Development of systematic process maps to enable comparison between different HTA and decision making systems: the first step to benchmarking

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Introduction

The variability in the organisation and the methodologies that are employed in health technology assessment (HTA) and decision-making processes between different countries results in considerable challenges to the meaningful comparison of the activities and outcomes of such agencies.

In addition, such variability represents a barrier to the understanding of which agencies to include in the current initiatives for HTA-Regulatory Authority interaction and perhaps even hampers new best-practice initiatives, such as those proposed by the EUnetHTA Joint Action.

Thus, there is a need to systematically characterise the organisations and their activities within each country in order to be able to understand, to compare, to measure and to identify what is effective and efficient in a national regulatory framework.

The aim of this study was to develop a systematic process-mapping methodology to both clarify how these systems are organised and to enable comparison between the different systems.

Methods

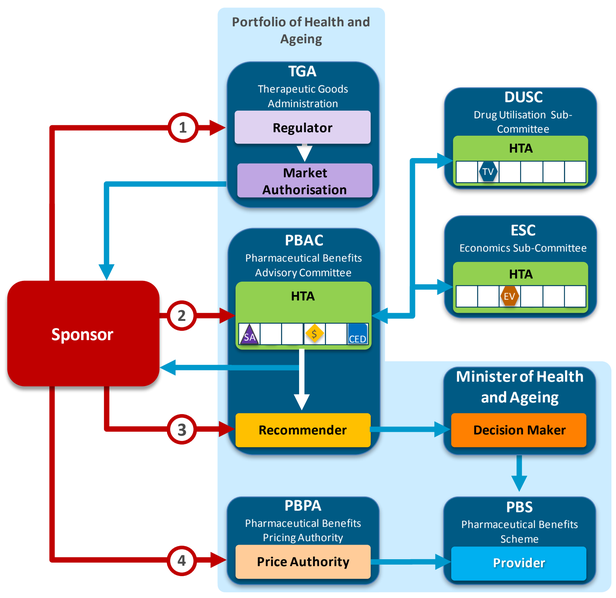
The process maps were designed from the point of view of the path that a new medicine takes from submission to a regulatory authority for market authorisation through to the national-level reimbursement decision for coverage (such as through a national health insurance scheme).

The process maps were limited to describing the systems in place for the authorisation and reimbursement of *new active substances* (i.e. a new pharmaceutical that has not been previously evaluated by that agency, or in the case of Europe, by any member state).

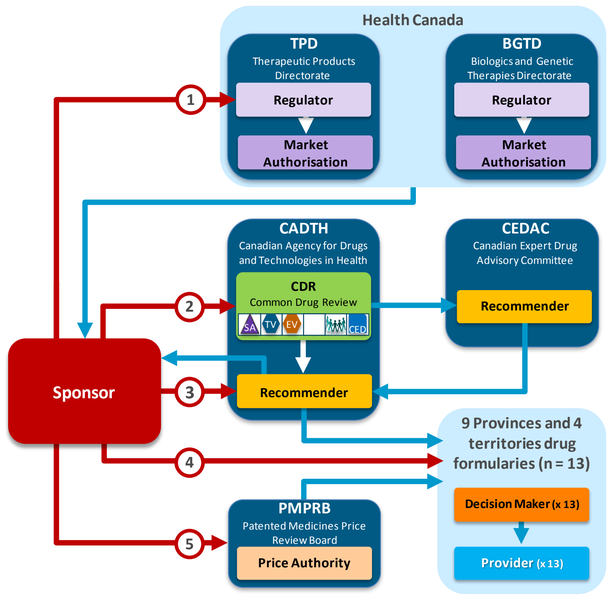
In order to describe the roles and activities of the different organisations in each system, key functions were overlaid onto the maps. Additionally, for the HTA function, a list of six key activities was included in the form of a 'task bar' to help to further illuminate and contrast the different systems.

