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More and earlier data from AIFA: do they impact on the regional policies? Results from an exploratory analysis

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ABSTRACT

Introduction: In Italy, drug prices and reimbursement are managed by the Italian Medicines Agency (AIFA), but regions actually enable patient access to medicines. Our aim is to provide evidence on (i) the current management of regional pharmaceutical policies, the use of resources and time to policy completion (TPC-procurement awarding), (ii) the potential impact on resources used and TPC of an earlier-enhanced access of regions to AIFA's data.

Methods: Four regions (Veneto, Emilia-Romagna, Campania, Puglia) were selected on a purposive basis. Data on policies and resources used were retrieved from a literature review and interviews with regional officers. TPC was tracked for medicines approved for reimbursement in Italy from January 2023 to June 2024. The potential impact of an earlier-enhanced access to AIFA's data was detected through perceptual questionnaires self-compiled by regional officers.

Results: To manage regional access, the regions employ a staff of 21 Full-Time-Equivalent (FTE) persons on average, ranging from 11 to 29. The mean TPC ranges from 135 to 361. The average score of perceived impact of an earlier-enhanced AIFA's data equals 3.3 within a range of 1-4 for both FTE and TPC. An earlier access to public information (e.g., innovativeness appraisal) is perceived as impactful on TPC. Availability of data that are currently not shared with regions may have a greater potential impact on FTE.

Conclusions: A great consensus emerged on the importance of timely access to revised P&R data. Systematic early disclosure by AIFA could help to improve efficiency in resource utilization and to expedite patient access to innovative medicines.

Keywords: AIFA, Data, Efficiency, Pharmaceutical policy, Regions

Introduction

In the Italian National Health Service (NHS), the regions are accountable for the provision of health care, including pharmaceuticals, and for the healthcare budget (1).

Price and reimbursement (P&R) and Managed Entry Agreements (MEAs) are negotiated at the central level by AIFA (Agenzia Italiana del Farmaco—Italian Medicines Agency) and the relevant pharmaceutical company (2). The companies submit a P&R dossier (3) that provides information on target disease, including the population size, the identification of alternative treatments, the unmet need, the added therapeutic value, the cost of the alternatives, the cost-effectiveness profile, and the drug and healthcare budget impact. Pharmaceutical companies may also apply for the innovativeness status, through a dedicated section of the P&R Dossier: innovative medicines have immediate access to the regional markets and could rely on a dedicated fund. The innovativeness status is decided on the grounds of the unmet need, the therapeutic added value and the quality of the evidence (4). The P&R Dossier is assessed by the AIFA's Offices, which may require clarifications or additional information; they prepare a summary of data included in the P&R (HTA Report henceforth), for internal use only, which is passed to the Scientific and Economic Committee for Medicines (CSE). CSE is charged

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with the appraisal of innovativeness and the P&R negotiation (5). If a P&R agreement is reached, the relevant draft contract should be validated by the AIFA's Board of Directors. Once this validation has occurred, the P&R decision (AIFA P&R Determina) is published on the Official Journal (Gazzetta Ufficiale). The AIFA P&R Determina includes information on the reimbursed indication, the reimbursement class, the ex-factory and list price, the existence (but not the amount) of discounts, the existence of MEAs, the innovativeness status and other access requirements (e.g., requests to regions to identify prescribing centres). Innovativeness appraisals are published on the AIFA's website (6). This appraisal includes the ranking assigned to each of the above-mentioned innovativeness domains. The HTA Reports, supporting the P&R negotiation, are not published. Only nine Technical Reports, including the cost-effectiveness analysis submitted by the pharmaceutical companies and revised by the AIFA's Offices, are published on the AIFA's website (7).

AIFA has also implemented a Horizon Scanning (HS) unit, which, at present, publishes an annual report on medicines approved by the European Medicines Agency (EMA) the year before the report and on medicines under evaluation of the Committee for Medicinal Products for Human Use (CHMP) (8).

