For the purposes of this provision, an official shall mean, in particular, a judge, a public prosecutor, the President of the Czech Republic, a Member of the Parliament of the Czech Republic, a member of the Government of the Czech Republic or another person in position of another public authority, a member of the municipal authority or a responsible official of the local authority, public administration or other public authority, a member of the armed forces or the security corps or an officer of the municipal police, a bailiff in the performance of enforcement activities and the activities carried out on behalf of a court or public prosecutor, a notary in carrying out acts in succession proceedings as judicial commissioner, financial arbiter and his/her representative, or any other natural person who has been appointed by a forester, a guard of nature, a hunting guard or a fishing guard, if he/she performs the tasks of the state authority or society and exercises the powers entrusted to perform these tasks.



# 6. BUSINESS PARTNERS OF COOPERATING PERSONS

6.1. The Cooperating persons are obliged to ensure that their employees or third parties, through which the Cooperating persons ensure the activities falling within the scope of business cooperation with the Company, meet the obligations determined by the Legislation and this Code.