ISPOR 19th Annual European Congress
Vienna, October 29th | November 2nd 2016

ASSESSMENT OF REGIONAL LEGISLATION RELATED TO THE USE OF SIMILAR BIOLOGICAL MEDICINAL PRODUCTS: THE ITALIAN CASE STUDY

Iorio A[1], Lanati E[1]
[1]MA Provider, Milano, Italy

Introduction: The interest in areas of similar biological medicinal products (biosimilar) is growing, also due to a second-generation wave of biosimilars, inclusive of monoclonal antibodies, because they are scheduling to come off patent during the next several years.
Although the European Medicines Agency's has developed scientific guidelines on specific biosimilar products and the Italian Medicine Agency has emanated its position paper, many questions about their use in clinical practice remain a hot topic. In Italy, the discussion on areas related to biosimilar use is carrying on by several years, through position paper of Scientific Society and Regional roles, but generating uncertainty and heterogeneity in their use. The topic of biosimilar use is very important, because these agents are expected to improve affordability and promote wider and earlier access to innovations.

Regions	Therapeutic Continuity guaranteed	Naïve Patient definition	Use in naïve patients	Motivated request	Monitoring System	Incentive scheme	Tender Process	Consequences for nn compliance
Piemonte	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*No*	*Yes*	*No*
Lombardia	*No*	*Yes*	*Yes*	*No*	*Yes*	*Yes*	*No*	*No*
Veneto	*No*	*Yes*	*Yes*	*No*	*Yes*	*Yes*	*Yes*	*No*
FVG	*No*	*No*	*Yes*	*Yes*	*No*	*Yes*	*No*	*No*
Emilia Romagna	*Yes*	*Yes*	*Yes*	*Yes*	*No*	*No*	*Yes*	*No*
Toscana	*No*	*No*	*No*	*Yes*	*Yes*	*No*	*Yes*	*No*
Umbria	*No*	*Yes*	*Yes*	*Yes*	*No*	*Yes*	*No*	*No*
Marche	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*No*	*Yes*
Lazio	*No*	*No*	*No*	*No*	*Yes*	*Yes*	*No*	*No*
Abruzzo	*No*	*No*	*No*	*No*	*No*	*No*	*No*	*No*
Molise	*No*	*Yes*	*Yes*	*Yes*	*Yes*	*No*	*No*	*Yes*
Campania	*No*	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*No*	*Yes*
Puglia	*No*	*Yes*	*Yes*	*Yes*	*Yes*	*No*	*No*	*Yes*
Basilicata	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*No*	*No*	*No*
Calabria	*No*	*No*	*Yes*	*No*	*Yes*	*No*	*No*	*Yes*
Sardegna	*No*	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*
Sicilia	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*No*	*No*	*Yes*

Table 1. Checklist of items analyzed (*Yes for item provided by Regional legislation and No for not provided)*

Objectives: To investigate the existing regional legislations related to the use of biosimilars in Italy, as a case-study of decentralised health care system.

Methods: A web-based analysis was designed to collect the current legislations, in the period from January 2010 to march 2016, and then analyze what are the recommendations about the use of biosimilars, through a checklist of items. The examined items included: (i) the definition and treatment of naïve patient, (ii) the switching from the originator product, (iii) the incentive schemes to increment biosimilar prescription, (iv) the type of tender process, (v) the monitoring system of the implemented rules and (vi) the consequences for non-compliance with regulations. (table 1)

Results: The collected legislation amounted to 27 documents representing the 80% of Italian Regions (17 out of 21 Regions, no low was available for Valle d'Aosta, Liguria, Bolzano and Trento).
Most of the legislations refers to small molecules (10 out 17 Regions), as human insulin or erythropoietin, while only 7 Regions have enacted rules on biosimilar with high degree of complexity, as monoclonal antibodies.Only 5 Regions have enacted specific roles on infliximab, the first monoclonal antibodies biosimilar. (figure 1) In 14 of these Regions (82% of the sample), the enacted rules prescribed the use of biosimilars for the treatment of naïve patients, without a clear definition of primary and secondary naïve. In 10 Regions (58% of the sample), if the clinician prefer to use the originator in naïve patients, they are asked to provide a motivated request. Regarding to the use of originator in patients already well-treated with a particular biological drug, 7 Regions provided that the therapeutic continuity should be guaranteed, of them 3 with a motivated request. (figure 2)
A dedicated percentage of biosimilar prescription is scheduled in 9 Regions out of 17 (53% of the sample).
Only 5 out of 17 Regions (30% of the sample) give recommendation for the purchase process: they specify to follow the same tender for originator and biosimilar products, based on indicating composition, administration path, therapeutic indication and dosages.
The monitoring system is implemented in 11 out of 17 Regions (65% of the sample) and regards drug prescriptions and the use of appropriateness indicators. (table 2)
7 Regions (5 of them under repayment plan) also provide consequences against non-compliance with rules, as the revocation of health authority head or the negative performance assessment of the clinicians.

