Benchmarking Time and Process in HTA and Decision making

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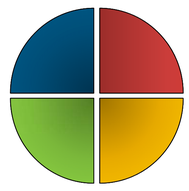
Introduction

There is considerable diversity between, and in some cases within, countries in terms of (i) the requirements of; (ii) the processes for; (iii) the extent of transparency in; and (iv) the use of; Health Technology Assessment (HTA) of new pharmaceuticals to inform coverage body decision making. This diversity represents a challenge to agencies as they try to learn from one another's strengths and capabilities and to understanding how to make their own processes better. Here we describe systematic comparison using performance indicators and benchmarking and show how such a methodology may be of benefit to HTA agencies as they evolve.

Summary

CIRS is commencing a programme to undertake comparative benchmarking of the HTA and coverage process for the review and approval of new pharmaceuticals. The objective of this programme is to provide a systematic framework for HTA and Coverage bodies to be able to compare and learn from each other and to identify best practices. In addition, increasing the transparency of HTA/Coverage process will be of benefit to other stakeholders including patients, industry and regulators.

CIRS Comparative Research Projects



- Regulatory Agencies Benchmarking (1997+)
- Benchmarking in Emerging Markets (2006+)
- Quality Scorecard Pilot (2007+)
- Company HTA Benchmarking Pilot (est. 2011)
- HTA and Coverage Bodies (*in development*)

CIRS run a series of benchmarking and comparative process mapping projects in the areas of clinical development, regulatory review and most recently on the impact of HTA requirements on industry decision making.

The purpose of measuring performance

Performance measurement is a tool by which management teams can appoint realistic internal goals and objectives and in addition provides information on areas of performance that require resources, development or improvement.

Performance indicators

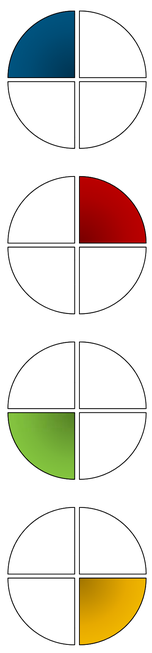
Use of performance indicators can aid both internal performance management as well as promote greater transparency and efficiency.

Benchmarking

Benchmarking is a continuous systematic process for comparing performance indicators across peer organisations for organisational improvement. Over time, trends can be determined, improvements measured and decisions made on resource allocation.

Benchmarking is commonly associated with measuring quantitative metrics such as time, process, resource and cost, however it is also possible to use qualitative measures in a systematic fashion to measure more difficult parameters such as quality.

Key parameters that can be measured



Timeliness
- Defined and efficient process
- Reasonable timeframes
- Project management
- Adherence to target times

Predictability
- Usefulness of published guidelines
- Consistency between reviews
- Alignment with other agencies
- Dialogue

Transparency
- Availability of detailed guidelines
- Publication of processes and procedures
- Publication of appraisal and decision making
- Publication of actual timelines

Quality
- Scientific appraisal of clinical evidence
- Consistency between reviews
- Standard operating procedures
- Competency of staff

Example: comparison of diverse processes

CIRS survey of regulatory process in Emerging Markets (2006)

Source: [4]

	Asia-Pacific								Middle East and Africa								Latin America						
	Hong Kong	India	Indonesia	Malaysia	Philippines	Singapore	South Korea	Taiwan	Thailand	Bahrain	Egypt	Jordan	Kenya	Kuwait	Oman	Saudi Arabia	South Africa	UAE	Argentina	Brazil	Chile	Costa Rica	Mexico	Venezuela
Review process and data requirements																								
Previous registration is essential for authorisation																						*		
Previous registration is not always a pre-requisite																						*		
ICH CTD format is not accepted (a)																								*
All ICH guidelines are accepted																								
Selected ICH guidelines only are accepted											b													
Certificate of a Pharmaceutical Product (CPP)																								
CPP is required with application																	c							
CPP accepted later but prior to approval																								
Legalisation of CPP required by Embassy																						*		
Other policy and procedural issues																								
IP protection laws implemented (d)		e									e					e						e		
Pricing is part of approval																								
Local clinical trials required for registration			f		f																		f	

