The Institute includes all key processes nto the quality Assurance System. Quality Policy is the indivisible part of quality Assurance System. The Quality Policy is promulgated by the Director of the Institute. The Institute declares its commitments both in the Direction to the external persons and to its employees by means of the Quality Policy.

The aim of the Quality Policy is to ensure that the Institute complies with its responsibilities as provided in the relevant national legislation, EU legislation and contributes to the development of veterinary medicine at the level of the up-to-date status of scientific knowledge as far as the issues related the veterinary medicines are concerned

Taking this into accountthe Director of the Institute has promulgated the following Quality Policy:

With regard to the

- customers and partners of the institute,
- legal framework,
- commitments of the Czech Republic resulting from the international agreements, including membership in the European Union and membership in the professional institutions,
- employees of the Institute

the Director of the Institute hereby promulgates Quality Policy which reflects accord of interests of the stakeholders of the regulation of veterinary medicines and their residues, veterinary non-medicinal products and veterinary technical devices.

The Institute shall

a) ensure, using relevant legislation, that for the needs of the veterinary practice veterinary medicinal products are authorised which comply with the up-to-date scientific requirements for their quality, safety and efficacy

b) **ensure, using relevant legislation, that veterinary non-medicinal products are**

authorised for the needs of the veterinary practice which comply with the up-to-date scientific requirements for their quality, safety and efficacy; in case of veterinary non-medicinal products the Institute shall contribute to establishment of such requirements which will not cause obstructions to the free movement of goods in the EU, which would be incommensurate to the protection of the protected interests of the Czech Repubic in frame of the protection of public health, animal health and of the environm,

c) **ensure, using relevant legislation, that clinical trials of veterinary medicinal products are approved and conducted at the territory of the Czech Republic according to the principles of Good Clinical Practice and under compliance of the requirements for protection of animals against torture.**

d) **ensure, using relevant legislation, that the manufactuiring licences, including licences for import of veterinary medicinal products from the third countries, certificates for the manufacturers of Active Pharmaceutical Ingredients and distribution licences are granted only to those persons which comply with the up-to-date legal and scientific requirements for Good Manufacturing and Good Distribution practices and, by means of the routine and random inspections adn controls, the Institute shall ensure that the up-to-date requirements are implemented continuously by relevant regulated persosns, including measures to be adopted when deficiencies are identified in gthe manufacture and/or distribution or in cases of quality defects;**

e) **ensure, using relevant legislation, that proper and systematic surveillance is implemented in the Czech Republic with regard to:**

- the martket of the veterinary medicinal products, veterinary non-medicinal products and veterinary technical devices, in particular that there are not non-authorised veterinary medicinal products, veterinary medicinal products which do not comply with the information submitted in the dossier and/or adulterated veterinary medicinal products placed on the market in the Czech Republic,

- the dispensing of veterinary medicinal products, in particular that the dispensing is carried out in accordance with the relevant legislation and veterinary medicial products are not dispensed to the persons not allowed to receive them, that the quality, safety and/or efficacy of products is not adversely affected during dispensing and that dispensing is properly documented;

- the use of medicinal products including records and that the abuse of medicinal products

does not occur,

- handling with substances with antiinfective, antriinflamatory, antiparasitic, hormonal and/or psychotropic effects and which can be used for the manufacture of veterinary medicinal products.

f) **ensure laboratory control of**

- Veterinary Medicinal Products and excipients,
- residues of veterinary medicines in the animal products and food stuffs of animal origin,
- Veteirnary non-medicinal products;

g) **ensure post-marketing surveillance of veterinary medicinal products and veterinary pharmacovigilance and evaluates benefit : risk baslance of veterinary medicinal products on a continous basis, using the information on**

- adverse reactions of veterinary medicinal products,
- serious adverse reactions of veterinary medicinal products,
- unexpected adverse reactions of veterinary medicinal products,
- human adverse drug reactions,
- violations of MRLs.
- adverse efects to the environment,
- adverse effects following off-label use,
- lack of efficacy of veterinary medicinal products,

h) **nevytváří nadbytečnými požadavky a neefektivní prací překážky praktickému uplatnění veterinárních léčiv, veterinárních přípravků a veterinárních technických prostředků a zavádění nových postupů a technologií;**

i) **využívá dostupné zdroje co nejefektivněji volbou optimálních postupů a s ohledem na priority dané stupněm rizika nepříznivého působení veterinárních léčiv, veterinárních přípravků a veterinárních technických prostředků na člověka, zvířata či životní prostředí;**

j) **spolupracuje s vhodnými partnery a využívá jejich odborného potenciálu a tím zvyšuje efektivitu činností;**

k) **je korektní a vstřícný k regulovaným subjektům, přispívá k vytváření prostředí důvěry v systém regulace veterinárních léčiv, veterinárních přípravků a veterinárních technických prostředků a vykonává činnost způsobem, který přispívá k mezinárodní integraci České republiky;**

l) **dociluje spokojenosti zaměstnanců;**