Region	Date	Health policy interventions	Description of health policy interventions
Campania (Caserta)	**30.11.2009**	Decreto Commissariale (DC) n. 15: "Piano di contenimento della spesa farmaceutica ospedaliera"[9]	Drug-naive patients must be treated with biosimilars, with lower cost, if provided they have the same therapeutic indications and administration route of the reference drugs. Exception is made in case of a different clinical judgment. The treatment with another biosimilar or reference product must be ensured to drug-naive patients or already treated patients, if the drug is ineffective or in case of intolerance to the biosimilar.
	14.07.2010	Decreto Commissariale n. 44**: "**Misure di controllo della spesa farmaceutica"[23]	The prescription of biosimilars, for the same therapeutic indications, is referred to naive patients, never treated, as well as the requirement to justify the different choice of treatment by the prescriber. The assessment of the use of biosimilar or not, for the continuity of therapy, is a choice of the prescriber. In both cases, it is not necessary any informed consent of the patient. The managers of the prescriber centers will respond, with the health care directors, of the drug prescriptions out of the indication for use provided by the decree A.I.C. of the drug and, for biosimilars, of the failure to achieve the savings targets to treat naive patients, with the health care directors.
	20.03.2012	Decreto n. 34: "Incentivazione dell'uso dei farmaci biosimilari. Razionalizzazione del File F dei farmaci oncologici ad alto costo "[15]	ESA prescribers should document the reason for which a drug other than a biosimilar is chosen. This must be done using a dedicated electronic form that is then sent online, monthly, to the control Unit of pharmaceutical appropriateness. This patient form should not be filled: 1) when the prescriber considers that, for the appropriate patient treatment, it is necessary the use of an ESA with different pharmacological properties (pharmacokinetics and pharmacodynamics) than an ESA belonging to the ATC class B03XA01; 2) for those biological drugs in the same category of fifth level ATC with a minor cost compared to that at the date of acting of commissarial decrees n. 15 in 30.11.2009 and no. 44 in 14.07.2010, allowing an expected 40% of the achievement; Within 30.04.2012, the control Unit of pharmaceutical appropriateness, in collaboration with the managers of the pharmaceutical service, will assess the performance of the prescription and consumption of ESAs with different pharmacological properties compared to the properties of ESAs belonging to ATC B03XA01 class, in 2011, for each prescribing center, including all not public prescribing centers, in particular dialysis centers, verifying the achievement of the objective of DC 15/2009. If there are significant dosage increases or switch from a type of ESA to another class, or to another higher cost therapy, or failure of therapeutic plan, the manager of the prescribing center will report the reasons of the prescribing behavior to the legal representative of the local health unit.
	15.03.2013	Decreto n. 27: "Misure di incentivazione della prescrizione di farmaci a brevetto scaduto e dei farmaci Biosimilari"[24]	The main objective of the General Managers of the hospital is to achieve a biosimilar utilization rate at least equal to the incidence of drug-naive patients on the total of the patients of the hospital. The same check must be made towards all public and private prescribing centers; General Managers will notify, on a three-monthly basis, to the public and private prescribing centers, of biologics (reference products) for which are approved biosimilar drugs with the same therapeutic indications, the expenditure related to these drugs. Over the next 30 days, the prescribing centers must produce sufficient explanation of the deviation of the assigned objective; the achievement of the biosimilars prescription objectives will be used as a criterion for confirmation or closure of the prescribing center; The control Unit of pharmaceutical appropriateness will verify the achievement of the appropriateness and the objectives by the prescribing center.
	02.12.2013	Decreto n. 114: "Modifiche e integrazioni del DC n. 25 del 14.03.2012 "Individuazione/Aggiornamento Rete Regionale	EX NOTE 30 AND 30bis – Drugs containing filgrastim, lenograstim and pegfilgrastim are prescribed by the NHS only for the clinical conditions, defined specifically in the Italian Agency of Medicines Template. REFERENCE PRODUCT AND BIOSIMILARS- For the prescription of biologics and biosimilars must be referred to the Commissarial Decree n.

		dei Centri prescrittori e codifica – monitoraggio induzione spesa farmaceutica"[25]	34 of 20.03.2011 and the Commissarial Decree n. 27 of 15.03.2013.
Tuscany	**07.06.2010**	Decreto n. 592: "Farmaci Biosimili: direttive alle Aziende sanitarie ed agli Enti per i Servizi Tecnico-Amministrativi di Area Vasta (ESTAV) della Regione Toscana"[10]	It is not possible the substitution with drugs equal in composition, dosage and pharmaceutical form produced from a different pharmaceutical company, unless otherwise therapeutic indication by the prescriber, for specific and justified reasons to be sent to the local health unit. It should: 1) establish that any additional economic burden, resulting from different prescriptions of those previously indicated should not be charged to the Regional Health Service; 2) instruct the general managers of hospitals to activate all procedures to respect of indications above and for the eventual recovery of the costs resulting from failure application of prescribers. ESA prescribers should document the reason for which a drug other than a biosimilar is chosen. This must be done using a dedicated electronic form that is then sent online, monthly, to the control Unit of pharmaceutical appropriateness. Such reason will be located on the request for the individual patient to be sent to hospital pharmacy, in the case of inpatient or outpatient (for direct distribution of the drugs), or must be indicated on the therapeutic plan. In the case of a private prescribing center, the electronic form should be sent to the Local Health Unit.