Once the AIFA P&R Determina is published, patient access to medicines depends on additional enabling regional actions/policies. Some policies must be implemented by regions, e.g., the identification of prescribing centres, if required by AIFA, and drug procurement; other policies are voluntarily introduced by some regions and can constitute elements of heterogeneity, e.g., regional formularies and guidance on prescriptions of alternative treatments (9).

To design and implement policies, regions rely on different data, including the dimension of the target population, the relative risk/benefit and cost effectiveness profile of alternative treatments, and the budget impact analysis. These data are included in the P&R dossier submitted to AIFA by the pharmaceutical companies (3) and revised by AIFA's offices (HTA Report). As already mentioned, the HTA Report is not public and, at present, not shared with the regions; this explains why some regions ask pharmaceutical companies to resubmit such information to their regional authorities.

A multidisciplinary and multistakeholder group has recently recommended (i) that the information included in the HTA Report is usefully shared with the regions (data sharing, henceforth) and (ii) to enhance the AIFA's HS, in terms of reporting frequency and content (in particular on unmet clinical need, standard of care and comparators) (10) to support pharmaceutical policies planning by the regions (improved HS, henceforth). These actions, according to the group, would reduce/optimize the resources used by the regions for their pharmaceutical policies, and accelerate the time for the completion (TPC) of those regional policies requested to make all drugs accessible to patients and, ultimately, foster patient access to medicines (10). Specifically, TPC can be defined as the time that occurs between the P&R negotiation completion (through the Determina publication in Gazzetta Ufficiale) and the official procurement awarding subsequent to the regional call for tenders (then excluding cases of early access programs).

More recently, another focus group discussed the equitable and timely access to medicines in the Italian context, discussing, among others, how to reduce the duplication of activities developed at both AIFA and the regional level and how to make access more homogeneous across the various Regions, confirming the relevance of the topic under analysis (11).

In light of the aforementioned discussion, the desirable preliminary access to AIFA's data mentioned throughout the study is defined as "earlier" when related to publicly available information (P&R Determina and innovativeness appraisals), and "enhanced" if they refer to the HTA report and the improved HS activity.

However, there is no evidence on (i) the resources currently used by the regions for pharmaceutical policies, (ii) which data from the HTA Report could better feed every single regional policy and (iii) the potential perceived impact of data sharing and improved HS on the resources used by the regions. Furthermore, the literature has investigated time to first patient access for cancer medicines (12) and orphan drugs (13), but no evidence is available on TPC, and some of these data are out of date (12). Our aim is to fill these information gaps through an explorative approach.

Methods

We selected four large Italian regions (Veneto—VEN, Emilia Romagna—ER, Campania—CAM, Puglia—PUG) on the grounds of purposive sampling (13), i.e., their willingness to participate and to guarantee a certain degree of heterogeneity. The four regions account for 31.8% of the Italian population in 2025 (15). The regions have been selected to guarantee a certain degree of heterogeneity according to some predefined criteria: 1) geographical representativeness, as they are located in different geographical areas (North / South); 2) organizational peculiarities, as the selected regions have implemented different pharmaceutical policies, e.g., in terms of presence/absence of a regional formulary (16), of regional HS activities and of health deficit recovery plan status (17). The main characteristics for each region are synthesized in Table 1.

TABLE 1 - Regional characteristics (2025)

Region	Geographical area	Recovery plan	Regional formulary	Structured HS activities
Veneto	North	No	No	Yes
Emilia Romagna	North	No	Yes	No
Campania	Centre-South	Yes	Yes	Yes (Rare diseases)
Puglia	Centre-South	Yes	Yes	No

HS = Horizon Scanning

Regional pharmaceutical policies and their management were retrieved from the grey literature (regional websites). The collected information was validated and integrated in two rounds: 1) online semi-structured interviews (average duration: 60'-90' each), carried out from December 2024 to March 2025, and 2) data collection through autonomously compiled

forms, which took place in Spring 2025. In both cases, two apical officers of the regional pharmaceutical departments were involved for each region. Ethics approval was not required for experts' participation in the study. All the invited officers accepted to be interviewed; all of them provided their consent to record the interviews and later validated the transcripts.

