

Regional access times in Italy. What makes the difference in the speed and equity of access?

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Background

The publication in the Official Journal for the reimbursement of a drug follows a regional access process consisting of 3 stages:

- Inclusion in the Regional Hospital Therapeutic Handbook (PTOR);
- Identification of authorised prescription centres;
- Tenders.

These phases are different between the Regions and this represents a time barrier of access of the drug to the patient.

Objective

Highlight the presence or absence of elements that differentiate and simplify regional access.

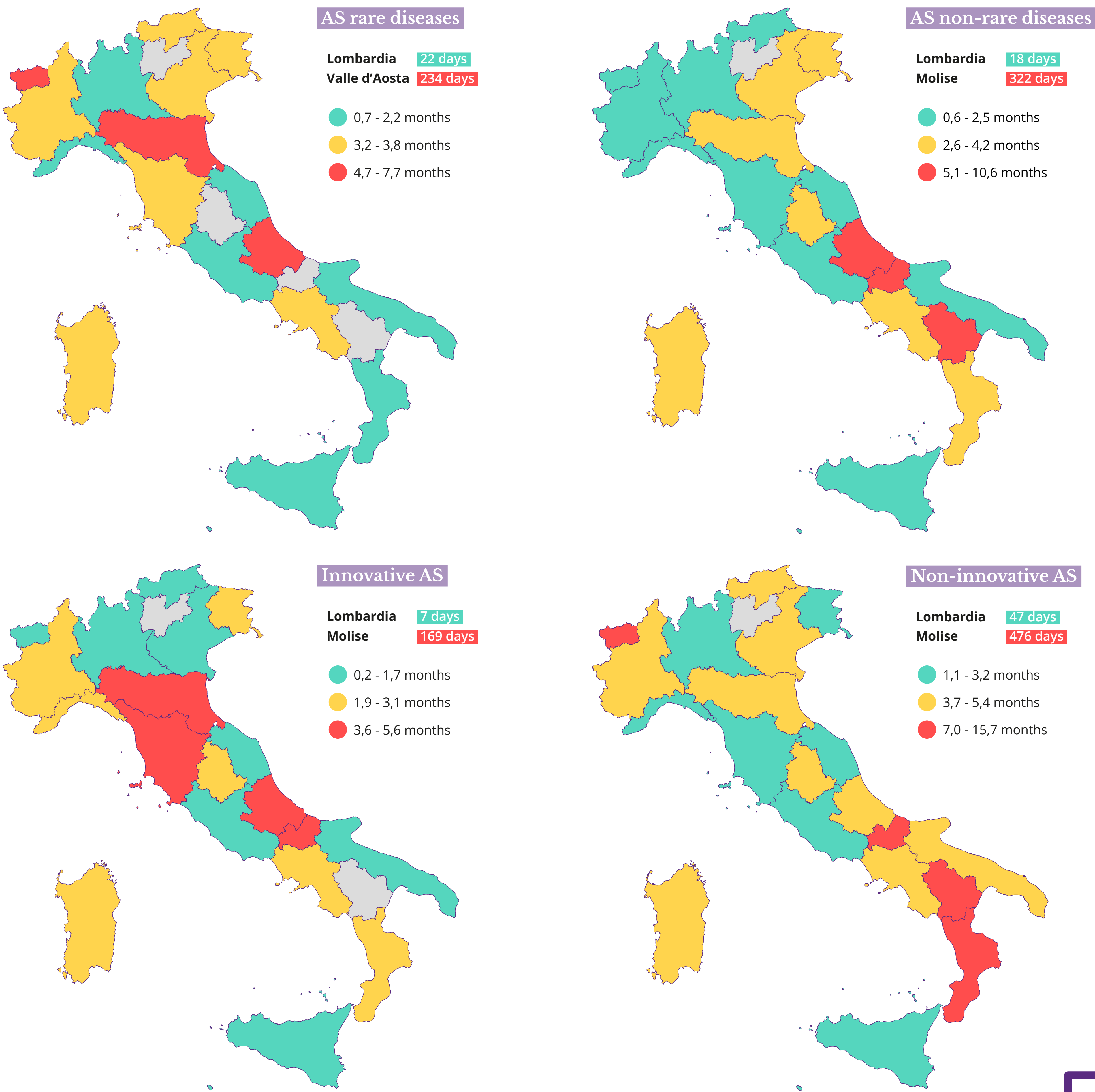
Materials and methods

An Excel database was created containing 184 procedures (new active substance and extension of indication) for which the access times of all Regions and Autonomous Provinces were defined from the date of publication in GURI to that of the tender.

Only the procedures for which it was possible to obtain the necessary information for the development of the analysis and approved from 11/12/2019 to 16/09/2022 have been included.

The sources used were: Regional Official Bulletins, publication websites of the Regional Pharmaceutical Services and Single Purchasing Centres. For all the procedures considered, the following information were found: type of procedure (New Active Substance, Extension of Indication), procedure for rare disease, recognition of innovation and date of publication in Official Journal and on regional source. For each category selected averages and ranges (MIN - MAX) were calculated in days from the date of publication in the Official Journal to the date of the competition.

FOCUS: Regional access of new active substances (AS)



Results

The analysis includes 91 indications, (49% of the total) for the period considered. Overall, the analysis estimated an average of 65.65 (range 1-773) days for regional access compared to the time of publication in the Official Journal. The extensions of indication have on average a shorter access time than the new active substances (Average 67 days range 11-222 vs Average 112 days range 20-298 respectively). Average access times increase for rare diseases compared to rare diseases for new active substances (Average 99 days range 22-234 vs 95, range 18-322 respectively) and decrease if AIFA recognises innovation (68-day average Range 7 - 169 for innovative PA vs Media 144 Range 33-476 for non-innovative PA).

AVERAGE REGIONAL ACCESS

Overall average

65,65 days

- minimum value 1 day
- maximum value 773 days

Extension of indication

67 days

- minimum value 11 days
- maximum value 222 days

New active substances

112 days

- minimum value 20 days
- maximum value 298 days

New active substances for rare diseases

95 days

- minimum value 22 days
- maximum value 234 days

New active substances for non-rare diseases

99 days

- minimum value 18 days
- maximum value 322 days

Innovative active substances

68 days

- minimum value 7 days
- maximum value 169 days

Non-innovative active substances

144 days

- minimum value 33 days
- maximum value 476 days

Bibliography

1. Official bulletin of each Region
2. websites of the Single Purchasing Centres (Soresa, CUC Sicilia, albo pretprio)
3. AIFA website on prescription centers update

Conclusions

It is the regional process that affects access times and not regional epidemiology. The path is partially affected by the characteristics of the drug. The type of indication affects the access of new active substances (the inclusion ex novo in the tender lengthens the process). For extensions of indication the timing is shorter (the tenders of that PA have already been called). Innovative and/or rare disease drugs are more advantageous than non-orphan, non-innovative drugs.

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GENERALE LEGEND

- regions with PTOR
- regions with PTO
- case-by-case evaluation

Timing

- national minimum value
- national maximum value
- 1st range
- 2nd range
- 3rd range

Regional access process