



UDC: 615.47.099:546/547

SETTING THRESHOLDS FOR POTENTIALLY TOXIC CHEMICALS MIGRATING FROM MEDICAL DEVICES

Petrova S.Yu., Ilyukova I.I., Kamliuk S.N., Gomolko T.N., Vasilyeva M.M.

Republican Unitary Enterprise "Scientific and Practical Center for Hygiene", Republic of Belarus

Summary

Introduction. As part of ensuring the safety of medical devices, the formation of a list of priority substances that are part of medical devices and pose an increased danger, is a necessary step that precedes the procedure for establishing permissible levels of toxic components from medical devices entering the human body during their use.

The aim of the study is to analyze the components of medical devices and data on the toxicity of potentially hazardous substances, followed by the formation of a list of substances hazardous to health.

Materials and methods. Analytical studies were carried out on the formation of a list of priority substances that are part of medical devices, as well as on the properties of these components hazardous to health.

Results. For the first time, a toxicological dossier of chemicals was formed taking into account the available information on the quantitative characteristics of carcinogenic and non-carcinogenic risks, a list of substances was developed to establish acceptable levels of entry into the human body when using medical devices.

Conclusion. The toxicological dossiers formed within the framework of these studies on the list of substances dangerous to health, in the future, will allow to scientifically substantiate the choice of relevant toxicity indicators and uncertainty factors to establish acceptable levels of intake into the human body when using medical devices.

Keywords: medical devices, toxicity, acceptable level, risk assessment