The following policies were investigated (Table S1): regional formulary, prescribing centres selection, regional procurement, policies on prescribing behaviour (NHS prescribing appropriateness, i.e., drug prescribed for the reimbursed indication, guidance on alternative treatments), actions on the clinical pathway (e.g., policies aimed at accelerating the identification and referral of eligible patients). For each policy we elicited: the resources used in terms of Full-Time-Equivalent (FTE) staff involved (time allocated to the relevant policy was estimated by the respondents, since the involved persons are employed also in other tasks, referring to 2025); the stakeholders' involvement, both internal (health care organizations) and external (pharmaceutical companies, scientific societies, patient associations); the information sources used to manage policies; the internal and external communication of decisions taken. Additional information was collected on: the required evidence to include drugs into the regional formularies—if any; the prescribing centers' selection criteria; how the region estimates the target population for procurement; and which actions are implemented for clinical guidance.

The regional officers were also asked to provide information on any HS activity and TPC for new molecular entities (NMEs) and indications approved for reimbursement between January 2023 and June 2024, to capture the overall regional access process.

Data on TPC have been directly provided by the regions. Time to inclusion into the regional formulary, prescribing centres selection, and procurement awarding were the three milestones considered. The regions were asked to refer to the official regional deliberations. VEN does not have a regional formulary, while in CAM the information on prescribing centres was not transmitted.

Due to missing data, the calculated mean and median values refer to samples that do not perfectly overlap. Data for new indications have not been considered as they are not available for PUG; in other regions, they are very similar to NMEs.

Respondents were finally asked to report their perception of the potential effects of data sharing on FTE and TPC, through a four-item scale ranging from 1 (no effects) to 4 (major impact, i.e., reduction up to 50%). Pair scores were preferred to avoid an over-representation of the central score (Table S2). The scale and its conversion into a percentage impact were preliminarily discussed and validated by all the authors, including the regional representatives, who deemed it appropriate based on their own professional experience.

Results

Pharmaceutical policies and FTE

Regional formularies are used by ER, CAM, and PUG (while it is absent in VEN). Innovative medicines and medicines for rare diseases are automatically listed; for other drugs and indications, the inclusion into the formulary is assessed by a regional committee. The assessment is based on the unmet need, the relative risk-benefit profile, the cost-effectiveness and the budget impact (Table S3).

The selection drivers of prescribing centres include the dimension of the target population, the clinical experience, any organizational requirements, and the current disease-specific networks (Table S4).

To estimate the dimension of the target population, two regions (VEN and ER) mostly rely on information provided by health care organizations integrated with internal estimates and, in ER, with an interaction with the pharmaceutical companies. CAM and PUG are used to interact with the pharmaceutical companies and to compare data coming from the industry with internal estimates. Internal estimates rely on different data: evidence on prevalence and incidence, number of patients currently treated with other medicines for the same indication, if any, and expected market penetration of the new drugs (Table S5).

Actions on prescribing behavior are mainly focused on NHS prescribing appropriateness and reporting in two regions (CAM and PUG). VEN and ER have implemented guidance on treatment choice among alternatives and on the treatment pathway (first and subsequent lines). Both regions have implemented working groups with clinicians (for oncology and onco-haematology in VEN, for more therapeutic areas in ER). Guidance may include information on comparative costs (Table S6).

Finally, two regions have been carrying out their own HS activity: CAM for rare diseases and VEN for many therapeutic areas. In general, the HS tends to start from the CHMP positive opinion and is aimed at planning in advance the regional market access process (Table S7).

