



Landing HTA Regulation: Insights into European Policies and Implementation in Southern Europe – Cases of Spain and Italy

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SECTION

1

HTA in Spain and the new Regulation - RedETS

The Spanish Network of Health Technology Assessment Agencies



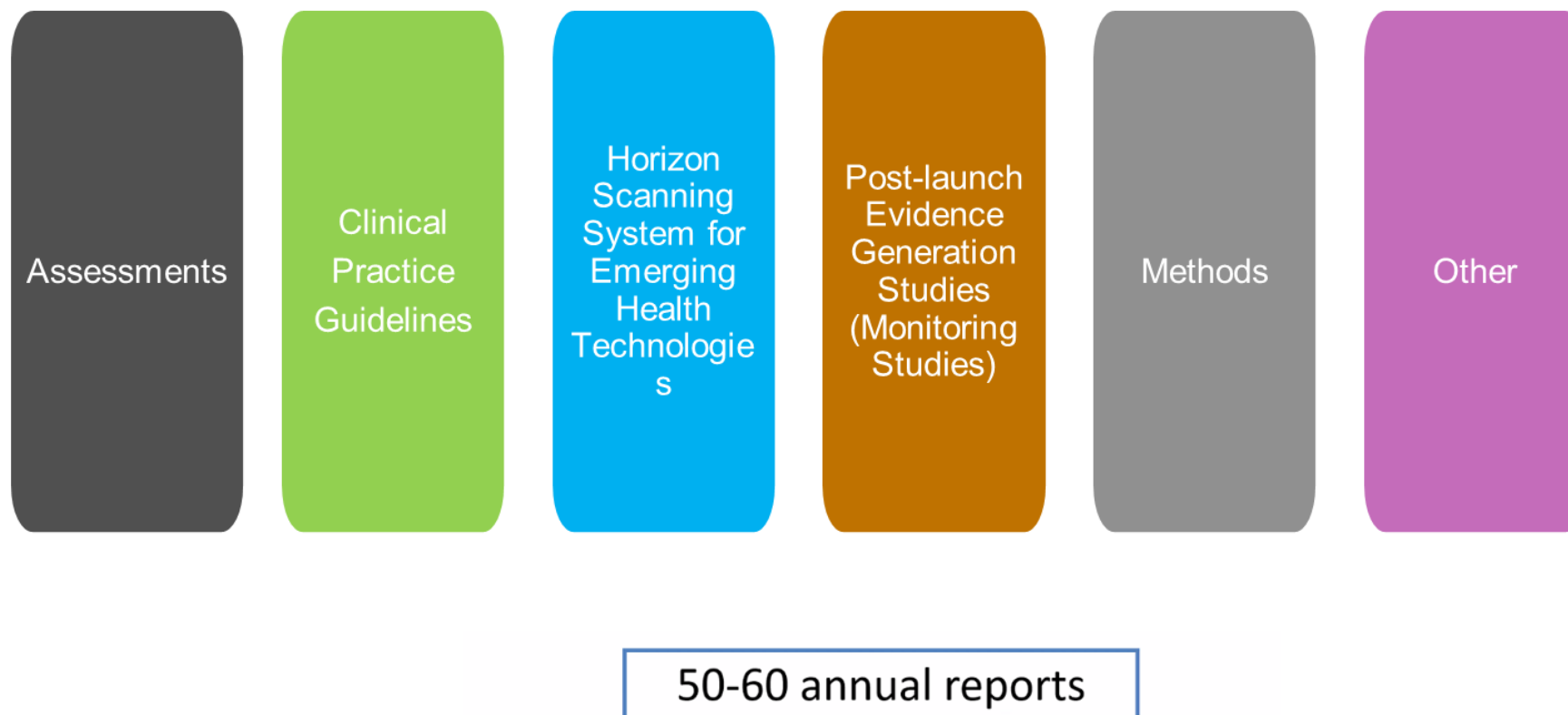
- Technologies: medical devices, diagnostic tests, interventions, programs (public health) or services (organization)
- Financed by Ministry of Health and Autonomus Communities

