What is happening with the supply of oncology drugs in Brazil and the world?

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The continuity of the supply of drugs used in oncology and oncohematology, which are on the whole irreplaceable, has been the cause of major concern in recent years and, in particular during 2011. We have passed through, over the last few months, several 'crises' in the provision of remedies that mobilized and worried many in the medical and pharmaceutical professions in Brazil. The supply of many drugs was halted or at least unpredictable causing much anxiety throughout the oncohematological patient care system. These medications included: alkylating drugs (melphalan hydrochloride, cyclophosphamide and chlorambucil); derived from podophyllin (BCNU); enzymes (L-asparaginase); antimetabolite agents (hydroxyurea, e.g. cytarabine, 6-mercaptopurina); anthracycline antibiotic (daunorubicin and doxorubicin), vinca alkaloids (vinorelbine and vinblastine); bleomycin and procarbazine among others. Another important but little addressed aspect is related to the quality of available products as the vast majority of the 'old' drugs used in oncology are products considered 'similar medications', whose origin, bioequivalence, production process and comparative results are often unknown or nonexistent.

In December 2011, in a publication of the American Society of Clinical Oncology,[1] Dr. Hagop M. Kantarjian, professor and director of the Leukemia Department at the M. D. Anderson Hospital in Houston, warned about a possible shortage in the United States of America of two key drugs used in the treatment of acute myeloid leukemia (AML), cytarabine and daunorubicin. The author recalled that "Cytarabine-containing chemotherapy regimens cure 40% of patients with AML; without cytarabine, the cure is 0%". This is a specific problem in the modern history of the USA that will affect thousands of AML patients.

However, for many years in Brazil, we have been faced with problems in the production, importation, marketing, quality control and supply of this group of drugs. We know that the number of cancer cases worldwide is increasing year by year (there are around 45 million new cases in the world at the moment). We also know that the world population is ageing and that companies in the Far East and Africa have started prescribing Western medicine to patients with neoplasms. The increasing utilization of similar and generic drugs in the Western world has reduced the prices of classical chemotherapeutic agents. This is certainly very good and important for access to cancer treatment except for two factors: i) possible reticence to innovate medications and to invest in research to discover new products and ii) the need for quality control by governments to guarantee the therapeutic action of medications and acceptable toxicity of alternative products. In relation to the theme of innovation, the pharmaceutical industry has reduced investment on new molecules due to the high cost of development and because of recent mergers between companies that has reduced competitiveness. Important newspapers both in Brazil and other countries had warned about this possibility. Probably the decade 2010-2020 will be 'poor' in terms of the discovery of new molecules which offer any great impact in oncology.

Considering the current 'pipeline' of the pharmaceutical companies, I believe that we will have few advances of any great impact in the near future. Certainly we will advance, but within a less optimistic scenario to what we would like in spite of the extraordinary advancements in the field of biology. Data published by the National Institutes of Health (NIH)[2] suggest that, in the area of cancer, for every two million molecules synthesized or developed only 80 reach the stage of clinical trials and only eight are used in routine treatment. This makes the cost of developing one new drug more expensive; in the order of two billion dollars or more depending on the product and its indications. For this there is need to invest which, in general, the industries, governments and communities are unwilling to do. I believe that multilateral institutions such as the World Health Organization (WHO) and the regulatory agencies of different countries, including Brazil, should discuss this theme in depth. The recent increase in life expectancy was due to several factors. However, advances in medicine and, particularly, the advances in basic knowledge and clinical research in the fields of oncology and oncohematology are changing the way we

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can look to the future. I have always had the hope that the future of oncology would use less invasive and more 'intelligent' approaches, e.g. approaches based more on biological knowledge. However, these advances are slow disease-to-disease and depend on investment in the development of molecules or modern procedures and on much scientific support. We must work hard in order to fulfill our duty to medical science with humanity.

xxx

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