National Process Maps

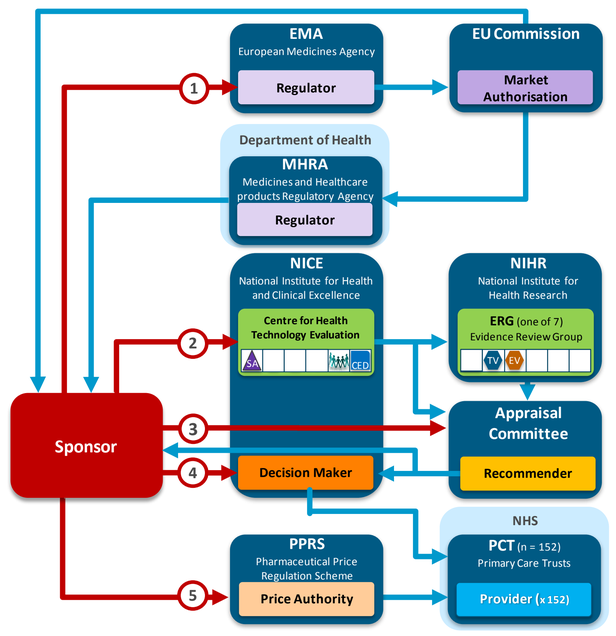
Australia



Canada



England



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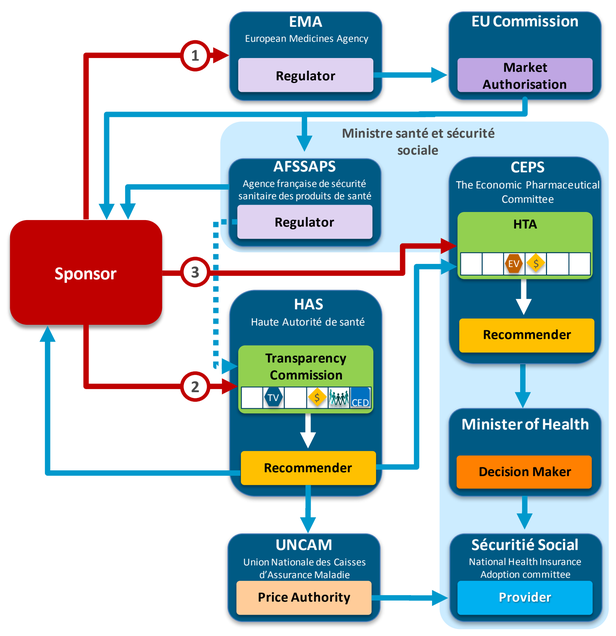
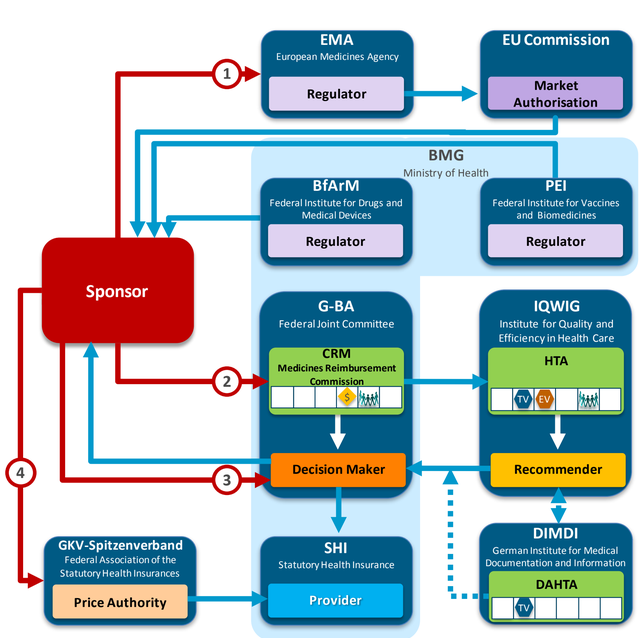
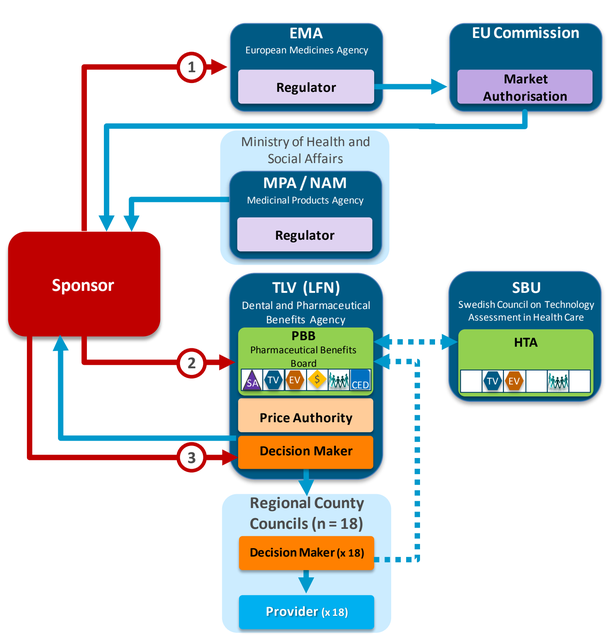