To design, implement, and monitor pharmaceutical policies, regions systematically interact with the healthcare organizations and hospital pharmacists. Clinicians are involved in the regional therapeutic committees and clinical guidance. The interaction with the pharmaceutical companies is limited to the procurement step (three regions) and the regional formulary (two regions). Data sources include AIFA (NHS prescribing appropriateness), regional sources (e.g., regional disease or drug registries and administrative databases), and the literature, which is commonly used to manage clinical guidance (Table S8).

Regional officers estimated that pharmaceutical policies are managed by 21 FTE on average, ranging from 11 in CAM to 29 in PUG (Table 2). FTE allocation to policies is diverse and mirrors the different investments in policies. Clinical guidance represents a priority in VEN, together with the selection of prescribing centres and clinical pathways, and in ER, where NHS prescribing appropriateness plays a crucial role. The allocation of FTE is more balanced across policies in CAM and PUG, with regional formulary and procurement the two major areas of investment, respectively.

Time to regional policy completion

In VEN, the identification of prescribing centres and publication of tenders should be completed in 30 and 60 days from the publication of the P&R AIFA Determina in the Official Gazette,

respectively. The other regions have not formalized any deadline for TPC. However, CAM has implemented a database where the date of inclusion into the regional formulary and the date of the procurement awarding are systematically checked.

From January 2023 to June 2024, 55 NMEs and 68 new indications, excluding generics and biosimilars, were reimbursed in Italy. Time to inclusion into the regional formulary, prescribing centres selection, and procurement awarding were the three milestones considered. Results are illustrated in Table 3 (mean and median days).

VEN shows the lowest mean and median time of prescribing centres selection and procurement awards. Among the regions with a regional formulary, CAM and PUG show the lowest and highest time to procurement awarding, respectively. ER takes the longest time to include NMEs into the regional formulary, but is more rapid than the other two regions in managing procurement.

TABLE 2 - Staff involved in the pharmaceutical regional policies (FTE)

#	Prescribing center selection	Clinical pathways	Regional formulary	Procurement	NHS prescribing appropriateness	Guidance on alternative treatments	Total FTE
Veneto	6.0	6.0	2.0	2.0	3.0	6.0	**25.0**
Emilia Romagna	2.0	2.0	5.0	1.0	5.0	5.0	**20.0**
Campania	1.8	1.8	2.8	1.0	1.8	1.8	**11.0**
Puglia	5.0	5.0	5.0	6.0	5.0	3.0	**29.0**
Average	**3.7**	**3.7**	**3.7**	**2.5**	**3.7**	**4.0**	**21.3**
%	**Prescribing center selection**	**Clinical pathways**	**Regional formulary**	**Procurement**	**NHS prescribing appropriateness**	**Guidance on alternative treatments**	**Total FTE**
Veneto	24%	24%	8%	8%	12%	24%	**100%**
Emilia Romagna	10%	10%	25%	5%	25%	25%	**100%**
Campania	16%	16%	25%	9%	16%	16%	**100%**
Puglia	17%	17%	17%	21%	17%	10%	**100%**
Average	**17%**	**17%**	**17%**	**12%**	**17%**	**19%**	**100%**

FTE = Full Time Equivalent

TABLE 3 - Days between the publication of the AIFA P&R Determina in the Official Gazette and the inclusion into the regional formulary, the selection of prescribing centres, and the procurement awards (mean and median)

Region		From P&R to Regional Formulary	From P&R to Selection of prescribing centres	From P&R to procurement awarding
Veneto	Mean value	-	66	135
	Median Value	-	59	133
	#	-	47	44
Emilia Romagna	Mean value	182	186	265
	Median Value	172	173	212
	#	50	51	43
Campania	Mean value	50	-	200
	Median Value	43	-	192
	#	35	-	39
Puglia	Mean value	158	102	361
	Median Value	144	96	349
	#	54	49	47

P&R = Price & Reimbursement

Potential impact of AIFA's data-sharing and improved HS

The overall perceived impact of data sharing on FTE and TPC is illustrated in Figures 1a and b, respectively. Per region and per policy data are presented in Tables S9 and S10.

