Advanced therapy medicinal products: availability, access and expenditure in Italy

Public Health

Pia Rivetti di Val Cervo[1], Eva Alessi[1], Marilena Lastella[1], Antonio La Greca[1] and Francesco Trotta[1]

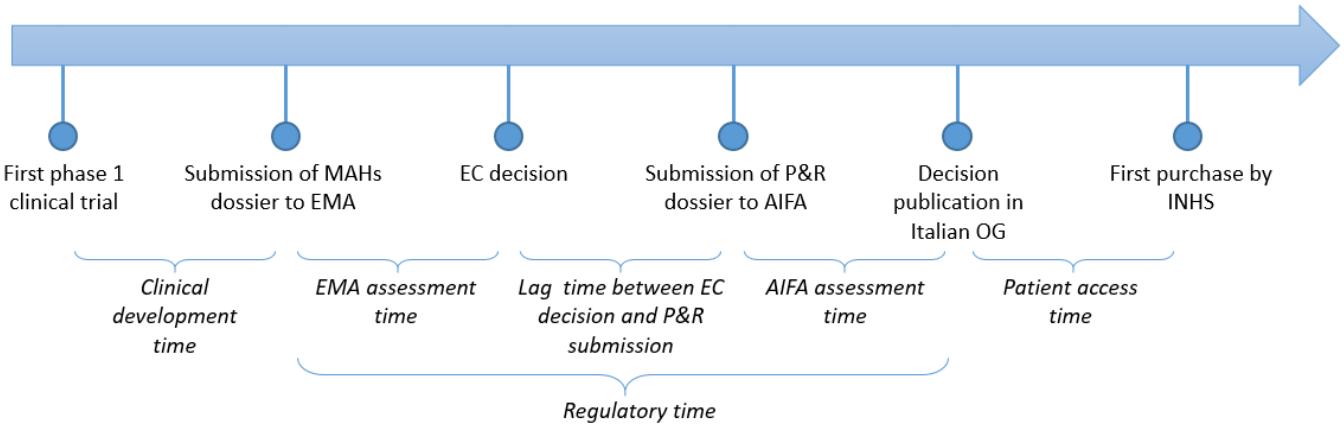
[1]Italian Medicines Agency, HTA & Pharmaceutical Economics Department
Via del Tritone 181, 00187, Rome, Italy

Corresponding author:
Pia Rivetti di Val Cervo
Email: p.rivettidivalcervo@aifa.gov.it
OrcID: 0000-0001-5999-1230

Supplementary Analysis

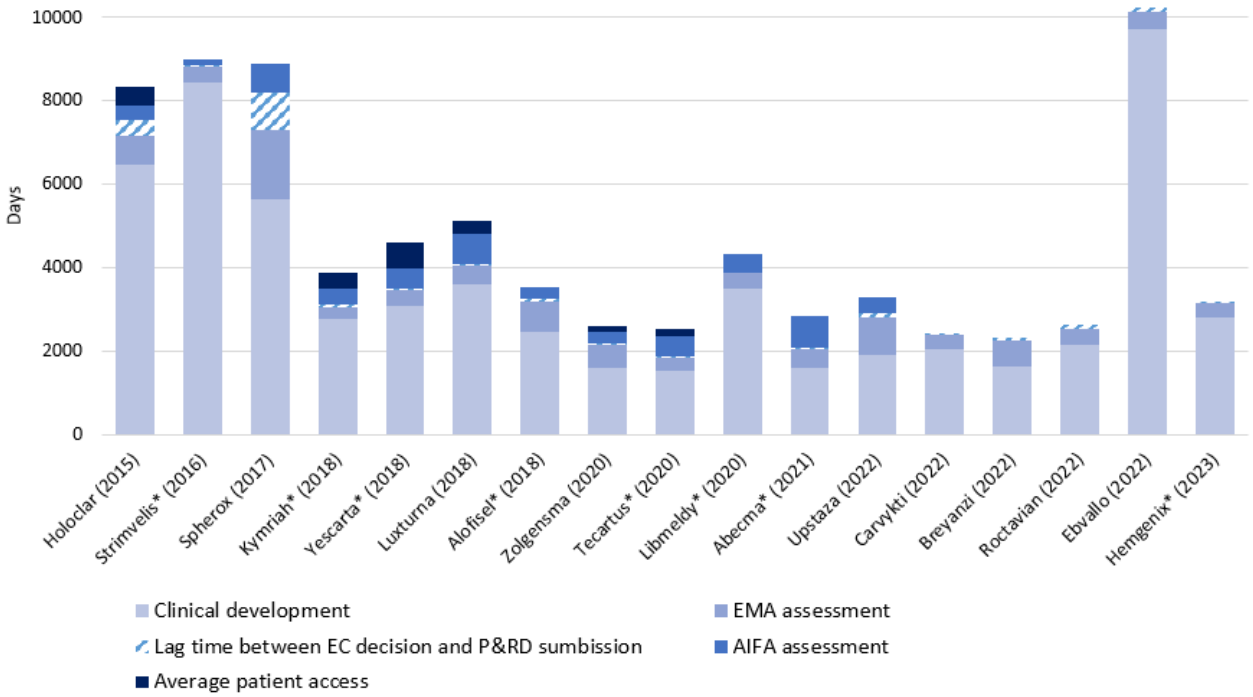
In this supplementary section, six indicators are shown to describe the time elapsed for the main milestones for each ATMP authorised at EMA level (Figure S1), all times were expressed in days. In Figure S2, the clinical development, regulatory assessment and patient access times are represented for all EC authorised ATMPs in Italy.

Figure S1: Timeline leading to patient access in Italy



Legend:
INHS: Italian National Health System, AIFA: Italian Medicines Agency; EMA: European Medicines Agency; MAHs: Marketing Authorization Holders; OG: Official Gazette of the Italian Republic; P&R: Pricing and Reimbursement; EC: European Commission.

Figure S2: Time of clinical development, regulatory assessment and patient access for ATMPs in Italy (data shown in days, therapies ordered by year of EC authorization).



Legend:
AIFA: Italian Medicines Agency, EMA: European Medicines Agency
*in 8 cases the dossier has been submitted to AIFA before the EC decision was published.