Germany



Sweden

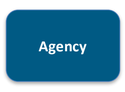


Development of Process Maps and Key

Step 1

For each country, the primary agencies that were directly involved in market authorisation & classification, HTA assessment, appraisal, pricing control and reimbursement decision-making of new active substances were identified. The pathways that a new medicine submission takes from the sponsor (manufacturer) to each agency, between the agencies and from the agency back to the sponsor were then determined.

Sponsor: The company that submits the dossier of evidence in application for market authorisation and reimbursement.



Agency: A specific organisation or committee tasked with performing key activities related to the regulatory, evaluation or reimbursement process .

Government*: An organisation run and controlled by the state and either directly or indirectly accountable to the government .

Connectors: to show the direction of movement of evidence between organisations. Sponsor (red) connectors have numbers to indicate the general order of process. Dashed connections indicate occasional connections, or connections that are not a mandatory part of the system

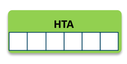
** Note: For simplicity of the visualisation, the independence of each agency from the national government was indicated as a binary (yes/no) decision, although a continuum of varying degrees of independence is acknowledged. Independence was based on how each agency described itself and its own relationship to the government.*

Step 2

Seven functions that represented significant measurable key components of the system were defined and then mapped onto the agencies that conducted those functions in order to show where in the system such functions occurred and how they related to one another. The functions were defined as:

Regulator: where scientific evaluation based on safety, quality and efficacy is conducted to determine if market authorisation should be recommended.

Market Authorisation*: the decision-maker who determines whether or not to grant market authorisation to the new medicine.



HTA: where assessment of the new medicine is conducted in relation to the therapeutic value and/or economic value of the new medicine to the health care system in question.

Price Authority: where the list price for the new medicine is either determined or otherwise controlled such as in the form of a voluntary price agreement or by imposing a price ceiling.

Recommender: where the HTA appraisal results in a recommendation for reimbursement but the decision itself is made elsewhere.

Decision-Maker: where the decision to reimburse the new medicine is made in relation to the national coverage scheme.

Provider: where the new medicine is adopted based upon outcome of the decision maker.

** Note: For European countries it is mandatory for new active substances to undergo review by the European Medicines Agency followed by approval at the EU Commission. The local regulator was also included in the process maps due to their responsibilities for characterisation of the EMA/EU decision at the national level.*

Step 3

For the HTA function, a "task bar" of key activities was developed in order to characterise a selection of defining elements of the HTA process. Each activity was given an identifying icon that was shown in the HTA task bar if it was a normal part of that agency's actions. For this poster, six of these activities are shown:

Scientific Advice: Provision of scientific advice to the sponsor in relation to the drug development program or the submission of evidence to that agency.

Therapeutic Value: Evaluation of the clinical evidence in order to determine if there is added-therapeutic value in the new medicine.