*= No response
a: The ASEAN CTD may replace the ICH CTD in ASEAN countries
b: ICH is not implemented in Egypt
c: CPP not essential in South Africa but, if available, must be submitted with the application
d: Intellectual property protection to meet TRIPs requirements (see page 9)
e: IP protection implemented after the survey
f: Requirement for CTs may depend on the type or regulatory status of product

A survey of regulatory authorities in 24 emerging market countries showed that there was considerable diversity in their processes and requirements. Although there has been considerable change in many of the regulatory systems since this time, the data are shown here to demonstrate that comparisons are useful even between very diverse systems.

Establishing a benchmarking process for HTA

Step 1: Systematically map the process for each agency

"…it is important to understand that agencies operate within very different frameworks…given these different backgrounds, an understanding of where each process fits into the organisation and indeed the nature of that organisation is vital for any valid comparison. "
(Source: *Fernand Sauer, first Executive Director, EMA at CIRS Workshop 1997 [1])*

A systematic methodology was developed in order to create the process maps in such a way that different systems were comparable. To maximise comparability, the maps were limited to only the National-level agencies that were directly involved in the assessment and reimbursement decision making of new pharmaceuticals.

To date systematic process maps have been completed for over 30 countries. While considerable diversity occurs between the different healthcare systems the are several broad groups into which the different systems can be characterised, for example based on the extent of independence between clinical and economic assessment, the final HTA recommendation and the coverage decision [2]. This suggests that a meaningful comparison between different countries might have to be organised in a hierarchical fashion.

Step 2: Define milestones and indicators for comparison

Process mapping enables a clear understanding of the similarities and differences of the HTA and coverage processes between countries. This understanding enables the identification of milestones and indicators that would enable meaningful comparison between such countries.

Clear and definitions of the milestones and performance indicators that are agreed upon in advance by all the participants is critically important in order to ensure that every participant is providing the same information.

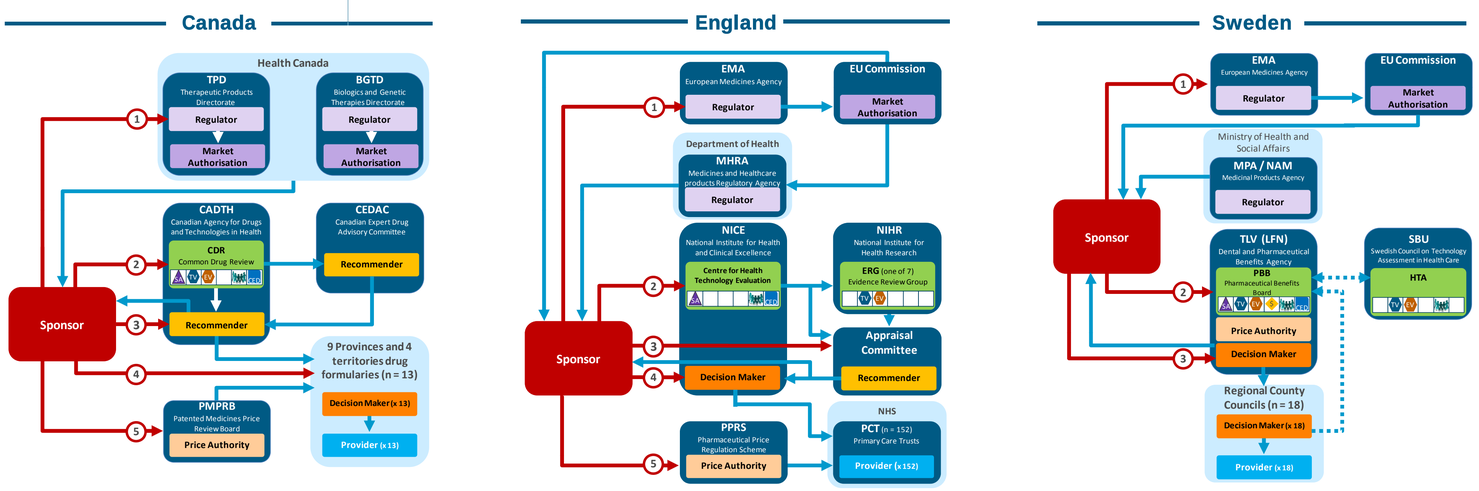
To obtain a full understanding of the process the measures will by necessity be a combination of quantitative metrics and qualitative and qualitative indicators (for example, for measuring quality).

