MArS Webinar
EU-HTA to come?

August 27th 2020

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1 MArS Market Access & Pricing Strategy GmbH, Germany
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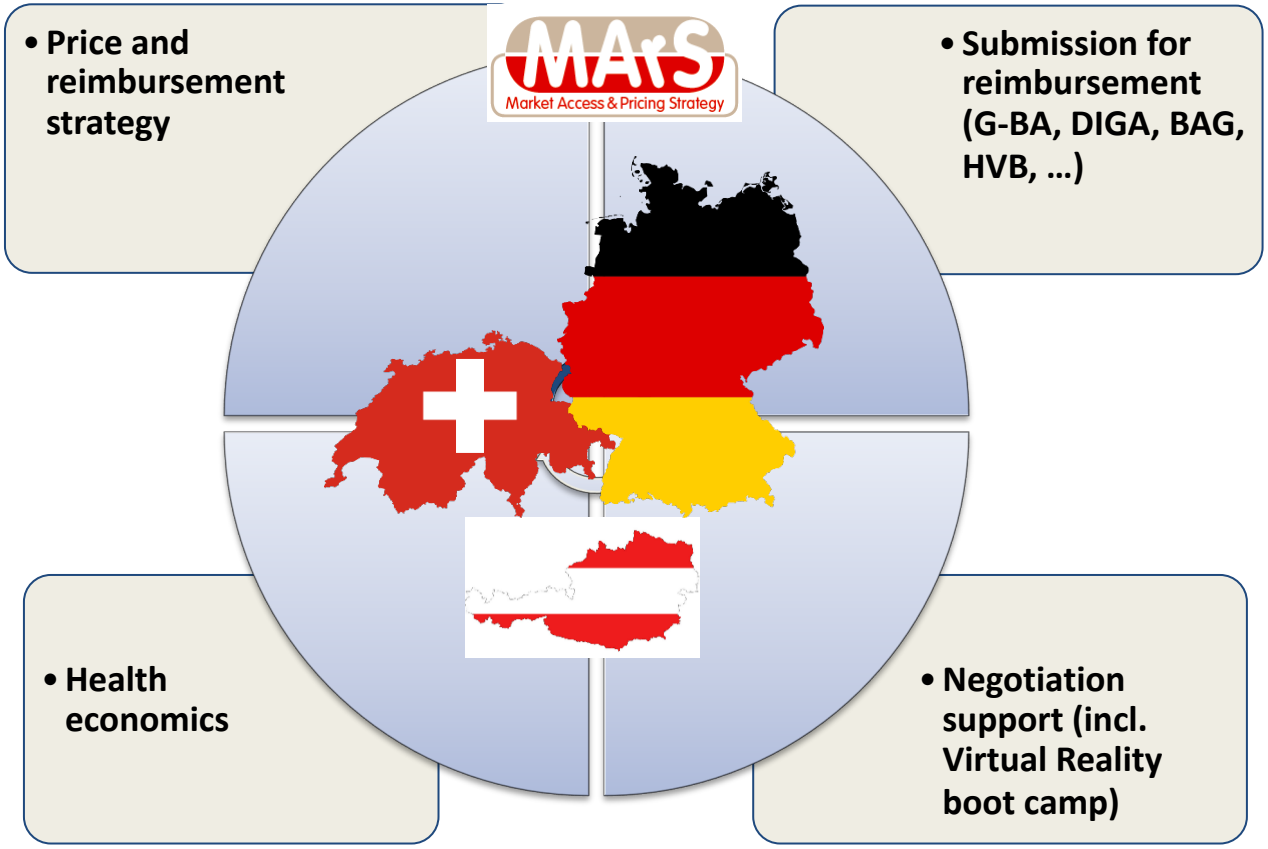
Your specialist in reimbursement, pricing and health economics in the D-A-CH region



Questions welcome!

- Feel free to ask questions. After the presentation, we will have time for your questions.
- Use either the Zoom chat function or the Q&A function to raise your questions or comments.
- As always, slides will be provided afterwards and the video will be published on our website.

Webinar

EU-HTA to come?

How could such a system be implemented in Europe and the different health care markets.

Dr. Stefan Walzer
Speaker

Lutz Vollmer
Moderator

MArS Market Access & Pricing Strategy GmbH

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27.08.2020
9pm CET /
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Disclaimer

- This research is partly based on a Master‘s thesis developed by Giuseppe Cuppuleri in cooperation with Dr. Stefan Walzer and the Zeppelin-University at Lake Constance (Germany).

An EU-wide, uniform and binding cooperation in HTA to harmonize the benefit assessment of health technologies

EU-wide uniform approval procedure through the EMA
vs.
National benefit assessment and reimbursement processes using different assessment methods

HTA for the systematic and transparent evaluation of health technologies

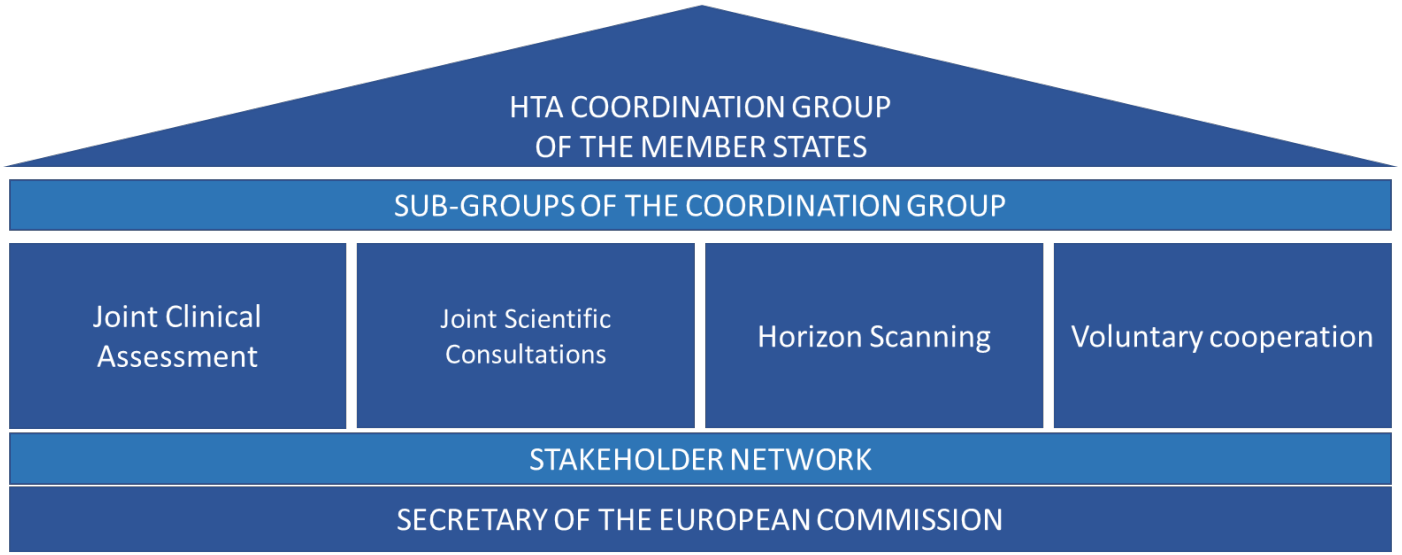
→

Voluntary European cooperation through the EUnetHTA network is only moderately successful

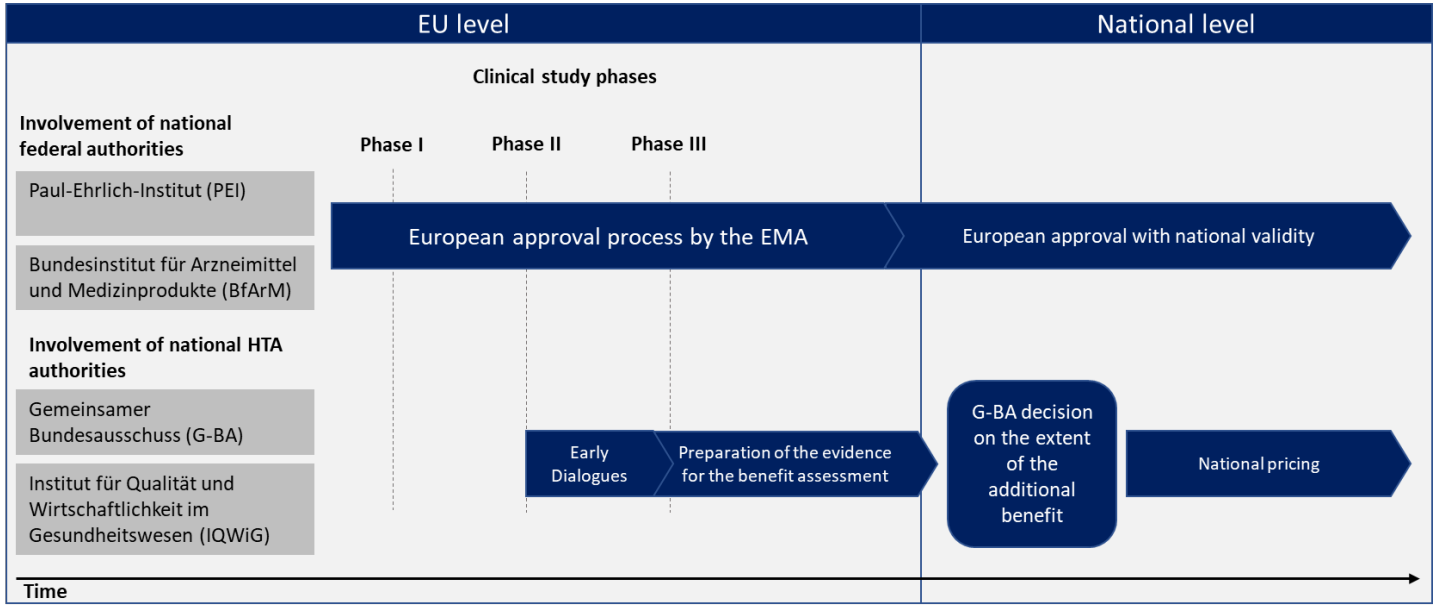
Jan.'18: Proposed regulation by the EU-COM for an EU-wide binding cooperation in the assessment of health technologies.
The aim is an efficient and sustainable cooperation between national HTA institutions.