Economic Value: Determination of the cost-effectiveness, cost-utility, cost-benefit and/or budget impact of the new therapy.

Reimbursement rate: Determination of the rate of reimbursement for the new medicine, usually into pre-defined categories.

Public consultation: Involvement of patients, patient advocates and/or public representatives, this includes both formal and informal forms of consultation.

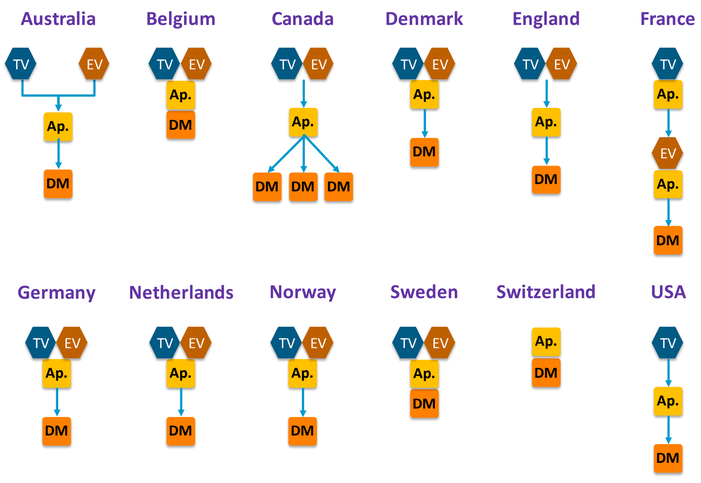
Coverage with Evidence Development: Provision of release of the new medicine where data is limited with the condition of further evidence development.

Expanding the task bar

To focus on the organisational differences and also the broad categories of therapeutic and economic evaluation, the task bar was limited to six activities for this poster. However, a more comprehensive task bar is being developed for several of the functions. For example, where joint scientific advice is offered between an HTA agency and a regulatory agency, then that activity would be located in the task bar for each function to show which agencies are involved in relation to the overall regulatory and reimbursement system.

Application of Process Maps

How therapeutic value and economic value activities are linked to appraisal and decision making functions



- Activities/Functions that are clustered together indicate that they occur within the same organisation.
- Blue arrows indicate a separation of Activities/Functions into different organisations.
- Missing activities indicate that the specific item is either not formally included in the decision-making process or is sourced from agencies external to that country.
- Multiple decision-makers indicate a decentralised (regional) system

Outcome

Systematic mapping is a useful tool for the comparative visualisation of the process of registration to reimbursement of new medicines. By creating the maps using systematic methodology, it is possible to compare and contrast the organisations of different nations. Additional layers of information added to the maps, such as key functions and activities further enhance the understanding of these systems and their differences.

Considerable differences in the systems were shown by these maps, including the extent of independence of the agencies from government, the timing and relationship of the assessment of therapeutic value and economic value components of the review, and the location of the decision-maker in the process. However, despite differences in the organisational structure and sequence of activities, the general path that a new medicine undertakes from registration to reimbursement is broadly similar.

Next Steps

Validation by agencies

These maps have been created from data in the public domain and in several instances such data was either conflicting or there was a lack of transparency in how particular agencies interacted. Therefore, to ensure the accuracy of this approach, it will be helpful for representatives from each agency to validate their agencies position within the relevant map.

Establishing a benchmarking framework

This methodology enables the identification of milestones that can be used to establish a benchmarking programme for the purpose of comparative performance evaluation between different countries. While benchmarking is feasible, at least at an organisational level, it will also be necessary to measure the activities to help achieve an understanding how and why these systems differ.

Data Sources

The process maps were originally developed using data gathered from the public domain, primarily from the agencies own websites and published literature as well as from ISPOR's Global Health Care Reimbursement Systems and Decision Making Working Group and IDRAC's (www.idrac.com) reference database .

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Acknowledgements

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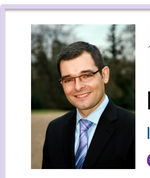

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