Veneto (Treviso)	**11.11.2010**	"Linee guida per l'impiego e l'acquisto dei farmaci biosimilari: parere espresso dalla Commissione Terapeutica del Prontuario Terapeutico Ospedaliero regione Veneto (PTORV)"[11]	Drug-naive patients must be treated with biosimilars, with lower cost, if provided they have the same therapeutic indications and administration route of the reference drugs. Exception is made in case of a different clinical judgment. ESA prescribers should document the reason for which a drug other than a biosimilar is chosen. This must be done using a dedicated electronic form that is then sent to the hospital pharm; it should be ensured the therapeutic continuity with a drug (reference product/biosimilar) to treat chronic patients; Direct dispensing is preferred than the territorial dispensing, because it allows to monitor the adherence to these provisions already in the process of distribution; In public procedures of buying of reference products and biosimilars, only products in PTOVR can enter. It should specify the composition, the route of administration, therapeutic indication and any dosages in these procedures.
	29.12.2011	DELIBERAZIONE DELLA GIUNTA REGIONALE n. 2369: "Integrazione obiettivi per l'anno 2012 alle Aziende ULSS del Veneto, all'Azienda Ospedaliera di Padova, all'Azienda Ospedaliera Universitaria Integrata di Verona e all'IRCCS Istituto Oncologico Veneto"[26]	The total packs of distributed biosimilars ESA in relation to total distributed packaging of ESAs in the ATC categories "B03XA *" must be greater than or equal to 20%.
	20.05.2013	Linee di indirizzo per l'appropriatezza prescrittiva dei farmaci nelle Aziende ULSS della Regione Veneto[27]	Share packages of distributed biosimilars by direct/ territorial dispensing and hospital consumption on the total packages of drugs belonging to the therapeutic categories for which are available biosimilars (colony stimulating factors, ESAs, somatropins) must be greater than or equal to 60%.
Sicily (Palermo)	**3.05.2011**	Decreto Amministrativo n. 804: Rete Regionale dei centri Prescrittori[12]	It was established, with regard to epoetins (biosimilars and reference products), that: "it is necessary to specify hemoglobin values for the prescriptive appropriateness".
	15.09.2011	Prontuario Terapeutico Ospedaliero-Territoriale	For drug classes identified by ATC codes B03XA e L03AA: "Drug-naive patients should be treated with biosimilars (if available); it should be

		della Regione Siciliana (PTORS). Allegato al Decreto Amministrativo n. 01718[28]	ensured the therapeutic continuity with a drug (reference product/biosimilar) to treat chronic patients".
	29.03.2013	Notifica delle decisioni della Commissione Regionale per il PTORS. Prot. n. 30449 [29]	For drug classes identified by ATC codes B03XA e L03AA: "Drug-naive patients must be treated with biosimilars, with lower cost; it should be ensured the therapeutic continuity with a drug (reference product/biosimilar) to treat chronic patients".
	8.01.2014	Decreto Amministrativo Approvazione dell'Accordo per la Distribuzione per conto (DPC) dei farmaci inclusi nel prontuario terapeutico ospedaliero (PHT)[30]	Drug classes identified by ATC codes B03XA, L03AA and H01AC01 are included in "distribuzione per conto" (DPC); for these therapeutic classes are available the appropriateness form.
	2.04.2014	Misure volte a promuovere l'utilizzo dei farmaci Originatori o Biosimilari a minor costo di terapia[16]	Drug-naive patients must be treated with biosimilars, with lower cost. Exception is made in case of a different clinical judgment. The treatment with another biosimilar or reference product must be ensured to drug-naive patients or already treated patients, if the drug is ineffective or in case of intolerance to the biosimilar. A biosimilar or a reference product with lower cost should be used, in case of switch to another drug or if the treatment was discontinued. ESA prescribers should document the reason for which a drug other than a biosimilar is chosen. This must be done using a dedicated electronic form that is then sent online to the own Local Health Unit.
	28.04.2014	Decreto Amministrativo n. 540/14. Misure volte a promuovere l'utilizzo dei farmaci Originatori o Biosimilari a minor costo di terapia. Circolare esplicativa[31]	For drug classes identified by ATC codes B03XA, H01AC01 e L03AA: "Prescribers could fill the therapeutic plan (with the reason for which a drug with higher cost, other than a biosimilar, is chosen) other than the therapeutic plan or the form attached to "Decreto Amministrativo n. 540/14"; the modified therapeutic plan should be attached to the prescription of the National Health Service. The pharmacist will verify if the therapeutic plan will be addressed to a naïve patient, if the prescriber filled the field of the prescription with higher cost.
	17.06.2014	Decreto Amministrativo n. 540/14. Misure volte a promuovere l'utilizzo di Farmaci Originatori o Biosimilari a minor costo di terapia. Chiarimenti[32]	The health care directors should adopt sanctions, according to *Article 9, comma 15 L.r. 12/2007*, in case of an inappropriate drug prescription, or prescriptions of a drug with higher cost. If a clinician prescribes an inappropriate drug, the Local Health Unit should send an invoice to the Health Unit of the clinician. This could lead to the suspension of the prescriber center.
	04.08.2014	Farmaci a PHT in Distribuzione per conto[33]	It was established, according to "Decreto Amministrativo n. 1766/11" with regard to epoetins (biosimilars and reference products), that it was necessary to specify hemoglobin values in the therapeutic plan for the prescriptive appropriateness.