information on recommendations for the incorporation of drug and other technologies into SUS
This report is a summary version of the technical report of the National Committee for Health Technology Incorporation into SUS — CONITEC and it was prepared in a simple, easily understandable language to motivate patient and public involvement in the health technology assessment process prior to the incorporation, desinvestment or alteration of health technologies used in SUS (Brazilian Public Health System).

All CONITEC recommendations are submitted to public consultation for 20 days. After analyzing the contributions received in the public consultation, CONITEC issues the final recommendation, which may be in favor or against the incorporation/desinvestment/ alteration of the analyzed technology.

CONITEC recommendation is then forwarded to the Secretary of Science, Technology and Strategic Inputs of the Ministry of Health, who decides which drugs, products and procedures will be made available in SUS.

For more information on CONITEC, please visit: http://conitec.gov.br/en
CARDIOTOXICITY CAUSED BY ANTHRACYCLINES IN CHILDREN

The Instituto Nacional do Câncer [Brazilian National Cancer Institute] (INCA) estimated in 2010 that there would be 11,000 new cases of cancer in children aged up to 18 years. The treatment of cancer with drugs from the anthracyclines class (antineoplastic agents, i.e., drugs that treat cancer) is often associated with the appearance of damages in the heart (cardiotoxicity). This group of drugs is intensely used and is part of approximately 60% of clinical protocols for the treatment of childhood cancer.

HOW SUS MANAGES PATIENTS WITH CARDIOTOXICITY CAUSED BY ANTHRACYCLINES

There are scientific studies indicating that it is possible to prevent the cardiotoxicity caused by the use of antineoplastic agents in adult patients. For such purpose, strategies such as the reduction in the dose of the antineoplastic drug and decrease in the time of its application through the patient’s vein have already been studied and exhibit good results in this population. However, in children, there are not enough scientific studies proving the benefits and warranting their use. In SUS, there is no prevention strategy defined in an official clinical protocol to be used in pediatric patients who are using anthracyclines.

ANALYZED TECHNOLOGY
DEXRAZOXANE HYDROCHLORIDE (CARDIOXANE®)

Dexrazoxane is an injectable drug whose indication is approved by Anvisa (Brazilian Health Surveillance Agency) for the reduction of cardiomyopathies (diseases of the heart muscle) associated with the administration of doxorubicin and epirubicin, drugs belonging to the class of anthracyclines, in patients under chemotherapy treatment.

Currently, dexrazoxane is not offered by SUS, and CONITEC is assessing this drug on request of the Sociedade Brasileira de Oncologia Pediátrica [Brazilian Society of Pediatric Oncology]. The proposal is to assess the potential inclusion into SUS of dexrazoxane for the prevention of cardiomyopathies associated with the use of anthracyclines in pediatric patients undergoing chemotherapy treatment.

In its assessment, CONITEC observed that in the studied found, the patient groups, in its majority, were under treatment with anthracyclines for acute lymphoblastic leukemia or Hodgkin’s lymphoma and were under 18 years old.
Dexrazoxane was shown to be effective in the prevention of change in the blood and imaging exams indicators, which may suggest protection against late cardiotoxicity. However, the scientific studies analyzed by CONITEC were unable to assess whether the use of the drug changes the occurrence of heart failure in the patients or interferes in their hospital admissions.

One of the side effects of the drug found in the analyzed studies was hematologic toxicity, i.e., the decrease in the development and production of some blood cells, such as hemoglobin, platelets, neutrophils, etc.

**INITIAL RECOMMENDATION**

Due to the scarcity of scientific studies indicating important and conclusive clinical results able to prove the actual benefit of the drug in children, CONITEC members initially recommended the non-inclusion into SUS of dexrazoxane hydrochloride for the prevention of cardiomyopathies associated with the administration of anthracyclines in pediatric patients undergoing chemotherapy treatment.

This recommendation was made available in a public consultation for 20 days.

**PUBLIC CONSULTATION RESULT**

13 technical-scientific contributions and 14 contributions of experience or opinion were received. All the contributions that contained technical-scientific arguments were contrary to initial recommendation. These presented arguments on clinical evidence, economic evaluation, and budget impact analysis. However, there was insufficient reasoning to change CONITEC initial recommendation.

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1 Treatment for cancer, chemotherapy.

2 Acute lymphoblastic leukemia and Hodgkin’s lymphoma are types of cancer.
**FINAL RECOMMENDATION**

CONITEC members unanimously recommended the non-incorporation of dexrazoxane hydrochloride for the prevention of cardiomyopathies associated with the administration of anthracyclines in pediatric patients undergoing chemotherapy treatment, as a specific procedure in the SUS Table. The recommendation shall be forwarded to the Secretary of Science, Technology and Strategic Inputs of the Ministry of Health.

**FINAL DECISION**

Based on CONITEC final recommendation, the final decision was made. The Secretary of Science, Technology and Strategic Inputs of the Ministry of Health, exercising his legal powers, has decided not to incorporate dexrazoxane hydrochloride for the prevention of cardiomyopathies associated with the administration of anthracyclines in pediatric patients undergoing chemotherapy treatment, as a specific procedure in the SUS Table into the scope of the Brazilian Unified Health System - SUS.

The full technical report on CONITEC recommendation is available on: