The pharmacotherapeutic harmonization program (PHF)

iPAAC INNOVATIVE PARTNERSHIP FOR ACTION AGAINST CANCER

Co-funded by the Health Programme of the European Union

TYPE	STATUS	LAST UPDATE	
	Fully implemented Ongoing program	June 2021	SPAIN (CATALONIA) • REGION-WIDE Diagnostic & Treatment • Access to innovative therapies

PROBLEM & OBJECTIVE

PROBLEM Access to innovative therapies is essential for improving patient outcomes. Cancer care is rapidly evolving and new drugs are emerging in the pharmaceutical market. Therefore, it is important to have tools for guaranteeing equity of access to innovative drugs within Catalonia.

OBJECTIVE The establishment of the Pharmacotherapeutic Harmonization Program (PHF) aims to (1) reduce variability in the utilization of new drugs within centres publicly financed by the Catalan healthcare system (SISCAT), and (2) optimize therapeutic effectiveness and efficiency while considering budgetary restrictions, availability of resources and sustainability of the system in the long-term

KEY COMPONENTS / STEPS

- The initiative was initially set through instruction 11/2008 1 as the Program for assessment, monitoring and reimbursement of highly complex drugs; In 2010 and 2012 the program evolved into two new programs called pharmacoterapeutic harmonization program for hospital medication (PHF-MHDA) and pharmacoterapeutic harmonization program for primary and community care (PHF-APC), respectively. Finally in 2017 both programs were integrated, through instruction 05/20172, into the Pharmacotherapeutic harmonization program (PHF)3.
- Type of drugs under assessment includes (1) hospital medication and (2) primary and specialized care medication under prescription.
- PHF meetings are held quarterly and include both new drugs with authorization for commercialization in Spain and already marketed drugs with new indications.
- A prioritizing system for drugs to be assessed under the PHF is in place, with criteria for drug selection including incidence, prevalence of clinical condition assessed, degree of innovation of the drug, potential clinical benefit, and availability of other therapeutic alternatives.

KEY CONTEXTUAL FACTORS

- Once a company gets authorization for commercialization of an innovative drug by the European Medicine Agency (EMA), the drug is assessed by the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) to establish its added clinical value in Spain.
- In Catalonia, the PHF was implemented to adapt criteria already established by AEMPS to the particularities of the specific region and its citizens.
- The program is managed by a pharmacotherapeutic commission in charge of transferring information and presenting the final proposal for approval to the Catalan Health Service (CatSalut) on the criteria and consensus reached with multidisciplinary advisory boards.
- Two advisory boards are responsible for developing technical reports on the new drugs; one for outpatient hospital medication (CAMH) and one for primary and specialized care medication under prescription (CAMAPCE).

MAIN IMPACTS / ADDED VALUE

- PHF guarantees equity of access to outpatient hospital medication and drugs under prescription within the public healthcare system according to the principles of rational use and consideration of the availability of resources and budget restrictions.
- The availability of information on use, access and provision of drugs within SISCAT centres in Catalonia is highly valuable for optimizing diffusion and accessibility of innovative medicines in clinical practice.
- In the context of hospital medications, there is a registry of clinical data of patients and treatments (RPT-MHDA) that has to be completed by health professionals, which allows verification of the effectiveness and adequacy of treatments.

LESSONS LEARNED

- The development of multidisciplinary technical committees supports integrated assessment of the drug, including critical aspects such as clinical, therapeutic, epidemiological and economic.
- The development of a registry for the systematic compilation of clinical data for the assessment of patient outcomes improves knowledge on drug effectiveness and safety.
- Reimbursement and conditions on provision are publicly available, which supports information transparency and maximizes diffusion within the territory.

CONTACT

Catalan Cancer Strategy
Josep M Borras
jmborras@iconcologia.net

Catalan Health Service (CatSalut)
Medication Unit
Caridad Pontes
cpontes@catsalut.cat
cristinacoll@iconcologia.net

REFERENCES & DOCUMENTATION

- Criteris i condicions per a l'adequació de la indicació i condicions d'utilització de medicaments d'acord amb els informes dels comitès d'experts registre i seguiment clínic: verificació i acreditació de les condicions de provisió i finançament pel CatSalut. Barcelona: Servei Català de la Salut; 2011. (CatSalut: instrucció; 01/2011)
- Programa d'harmonització farmacoterapèutica del CatSalut. Barcelona: Servei Català de la Salut; 2017. (CatSalut: instrucció; 05/2017)
- https://catsalut.gencat.cat/ca/proveidors-professionals/farmacia-medicaments/programa-harmonitzacio-farmacoterapeutica/normativa/

More over IPAAC Roadmap

This publication was funded by the European Union's Health Programme (2014-2020)