New cancer drugs: the Italian unsatisfactory solution

New oncology drugs in the European Union (EU) are assessed under a centralized procedure by the European Medicines Agency (EMA); however, even if a European marketing authorization (MA) has been granted, this does not imply that the product will be available to patients everywhere in the EU [1].

In Italy, new provisions on health care have been introduced through the legislative decree nr. 158/2012, so-called Balduzzi Decree, converted by law nr. 189/2012 [2]. Among other things, Italian Agency for Drugs (AIFA) is required by law to MA promptly after the EMA’s approval for innovative drugs, also including anticancer agents, even before negotiation begins. Initially, these drugs are not reimbursed and are listed in a newly defined class Cnn, where ‘C’ stands for not reimbursed and ‘nn’ stands for not negotiated. On June 2013 pertuzumab and alibercet, while on December 2013 regorafenib, were included in the Cnn class and are still waiting for the reimbursement approval.

This means that the cost, if sustainable, is covered by the structure in which the drug is prescribed or by the patient. As denounced by the Italian Association of Medical Oncology (AIOM), the Cnn class is resulting in a lower utilization of the new anticancer drugs with a risk of discrimination for the patients.

In conclusion, the advantage of an early availability of the new drugs is canceled by the simultaneous absence of certainty of reimbursement, particularly in Italy where the National Health Service (SSN) has historically offered universal coverage with very few restrictions.

A. Tartarone*, R. Lerose & M. Aieta

Unit of Medical Oncology, Department of Onco-Hematology, Hospital Pharmacy, IRCCS Centro di Riferimento Oncologico della Basilicata, Rionero in Vulture, Italy

(*E-mail: tarta1@virgilio.it)

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