Network Structure

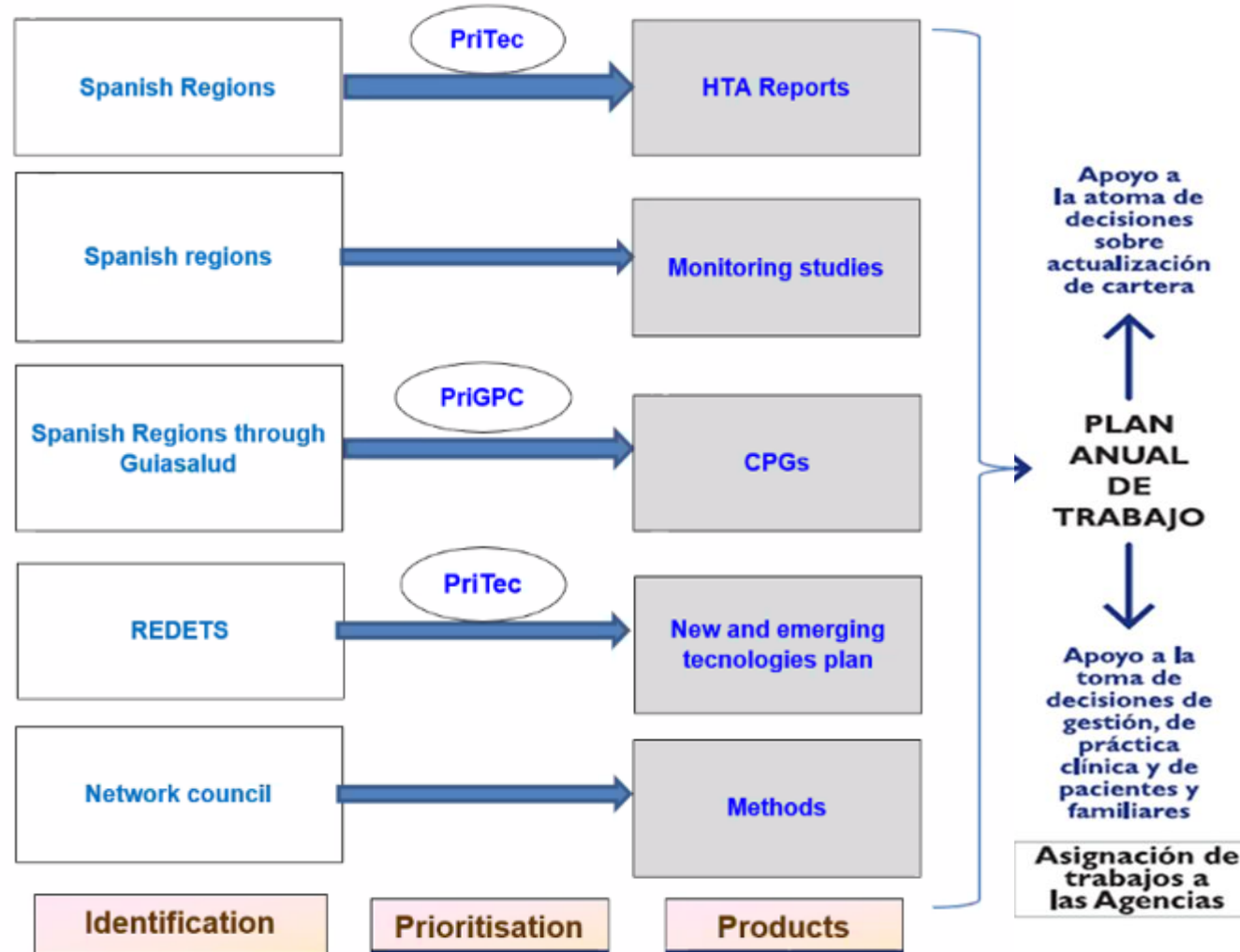
- Members: AETSA, AETS-ISCIII, AQuAS, Avalia-t, IACS, Osteba, UETS and SESCS
- Public Health and Portfolio Services General Directorates
- Secretariat and Funding, MoH

AQuAS	IACS	Avalia-t	SESCS	AETSA
6 HTA technicians 1 Information Specialist 1 Supervisor of methodological quality 1 Coordinator	10 HTA Researchers 1 Health Economist 1 Information Specialist 1 Project manager 3 Support staff (administrative)	9 HTA Researchers 1 Health Economist 2 Information Specialist 2 support staff (administrative)	15 HTA Researchers 6 Health Economists 2 Information Specialist 3 Qualitative Researchers 5 Stats 3 Project managers	12 HTA Researchers 1 Health Economist 3 Information Specialist 1 Project manager 1 Coordinator 1 Support staff (administrative)

Products in RedETS



Identification, Prioritization and HTA Development



RedETS Annual Working Plan






Year	HTA Topics identified	HTA Topics filtered for Prioritization	HTA Topics included in RedETS Annual Working Plan for Assessment		
			From Prioritization	From Ministry of Health	Total
2019	46	32	18	4	22
2020	63	39	23	5	28
2021	62	41	28	8	36
2022	78	45	33	7	40
2023	59	35	35 ¹	7	42

SECTION

2

HTA in Spain and the new Regulation

HTA in Spain

DECISION	DECISION-MAKER	EVALUATION BODIES	LEVEL
Marketing authorization. <u>Pharma and Devices</u>	AEMPS 	EMA,  AEMPS 	European National
PHARMA Price and Reimbursement 	Ministry: CIPM	AEMPS,  REvalMed REvalMed SNS	National
National Portfolio of Benefits (MD...) 	Ministry: Interterritorial Council	RedETS 	National
Health Services Provision, Complementary Benefits 	Autonomus Communities	Agencies or Departments from the Regional level	Regional
Hospital purchase of health technologies 	Regions Hospitals	Hospitals	Local



DA tercera de la Ley 10/2013 y el artículo 31.3 de la Ley 16/2003, de 28 de mayo, de cohesión y calidad del Sistema Nacional de Salud



