

Conclusion and relevance BM expenditure increased by more than 50% in the last five years, with MAb being mainly responsible. The biological active substances with the highest budgetary impact were medicines to treat immune mediated diseases. The incorporation of BS will lead to a reduction of 20% in BM costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

Section 2: Selection, procurement and distribution

2SPD-029 OFF-LABEL DRUGS: USE ANALYSIS AND PHARMACOEPIDEMIOLOGY IN A COVID CENTRE IN ROME

¹G Gambarelli*, ²G Gambarelli, ³L Fiorito, ³R De Feo. ¹Ministero Della Sanita, DGDFDM, Roma, Italy; ²Ministero Della Sanita, DGPM, Roma, Italy; ³AOU Policlinico Umberto Primo Roma, UOC Farmacia, Roma, Italy

10.1136/ejhpharm-2021-eahpconf.12

Background and importance The coronavirus pandemic has involved the sudden management of innovative therapeutic opportunities to counter it. A drug's off-label use has required a sudden supply and the production of legislation to settle such handling to target real data towards a shareable and objective data collection flow.

Aim and objectives The aim of the study was to analyse the supply process of off-label drugs and reference to the national legislation for each medicinal product, regarding consumption data and the number of COVID-19 patients treated in a COVID centre in Rome, with 200 COVID beds and 40 beds in two intensive care units.

Material and methods For the following products, the supply and handling data were analysed from 1 February 2020 to 31 July 2020: chloroquine, hydroxychloroquine, lopinavir/ritonavir, darunavir/colbicistat, raltegravir and tocilizumab. The AIFA's reference regulations of these drugs were highlighted in the same period. Pharmacoepidemiological data were obtained.

Results The drug's off-label request was first considered. After the AIFA's decision to include in the 648/96 Law (GU 69 17.03.2020) chloroquine, hydroxychloroquine, lopinavir/ritonavir, darunavir/colbicistat, the UOC Pharmacy drafted a specific request form according to the 648/96 Law, to convey the supply and distribution of drugs to the departments through a reporting channel as the regulations required. 10 658 tablets of lopinavir/ritonavir were given to 250 patients, 660 tablets of darunavir/colbicistat to 32 patients, 302 150 tablets of hydroxychloroquine to 350 patients and 330 tablets of chloroquine to 33 patients. Raltegravir tablets were obtained for compassionate use for one patient. Tocilizumab was introduced through an off-label company procedure. Later, the centre was included in the TOCIVID-19 clinical trial (19 March 2020) and patients were moved to the clinical trial. During the off-label use period, 54 therapies were provided and 34 of these required a second dose. From an analysis of the epidemiological data, 80% of patients had at least one comorbidity and age over 75

years; 60% were men. Death occurred in 6% overall, with a 30% death rate for patients over 75 years, according to national data.

Conclusion and relevance The COVID-19 emergency has highlighted the pharmacist's role in the supply of innovative drugs and in the management of National Regulations. A close relationship with physicians has allowed sharing of views, focused on streamlining bureaucracy that often slows down the drug distribution process. Sharing opinions, bureaucratic streamlining and development of communications with online systems, web servers and phone chats can speed up the timing of organisation of the services.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. <https://www.aifa.gov.it/web/guest/-/schede-informative-sui-farmaci-utilizzati-per-emergenza-covid-19-e-relative-modalita-di-prescrizione>

Conflict of interest No conflict of interest

2SPD-030 POSITIONING OF DORAVIRINE IN THE PHARMACOTHERAPEUTIC GUIDE OF A THIRD LEVEL HOSPITAL

A Pintado Alvarez*, A Linares Alarcon, R Asensi Diez. Hospital Regional Universitario Malaga, Farmacia Hospitalaria, Malaga, Spain

10.1136/ejhpharm-2021-eahpconf.13

Background and importance Recently, the EMA and AEMPS have approved the use of doravirine (DOR) a non-nucleoside reverse transcriptase inhibitor (NNRTI) for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class. At present, the therapeutic arsenal available in Spain presents various options within each class.

Aim and objectives To position DOR within the antiretroviral therapies (ART) already available in the hospital's pharmacotherapeutic guidelines and assess its incorporation.

Material and methods A bibliographic search was conducted on DOR's positioning in the main national and international guidelines with the following terms: HIV, adults and guidelines; GESIDA (Spain); DHHS (American) and EACS (European). Possible advantages with respect to the ART already available in hospital were analysed. In addition, an economic evaluation was conducted comparing with available ART and the potential patients who would benefit from its use. The official list price was used with the deduction described in the Royal Decree Law 8/2010 as well as 4% VAT.

Results Gesida guidelines (July 2020) recommended the combination DOR+FTC/TAF or DOR/3TC/TDF (not yet marketed in Spain) as an alternative to the preferred regimens (C-I), but never as the initial therapy. On the other hand, the DHHS guidelines (June 2020) recommended DOR as the initial regimens in certain clinical situations. EACS guidelines (2019 update) recommended it as an initial regimen in combination with two NRTIs or as DOR/3TC/TDF.

The main advantages of DOR are: efficacy in high viral loads (rilpivirine (RVP) is not effective), lower potential for drug interactions, lack of food restrictions, fewer adverse effects on the CNS compared with efavirenz (EFV) and a neutral lipid profile (avoiding dyslipidaemia induced by EFV or boosted protease inhibitors).

The number of patients undergoing treatment with NNRTIs in our hospital was 322 (n=1894 total active HIV positive