Step 3: Establish data collection protocols and pilot

Collection of data should be developed within a structured framework to ensure accuracy, timeliness and confidentiality. The requirements for a successful data collection tool are clarity, simplicity and robustness. Returned data must be held securely and all data and analyses should be confidential to the participants, except where mutually agreed-upon high level results are published (e.g. see [3] - [5])

Piloting the process enables refinement of the methodology and ensures that the comparisons are optimised for the needs of the participants.

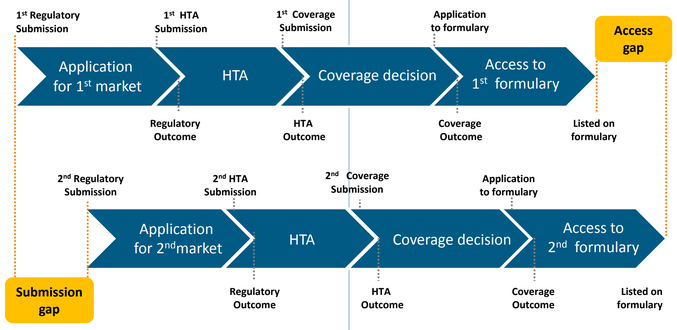
Processing mapping of registration to reimbursement for new pharmaceuticals



The agencies (blue) involved in the system were identified. Connections were added to indicate where the sponsor (red) of the new medicine interacts with the agencies and where the agencies interact with each other. Independence from or inclusion within government was indicated by light blue shading.

Seven key functions were then mapped on to the agencies to allow identification of where in the system such functions occur and how they interact. For the HTA function a task bar was developed in order to characterise a selection of defining elements of the process

Development of common milestones



High-level timeline milestones related to broad steps in the pathway from submission of a new pharmaceutical for regulatory review to availability on a national formulary.

Shared information sources

In certain circumstances it might be necessary to obtain information from multiple stakeholders in order to fully understand aspects of the process. Each stakeholder provides different information which when brought together can add value to the understanding of the process as a whole. It is for this reason that CIRS is establishing a parallel benchmarking project for collection of data from industry and agencies.

For example: HTA agencies can provide what guidance is given during early development and the company can provide information about their decision to comply (or not) with the guidance.

References to CIRS benchmarking studies

[1] McAuslane N and Walker S (ed.), Improving the regulatory review process: assessing performance and setting targets (1997) Lancaster, UK, Kluwer Academic Publishers, 163pps

[2] Pichler F *et al.* (2010) Development of systematic process maps to enable comparison between HTA and decision making systems: the first step to benchmarking. ISPOR 13th Annual European Congress, Prague

[3] Hirako M *et al*. (2007) A comparison of the drug review process at five international agencies. *Drug Info J.,* **41**: 291-309.

[4] McAuslane N *et al*. (2006) A cross-regional comparison of the regulatory environment in the emerging markets. *R&D Briefing* 50, 12pps

[5] McAuslane N *et al.* (2009) A comparative study of the way in which key regulatory agencies in Asia-Pacific, Latin America, the Middle East and Africa are developing their regulatory processes and review models for new medicinal products. *Drug Info J.*, **43**: 349-359.

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CIRS Centre for Innovation in Regulatory Science

About: CIRS is an independent, non-profit organisation providing a neutral forum for discussion and research between stakeholders.

Mission: The mission of CIRS is to establish a thought leadership role in the development and implementation of regulatory and reimbursement policy in the field of medicines innovation.

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