ACCESS TO ‘FONDO AIFA 5%’ AS AN INSTRUMENT SUPPORTING THE SUSTAINABILITY IN A SHARED CLINICAL MANAGEMENT OF RARE AND DIFFICULT-TO-TREAT DISEASES

G. Valinotti, M. Scaldaperri, M. Tonelli, P. Crosasso, M. R. Chiappetta, F. Cattel
AOU Città della Salute e della Scienza di Torino

Objectives

The Italian Law 326/2003 requires to all drugs Companies operating in Italy to pay 5% of their promotional expenses to an independent research fund (Fondo AIFA 5%), designed to promote orphan diseases research and to make available to rare diseases’ patients medicines awaiting market entry or off label drugs through a named patient program.

The objective of this work was to assess the applications submitted during 2017-2018 in our hospital and the potential cost-saving.

Methods

The identification of patients, that could access the Fondo AIFA 5%, takes place through direct reporting by the physician or through evaluation of the pharmacist during the discussion of cases during the Interdisciplinary Rounds or following the reporting of off-label drug use.

The Hospital Pharmacy has drawn up a standard operative procedure that basically provides:
- request to AIFA and obtaining the authorization
- management of orders and reimbursement by the pharmacy

Results

Diseases authorized to access to ‘Fondo AIFA 5%’

From July 2017 to September 2018, 52 clinical cases were identified as eligible for the access request.

Cases related to rare diseases reported in G.U. n. 65 of 18/03/2017 are thirteen (membranoproliferative glomerulonephritis, autoimmune hypoparathyroidism, peripheral T-cell lymphoma, gigantocellular arteritis, neuroblastoma, systemic sclerosis).

The total amount currently authorized is: 2,049,425 €.

Conclusions

The results obtained demonstrate how the activity of the pharmacist within the Interdisciplinary Rounds and in the Hospital Pharmaceutical Commission allows to obtain an excellent integration between the prescriptive appropriateness and the economic sustainability in rare or highly complex diseases through the access to the Fondo AIFA 5%.