

EARLY ACCESS TO THE DRUG: THE ROLE OF THE PHARMACIST IN THE MANAGEMENT OF CNN DRUGS IN ONCOLOGY

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WHAT WAS DONE?

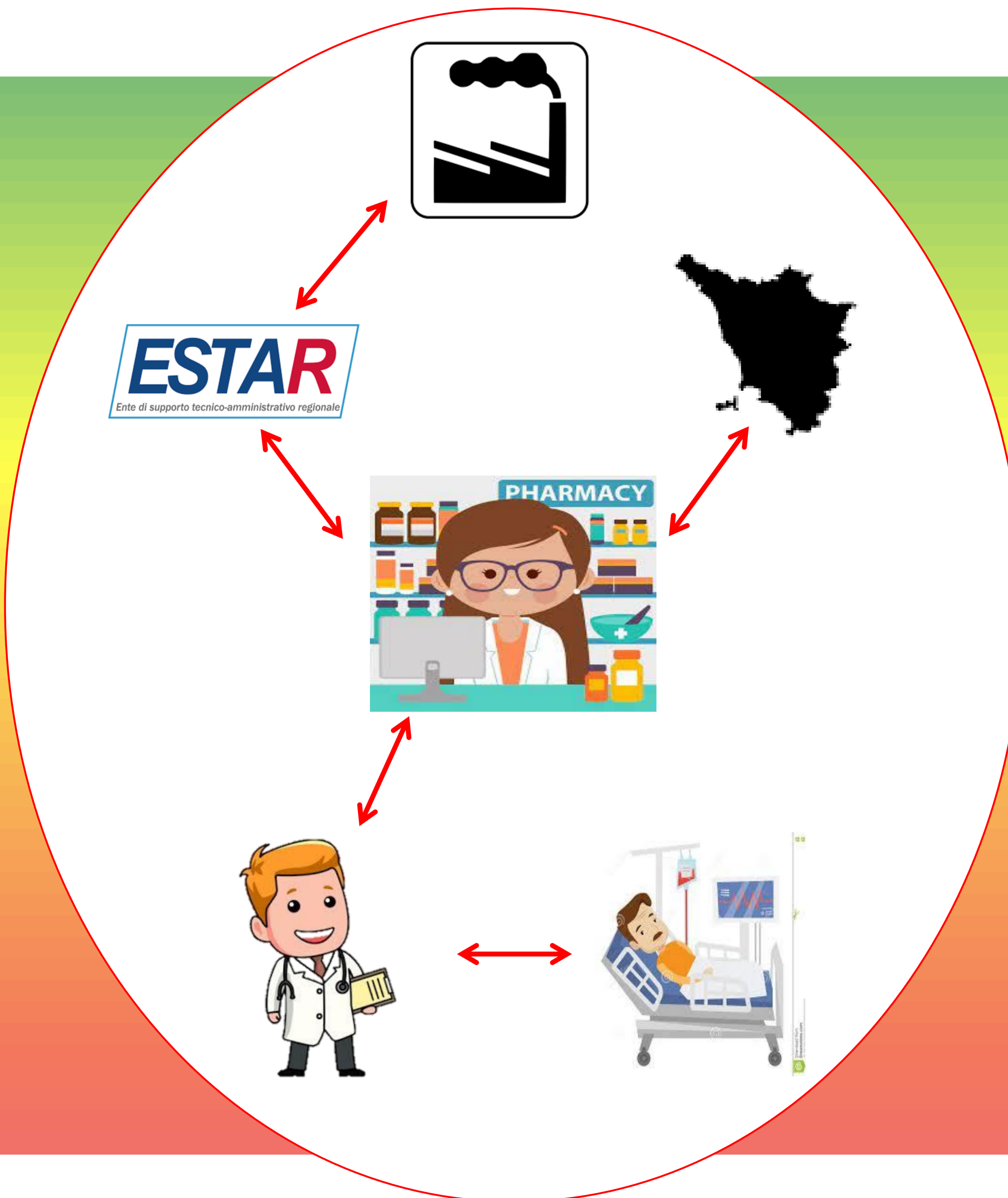
A path has been developed at regional level to promote early access to new drugs and further therapeutic possibilities.

WHY WAS IT DONE?

CNN drugs are drugs that have obtained authorization from EMA and AIFA (italian drugs authority) but that have not been negotiated for the purposes of the reimbursement of the National Health System. These drugs are often clinical innovations that fill therapeutic gaps. In our Region, access to these therapies is allowed only on a special request made by the clinicians at the Pharmacy that is evaluated positively, presents it to the Regional Authority. The regional assessment is also implied by the presence of specific contractual agreements with the pharmaceutical companies. Have been considered requests for enfortumab vedotin (EV), indicated for urothelial carcinoma, and trastuzumab deruxtecan (T-DXd), indicated for breast cancer. The objective of this article is to highlight the activity of the pharmacist in the management of drugs in the CNN range.

HOW WAS IT DONE?

All requests for CNN drugs received in the semester November 2022-May 2023 to our Operations Unit and subsequently included in the regional portal were analysed on the basis of approved indications, bibliography, clinical reports, and eligibility card (for T-DXd only) validated by the medical division of the Pharmaceutical Company.



WHAT HAS BEEN ACHIEVED?

During the period analysed, 25 applications were made (11 for EV, 14 for T-DXd) for a total of 30 treatments (11 for EV, 19 for T-DXd). Of the 25 requests received by the Pharmacy, 24 (96%) were sent to the region for treatment authorization; 1 was not submitted because the patient did not comply with the approved indication. We obtained 100% of the required treatment approvals.

WHAT NEXT?

The hospital pharmacist is configured as a collector of clinical requests with an important function as a filter of prescriptive appropriateness in requesting regional authorisation for the treatment of drugs in the Cnn range; moreover, he is a necessary reference figure between the need for clinical innovation and the need to guarantee sustainability of the system in order to ensure early access to innovative therapeutic opportunities. This model could be exported to other regions at national and european level.