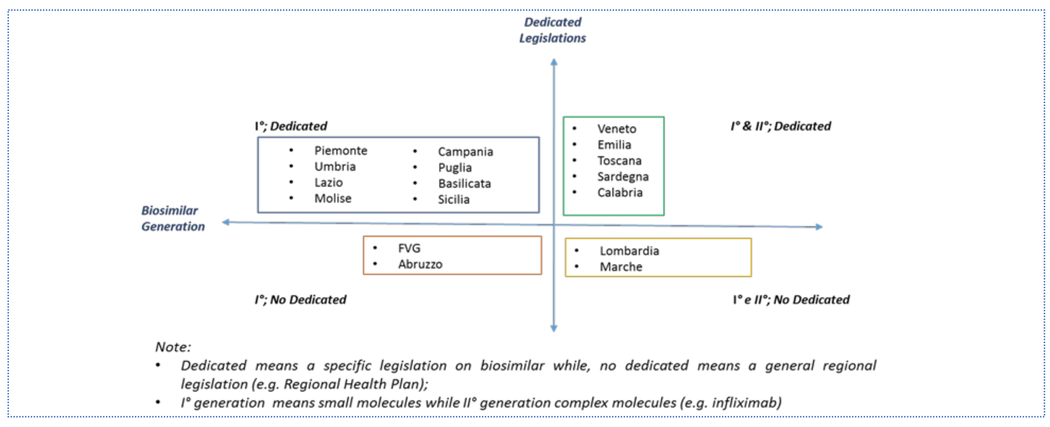

Figure 1. Regional correlation on legislation type and application setting

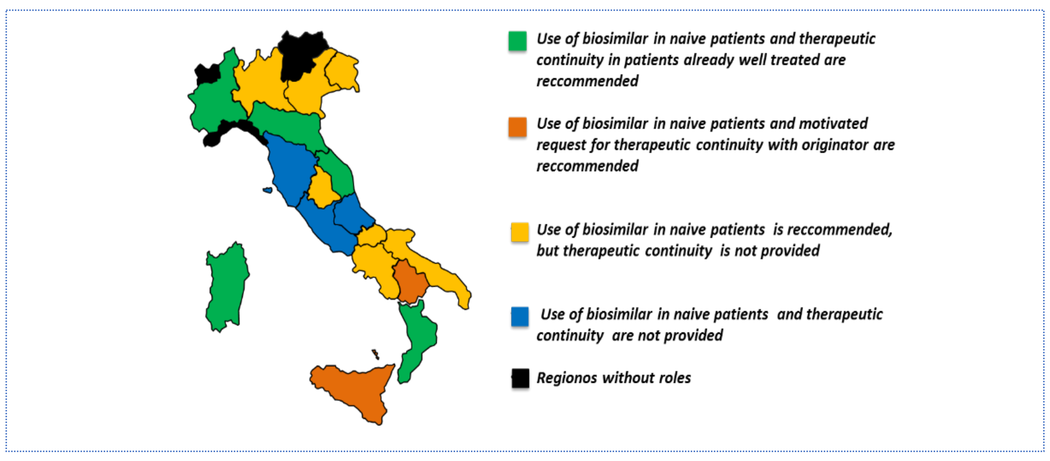

Figure 2.Recommendations on biosimilar use in naïve patient and therapeutic continuity

Monitoring System				
Appropriateness of drug prescription /KPI			Check of motivated requests	Analysis on File F or Registries
- Sardegna	- Toscana	- Basilicata	- Sicilia	- Piemonte
- Lombardia	- Marche	- Puglia	- Sardegna	
- Veneto	- Calabria	- Campania		

Table 2. Regions who implemented monitoring systems

Conclusions: The Italian case-study provides useful insights about the fragmented regional legislations on the biosimilar use. According to last data published on Osmed Report, even if the use of biosimilar in Italy is yet limited, the use of epoetin and growth factors biosimilars in 2015 increased compared to 2014. A more integrated approach to avoid inequality of statement, is necessary to pursue consistency on all aspects related to the use of biosimilars, also considering the upcoming introduction of more complex biosimilar antibodies, that could generate saving to promote access to innovations.

MAProvider
MARKET ACCESS PROVIDER
via Carducci 24
20123 Milan - Italy
tel +39 02 89096682
fax +39 02 89098927
e-mail | info@maprovider.com
piazza San Salvatore in Lauro 10
00186 Rome - Italy
tel | fax +39 06 68806614
e-mail | info.roma@maprovider.com
web | www.maprovider.com