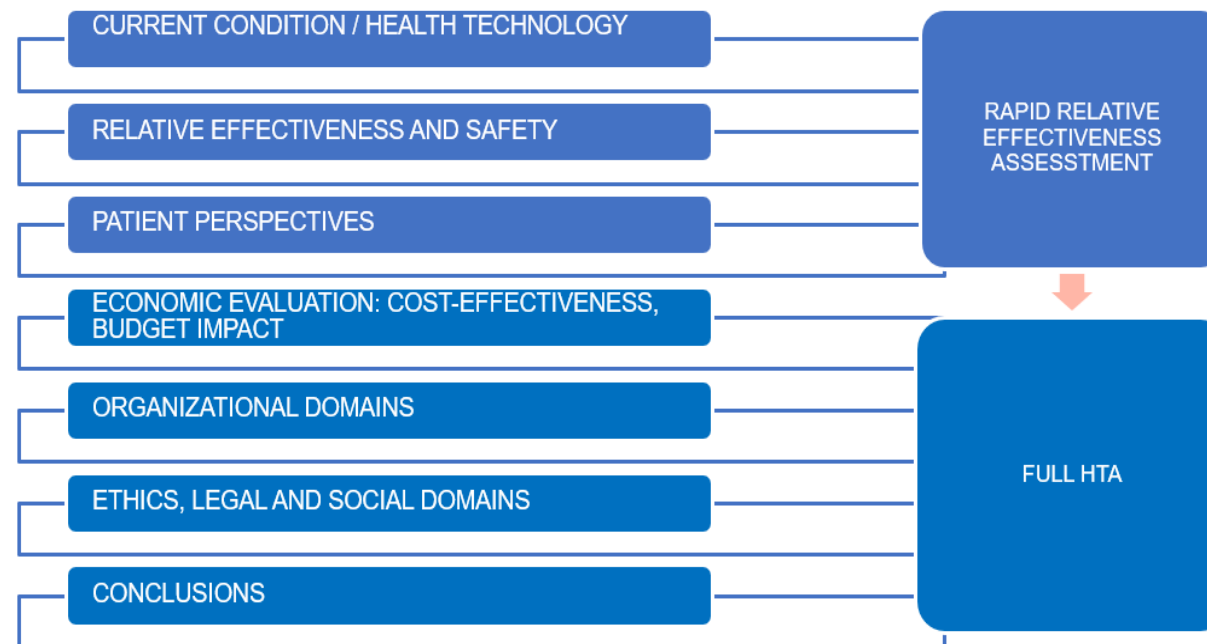
Arts. 20 y 21 de la Ley 16/2003, de 28 de mayo, de cohesión y calidad del Sistema Nacional de Salud

Process for early dialogue / JSC in RedETS

- The framework for early dialogues within RedETS is currently under development
- It is included within the working line of methodological guidelines
- Osteba has been assigned to lead this framework

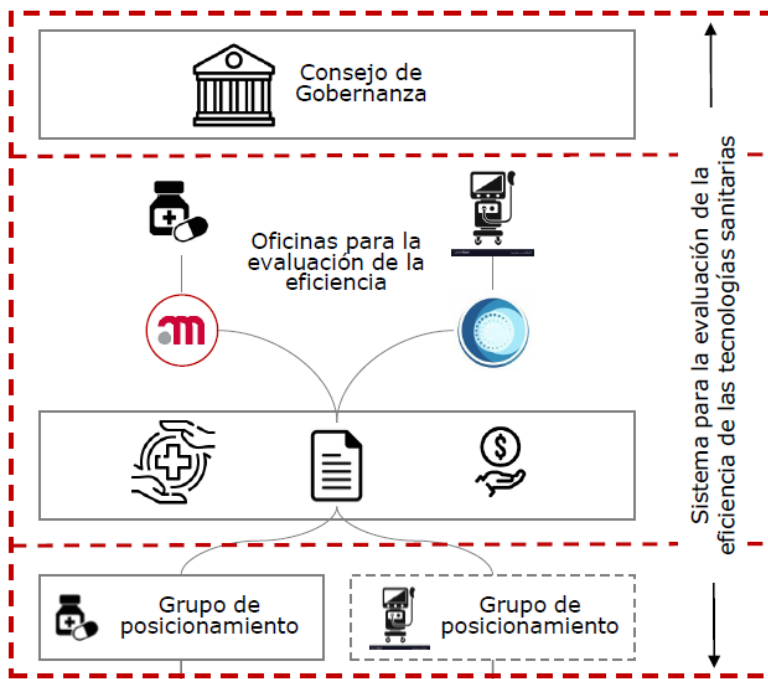
How the JCA will fit into RedETS

- RedETS Experience in the previous Joint Actions has shown us how to adopt/adapt the JCA to the Spanish context
- RedETS is participating in the JCA Subgroup and **in all subgroups**



New Spanish Law on HTA

- RD will ease the participation of RedETS in all the HTA coming activities derived from HTAR, including JCA, JSC in MDs
- Office for Drug Efficiency Assessment
- Office for other HTs Efficiency Assessment



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