The overall expected impact is rather high (3.3), with limited variations across regions. All data have an impact index over 3 (i.e., more than 30% of FTE). The highest scores were assigned to the target population estimate and the evidence on budget impact and cost-effectiveness profile. Clinical guidance, which would benefit from any relative assessment, and selection of prescribing centres are the most and least affected policies on average (3.8 vs 3.0). Procurement has the second-lowest index score (3.2), but with a high impact (4) assigned to the target population estimate.

The perception of the impact of data sharing on TPC is very similar to that on FTE, but the per-policy ranking is different. An earlier availability of information that is currently published (P&R Determina and Innovativeness Appraisals) was assigned, together with the identification of alternative treatments and their costs, the highest score.

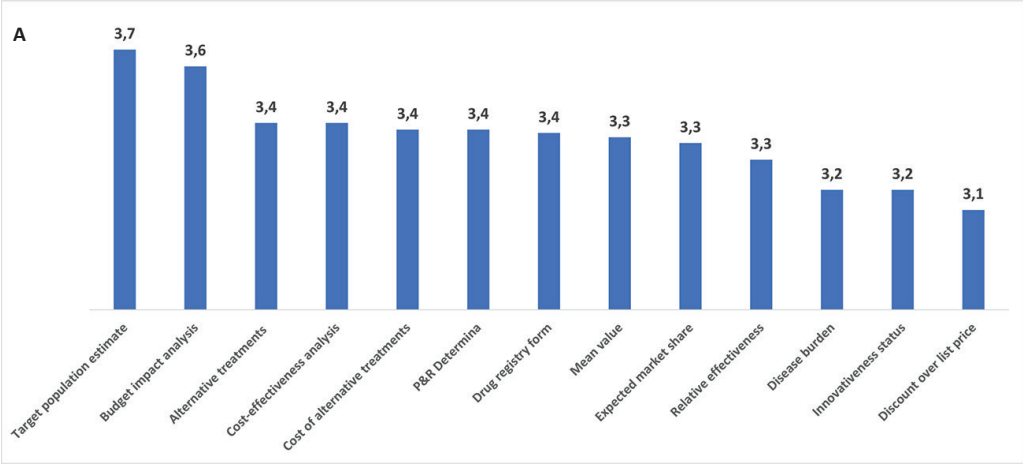
An improved HS would have more impact on TPC than on FTE. The effects are quite similar across policies. The highest and lowest scores were assigned to the time to inclusion into the regional formulary and the time to selection of prescribing centres (Figure 2 and Table S11).

Finally, regional officers were asked to quantify the potential overall reduction of data sharing on FTE. On average, the four regions claimed they would experience a 38% reduction in FTE, with a remarkable variation across regions (from 10% in ER to a 75% in CAM).

Conclusions

This study has investigated, through an exploratory approach, (i) the present management of pharmaceutical policies in four large Italian Regions, including FTE and TPC, and (ii) the potential impact of data sharing and of an improved HS by AIFA on FTE and TPC.

Regional policies may greatly benefit from the availability of AIFA's data. Data required for the inclusion into the regional formularies are mostly included in the P&R Dossier revised by AIFA and can be directly used by regions (innovativeness status, unmet need, relative risk-benefit profile, cost-effectiveness). Other information (e.g., budget impact and target population estimate) is available at the national level, but pharmaceutical companies are used to prepare



