§ 33

Rights and obligations of the marketing authorization holder

(1) The marketing authorization holder must make all necessary changes to enable the medicinal product to be manufactured and controlled by generally accepted scientific methods. These changes are subject to notification or approval by the Institute or the Veterinary Institute. The marketing authorization holder shall without delay provide the competent authority with any new information which might lead to a change in the particulars and dossiers submitted in the marketing authorization procedure. , and shall communicate any other new information which might influence the evaluation of the benefits and risks of the medicinal product concerned. The positive and negative results of clinical trials or other studies in all indications and in all population groups, as well as data on such use of the medicinal product that is not in accordance with the terms of the marketing authorization, shall be considered as such information. The MAH shall further ensure that the product information is kept up to date with current scientific knowledge, including the conclusions of the evaluation and the recommendations published in accordance with the directly applicable European Union legislation governing the marketing authorization and supervision of medicinal products ([89]). The Institute may at any time request the marketing authorization holder to provide a copy of the basic document of the pharmacovigilance system and the marketing authorization holder is obliged to provide this copy to the Institute within 7 days of receipt of the application. The marketing authorization holder is obliged to submit data demonstrating at the request of the relevant institute that the risk-benefit balance of the medicinal product remains favorable.

(2) After issuing the marketing authorization, the marketing authorization holder shall notify the Institute or the Veterinary Institute of the dates of actual placing of the medicinal product on the market, type of packaging and code assigned by the Institute or Veterinary Institute in the Czech Republic, no later than 2 months after its actual placing on the market; in the same way, it shall also notify the Institute or the Veterinary Institute at least 2 months in advance of the interruption or termination of the marketing of the medicinal product in the Czech Republic, including the reasons for such interruption or termination. In exceptional circumstances, such notification may be made at the latest at the same time as the suspension or termination of the marketing of the medicinal product in the Czech Republic. If the marketing of a medicinal product is resumed, the marketing authorization holder is obliged to immediately notify the Institute or the Veterinary Institute. The marketing authorization holder provides the Institute with complete and correct data on the volume of deliveries of medicinal products placed on the market in the Czech Republic electronically; the data provided shall include the identification of the marketing authorization holder, the identification of the medicinal product, an indication of the price of the medicinal product covered by public health insurance and whether the medicinal product has been supplied to a pharmacy or distributor; the structure, method, form and time interval of their provision by means of an electronic report shall be determined by an implementing legal regulation. At the request of the Institute or the Veterinary Institute, the marketing authorization holder shall provide the Institute or the Veterinary Institute with data concerning the volume of prescribing of the medicinal product and data on the volume of deliveries of medicinal products placed on the market in the Czech Republic.

(3) The holder of the registration decision is further obliged

(a) ensure that the characteristics of the authorized medicinal product and the current dossier, including the summary of product characteristics, package leaflet, labeling and dossier relating to its classification for dispensing, correspond to the current data and dossier on the basis of which the marketing authorization was issued; registration, as

amended; he is also obliged to keep records of deliveries of medicinal products placed on the market in the Czech Republic, using codes assigned by the Institute or the Veterinary Institute and in case of deliveries of homeopathic products registered by the simplified registration procedure and radiopharmaceuticals their records in a way that allows traceability,

b) have available for each batch of the medicinal product a document on the quality controls of the medicinal product performed in accordance with the registration dossier,

(c) take any available measures, in the event of a risk to the health of the persons or animals being treated, to ensure remedial action and to minimize the adverse effects of the authorized medicinal product; notify the Institute or the Veterinary Institute of such measures; if the marketing authorization holder finds a defect in the quality of a medicinal product for human use or if such a defect is found and notified to him by the Institute, the marketing authorization holder shall, unless the Institute instructs him otherwise, take measures to ensure the possibility of exchanging the medicinal product for the patient by any pharmacy for a medicinal product without such a quality defect and if such a medicinal product is not available or if such exchange cannot be ensured, it shall ensure the complete withdrawal of the medicinal product from the market and its disposal pursuant to Sections 88 and 89,

(d) to provide the necessary cooperation at the request of the Institute or the Veterinary Institute, including the provision of samples of the authorized medicinal product for laboratory control, reference substances in quantities corresponding to the number of batches inspected and any need for re-inspection; veterinary medicinal product and to provide the necessary cooperation in the implementation of the analytical method for the detection of residues of veterinary medicinal products in the national reference laboratory established in accordance with legal regulations [50)],

e) inform the Institute or the Veterinary Institute without delay of any change in the data necessary to ensure the cooperation of the Institute or the Veterinary Institute with the marketing authorization holder; these changes are not considered as changes to the registration,

f) ensure the establishment and maintenance of a system guaranteeing the registration of each advertising sample of the medicinal product, its traceability and compliance with storage conditions, including transport in accordance with the summary of product characteristics,

(g) in the case of a medicinal product for human use

1. to establish and operate a publicly accessible professional information service on medicinal products for which it holds a marketing authorization and to inform the Institute about the address and possible change of address, the publicly accessible professional information service may not be used for advertising [51)] and information provided through it must be in accordance with the summary of product characteristics, part of the information provided through the publicly accessible professional information service is also up-to-date information on whether or not the medicinal product is supplied to the market in the Czech Republic,