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THE EUROPEAN PHARMACOPOEIA COMMISSION ADOPTS THE MONOGRAPH ON SODIUM PERTECHNETATE (99mTc) (ACCELERATOR-PRODUCED) INJECTION (2891)

At its 156th Session the European Pharmacopoeia Commission adopted the monograph on Sodium pertechnetate (99mTc) (accelerator-produced) injection (2891).

More than 80 % of medical investigations involving radiopharmaceuticals are based upon technetium-99m. The current monograph Sodium pertechnetate (99mTc) (fission) injection (124) covers quality criteria for technetium-99m used currently for production of these radiopharmaceuticals. It is obtained from so-called radionuclide generators, in which technetium-99m is formed as a decay product of its parent radionuclide – molybdenum-99 – that is extracted from the fission products of uranium-235. In 2009, the medical world faced a severe shortage of molybdenum-99 due to unexpected shutdown of some of the five nuclear research reactors that then supplied practically whole world consumption of molybdenum-99. As a consequence, medical examinations could not be performed and were either omitted, or replaced by alternative diagnostic methods, if available. This event, together with the significant age of the nuclear reactors involved in the production of molybdenum-99 and the requirement to minimize radioactive waste, triggered off the search for alternative production ways of technetium-99m.

The European Pharmacopoeia has now adopted a monograph on Sodium pertechnetate (99mTc) (accelerator-produced) injection (2891). Technetium-99m covered by this monograph is produced directly by proton irradiation of stable molybdenum-100. It is produced in accelerators, such as cyclotrons. There is an existing network of cyclotrons in nuclear medical departments that are capable in the emergency case to produce technetium-99m. This approach provides a viable alternative to the molybdenum-99 production in nuclear reactors and may compensate future shortages or provide a complementary production route for technetium-99m.

The adoption of this European monograph should avoid future potential supply problems for the medical world and benefit patients.

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Note for the Editor: Further information is available on the internet site **www.edqm.eu**
The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopeia is legally-binding in Member States[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.

[1]There are thirty-eight members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the Former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union.*