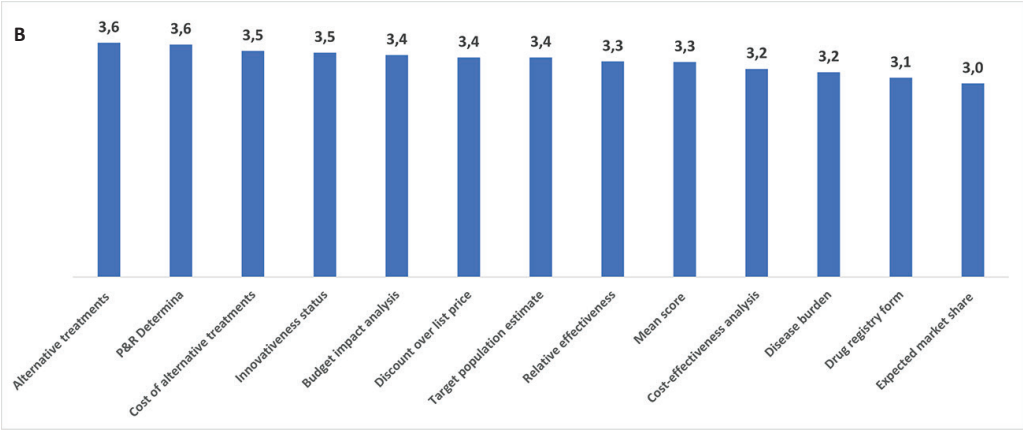


FIGURE 1 - (A) Perceived impact of data sharing on FTE (mean value).
Values range from 1 to 4, depending on the expected impact on FTE (Full Time Equivalent staff involved): 1 = absent, 2 = up to 10%, 3 = up to 30%, 4 = up to 50%.
(B) Perceived impact of data sharing on TPC (mean value).
Values range from 1 to 4, depending on the expected impact on TPC (Time to policy completion) 1 = absent, 2 = up to 10%, 3 = up to 30%, 4 = up to 50%.
P&R = Price and Reimbursement

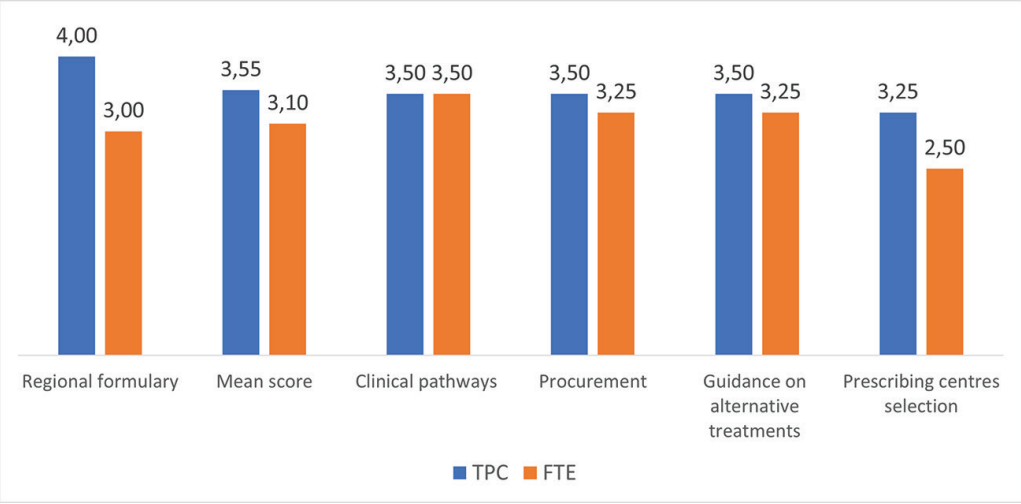


FIGURE 2 - Perceived impact of an improved HS on FTE and TPC (mean value).
Values range from 1 to 4, depending on the expected impact on FTE (Full Time Equivalent staff involved) and TPC (Time to policy completion: 1 = absent, 2 = up to 10%, 3 = up to 30%, 4 = up to 50%.
HS = Horizon Scanning

in advance estimates at the regional level. This information is very important for procurement as well and could be discussed in advance with every single region, which may compare their internal estimates with the ones provided by the industry. Clinical guidance relies on relative assessment. The identification of alternative treatments and comparative evaluations is available in the P&R dossier. This information could be used by the regions to prepare their advice materials for prescribers and start the interaction with clinicians in advance. An improved HS by AIFA could be very useful to prepare clinical pathways, e.g., through an anticipated identification and removal of barriers to diagnosis, and the selection of prescribing centres. This may complement or substitute the regional HS activity, if any.