The aim of the EU-COM is an efficient and sustainable cooperation between the national HTA institutions

- Jan'18: Proposed regulation by the EU-COM for an EU-wide binding cooperation in the benefit assessment of health technologies.
- Sustainable cooperation between national HTA institutions under the leadership of the EU-COM is intended to ensure a better functioning of the domestic market and health care system in the EU.



The regulation shifts the clinical benefit assessment to an EU level and devides the process into an “assessment” and “appraisal” phase



- Based on the reports of the joint clinical benefit assessment, member states should draw conclusions about the added benefit for the national health system
  - In Germany, the G-BA should continue to retain the decision-making authority over the extent of the additional benefit

Canada as potential role model for a European unified HTA?

In 2002, Canada harmonized HTA processes to help standardize drug coverage.

- Canada's health care system is a decentralized one, comprised of 13 separate provincial and territorial health insurance plans.
- Prior to 2002, Canadian provinces and territories conducted their own assessments of the added therapeutic benefit of drugs
- The Common Drug Review **(CDR)** was implemented in 2002 by the Canadian Agency for Drugs and Technologies in Health **(CADTH)**, to help standardize drug coverage across Canada by maximizing the use of resources and avoiding the duplication of work.
- The CDR undertakes HTA's of new drugs for the purposes of providing listing recommendations to all of the drug plans.
- Cancer drugs are submitted to the pan-Canadian Oncology Drug Review **(pCODR).**

Mandatory assessment in Canada?

- CDR and pCODR are based on voluntary action.
- At the beginning of each benefit assessment, provinces and territories have the **option of opting** out of the joint assessment procedure and carrying out independent clinical and economic assessments through a so-called "opt-out" rule.

The Common Drug Review process
(all provinces except Quebec)

- The CDR process broadly comprises following steps:

A submission is prepared by the manufacturer in accordance with explicit submission guidelines and sent to the CDR Directorate

A Review Team is assembled to draft a report based on clinical and economic evidence provided by the manufacturer and identified through independent literature searches.

The report is then reviewed by the Canadian Expert Drug Advisory Committee (CEDAC), which evaluates the comparative therapeutic benefits and cost-effectiveness of the drug and makes one of three funding recommendations to participating plans: list without conditions ("yes"), list with conditions, or do not list ("no").

Lastly, the recommendation is considered separately by each plan, which independently makes its own final decision.

- As a result, drug dossiers no longer have to be submitted specifically for each province and territory.

Pricing and Reimbursement is managed by the Patented Medicine Prices Review Board (PMPRB)

- Manufacturers who want a product to appear on the provincial / territorial reimbursement lists must apply to the CDR or pCODR to make a reimbursement recommendation.

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- It is up to the individual provinces and territories to decide which new drugs should be included in the basket of publicly funded services.
- The role of the federal government remains primarily limited to marketing authorization and, in the case of patented medicinal products, to price regulation.

Does it work in Canada?

- „The introduction of the CDR procedure in Canada has proven to be a successful model for harmonizing decentralized HTA assessments in order to enable more efficient use of resources and support health policy decisions in population health care“

Source: N. Allen, Walker, Liberti, Sehgal, & Salek, 2016

Conclusions

- The rationale behind the establishment of EUnetHTA is similar to the rationale behind the CDR, as both aim to reduce duplication of work, make more efficient use of HTA resources and provide access to innovation.
- The differences in drug supply in the various Canadian provinces and territories were a key concern that led to the introduction of the CDR procedure.
- European countries are certainly in many ways more heterogeneous than Canadian provinces and territories. However, similar concerns have been expressed regarding the different access of patients to new medicines…

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