The Italian Region **Emilia-Romagna** implements an **evidence-based drug governance policy** involving multi-stakeholder workgroups to promote equitable and sustainable access to drugs

Drug Governance in the Emilia-Romagna Region, Italy

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Background

- The Italian National Health Service provides assessment, pricing and reimbursement of medicines through the Italian Medicines Agency (AIFA).
- However, each Italian Region can implement its own tailored drug governance policy within the national reimbursement regulation

Methods

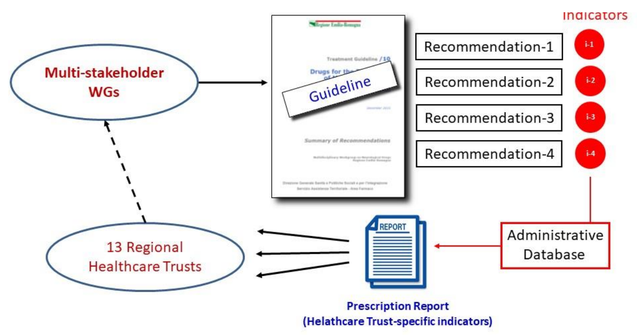
1. In the region Emilia-Romagna (RER) evidence-based recommendations on the use of medicines are issued by multi-stakeholder workgroups (MSWG), informing the decisions of a regional Drug and Therapeutic Committee (DTC) that monthly updates the Regional Drug Formulary (RDF)
2. Recommendations produced by means of the GRADE method are monitored through quantitative indicators expressing the expected prescription rates. **Yearly reports are produced for** conditions with high impact on resources
3. Drugs are purchased through centralized procurement procedures by a public independent regional agency.
4. Cost-opportunity evaluations to foster competition among pharmaceutical companies are part of RER's drug governance policy

Results

- **1,242** drugs included in the Regional Drug Formulary
- **255** documents on drugs issued by the DTC since 2006
- **79** with evidence-based recommendations and quantitative expected prescription rates
- **62** produced with the GRADE methodology
- **12** active workgroups

Discussion

- RER implements a drug governance policy based on evidence-informed, structured, explicit and flexible guidance process involving MSWGs
- Differences between observed and expected prescription rates help understanding the determinants of variability among prescribers and can inform decisions about resource allocation.
- Appropriate use of drugs is key for the sustainability of a reimbursement-based system, warranting equitable access to treatments



Workflow of drug governance policy in the Emilia-Romagna Region (Italy)

Strength/ Direction	Definitions and implications	Expected prescription rate
Strong Positive	Most (although not ALL) patients should be offered the treatment. The recommendation could be used as a quality of care standard.	**> 60-70%**
Weak Positive	Wider range of uncertainty: it may indicate that only a relative minority of patients (30%) or a substantial proportion (50-60%) of patients should be offered the drug. Patients must be informed about expected desirable and undesirable consequences (and their magnitude), exploring their values and preferences and discussing possible alternatives	**30-60%**
Weak Negative	The treatment should be offered to a minority of patients or in selected cases. The decision should be thoroughly discussed with the patient about desirable and undesirable consequences of the treatment (and their magnitude) exploring their values and preferences and discussing possible alternatives	**5-30%**
Strong Negative	The treatment should not be routinely offered, not even to a subgroup of patients, but only in highly selected cases. The benefit/risk balance is unfavourable and safer alternatives are available.	**< 5%**

Translating GRADE's «strength» and «direction» into prescription expected rates

Area	Active Multi-Stakeholder WGs	Topic	Specific guidance
Oncology	• GReFO (Gruppo Emiliano Farmaci oncologici)	Various onco-ematological malingancies	Various onco-ematology medications
Dermatology	• Psoriasis	Chronic plaque psoriasis	Multiple medical treatments, with focus on biologic drugs
Rheumatology	• Rheumatology (children and adults)	Spondylitis Ankylosans; Psoriatic Arthritis; Rheumathoid Arthritis; Juvenile Idiopatic Arthritis	Multiple medical treatments, with focus on biologic drugs
Gastroenterology	• Hepatitis-B	Hepatitis-B	Nucleos(t)ide analogues
	• Hepatitis-C	Hepatitis-C	Direct Antiviral Agents
	• Inflammatory Bowel Diseases	Inflammatory Bowel Diseases (ulcerative colitis, Crohn's disease)	Multiple medical treatments, with focus on biologic drugs
Neurology	• Multiple Sclerosis	Multiple sclerosis not responding to interferon/glatiramer acetate	Monoclonal antibodies
	• Parkinson's Disease	Parkinson's disease	Dopamine receptor agonists Device-assisted medical treatments
	• Migraine	Episodic and chronic migraine (adults)	Monoclonal antibodies Botulinum toxin
Cardiovascular	• New Oral Anti-Coagulants	Preventive anticoagulation (non-valvular atrial fibrillation)	New Oral Anti-Coagulants
	• Acute Coronary Syndrome	Acute Coronary Syndrome (pre-admission and in-hospital management)	Antiplatelet agents
	• PCSK9	Hypercholesterolemia	PCSK9 inhibitors
Chronic Renal Impairment		Secondary hyperparthyroidism in chronic renal impairment (CKD-MBD)	Vitamin D, phosphate chelating agents, calcimimetics
Diabetes		Type 2 diabetes	Oral hypoglycemic agents in DM2 not controlled by metformine alone (DPP-4i, GLP-1a, SGLT2i)

Multistakeholder Workgroups in Emilia-Romagna

A full list of guidance documents (in Italian) is available at:
http://salute.regione.emilia-romagna.it/documentazione/ptr/linee-guida-e-raccomandazioni-ptr

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