The importance of data sharing was confirmed by the perceptual analysis. On the one hand, earlier access to public information (P&R Determina and Innovativeness) was considered impactful on TPC. Shortening TPC could also contribute to reduce disparities across regions, which is difficult to accept in a health care system modelled as a national health service. On the other side, regional respondents pointed out that the availability of data, which are currently not shared with the regions, may considerably reduce duplications and the need for resources, which could be reallocated or concentrated on those policies that are key priorities for the regional governments.

The impact of data sharing on every single policy was consistent with expectations. A robust estimation of the target population would be important to manage regional procurement. The identification of alternative treatments and the assessment of the comparative risk-benefit profile would be impactful on clinical guidance, especially in those regions that have invested a high proportion of FTE personnel in such a policy. This does not mean that clinical guidance at the regional level would be cancelled, but that the regions could be more focused on its implementation than on evidence collection and assessment. Conversely, it is surprising that an improved HS was not perceived as crucial for a timing selection of prescribing centres. It is likely that perceiving the potential impact of what should be enhanced to generate this impact is more difficult than estimating the potential effect of what is already available in AIFA. In addition, an HS activity was implemented by two regions and regional domains, like disease-specific networks, are crucial for the selection of prescribing centers.

Our analysis has some limitations. The study has adopted an exploratory approach, and our findings cannot be generalised to all Italian regions. TPC was referred to procurement awarding, which is the necessary final step to make accessible a drug used in a hospital setting or distributed by hospitals, but some drugs may require additional actions to guarantee the actual access (e.g., implementing organisational changes or complex referral processes). Mean and median TPC were calculated for all NME (and new indications), on available data per region: hence, the samples do not exactly overlap. We have not carried out subgroup analysis, e.g., innovative vs not innovative and orphan vs non-orphan medicines. The number of observations was not sufficient to make these sub-analyses, which could reveal that behind (i) an average long TPC, TPC for innovative and orphan medicines is much shorter, and TCP for me-too drugs is much longer; (ii) an average short TPC, there is no difference among drugs.

Perceptual analysis on several items has the risk that respondents replicate the same evaluation for different information and different policies. Actually, not huge variations in scoring were highlighted. However, variations were not negligible and were mostly consistent with the expectations.

The reduced number of respondents could constitute another issue, but this followed a precise strategy to directly involve only the senior positions, given their wider view on the phenomena under analysis. Surveying all their subordinates on one side would have increased the sample, but at the same time, it would have decreased the overall quality of the information retrieved, being based on the knowledge of professionals focused just on specific duties.

Finally, on one side, scoring assigned to the potential impact of data sharing on FTE was quite homogeneous across regions, ranging from 3.1 to 3.5 on average; on the other, the direct estimate of this impact ranges from 10% (ER) to 75% (CAM). This discrepancy could be explained by the possible circumstance that a region with a more structured and systematic action on prescribing behaviour may provide an overall lower perception of the impact of data sharing.

Despite these limitations, this paper has highlighted the importance of a greater collaboration between AIFA and the regions to optimize policy implementation, access to medicines and efficient use of resources. This should not be limited to data sharing from AIFA to the regions, but extended to data sharing from the regions to AIFA. For example, regional administrative data, integrated databases, and clinical pathway issues emerging at the regional level could be useful for AIFA and, ultimately, for all stakeholders: patients could benefit from faster and homogeneous access to medicines, and the pharmaceutical companies would avoid duplication of activities at the national and regional levels and possible inconsistencies between the central and regional assessments.

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