Use of RWE by HTA Agencies

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Project Objective

To understand and map the use of Real World Evidence (RWE) by three different stakeholders in their decision making

Health Technology Assessment (HTA) Agencies

- Literature Review
- Interview (NVS employees – HEOR, Market Access and Patient Access)

Use of RWE in HTA Decision Making

Initial Reimbursement Discussions

Pharmacoeconomic Analyses

Conditional Reimbursement Schemes/ Price Renegotiations

	RWD Accepted	RWD to inform other parameters and Treatment Effects	Type of RWD source preferred	Impact of RWD on decision making
Netherlands		Requirement for Rare disease, Burden of Disease, Cost and Resource Utilization	Local data preferred. Guidance on RWD source to be used	
France		Treatment Effects, Burden of Disease.	Local data preferred	
United Kingdom		Burden of Disease, Cost and Resource Utilization	Local data preferred. Limitations with RCT data recognized.	
Mexico		Burden of Disease, Cost and Resource Utilization	Local RWD limited. Data quality, medical need and priority disease	
Italy -Sweden		Burden of Disease, Cost and Resource Utilization	Local data preferred	
United States		Burden of Disease, Cost and Resource Utilization.	Local data preferred; non-US data accepted in exceptional circumstances	
China		Burden of disease, Cost and Resource Utilization	Local data preferred; Big sample size and reliable data source	
Australia-Germany		Economic Modelling, Cost and Resource Utilization	Administrative data collected by Dept. of Health	
Canada		Epidemiological data, Cost	Local RWD is limited	
Spain, Japan, and Brazil				

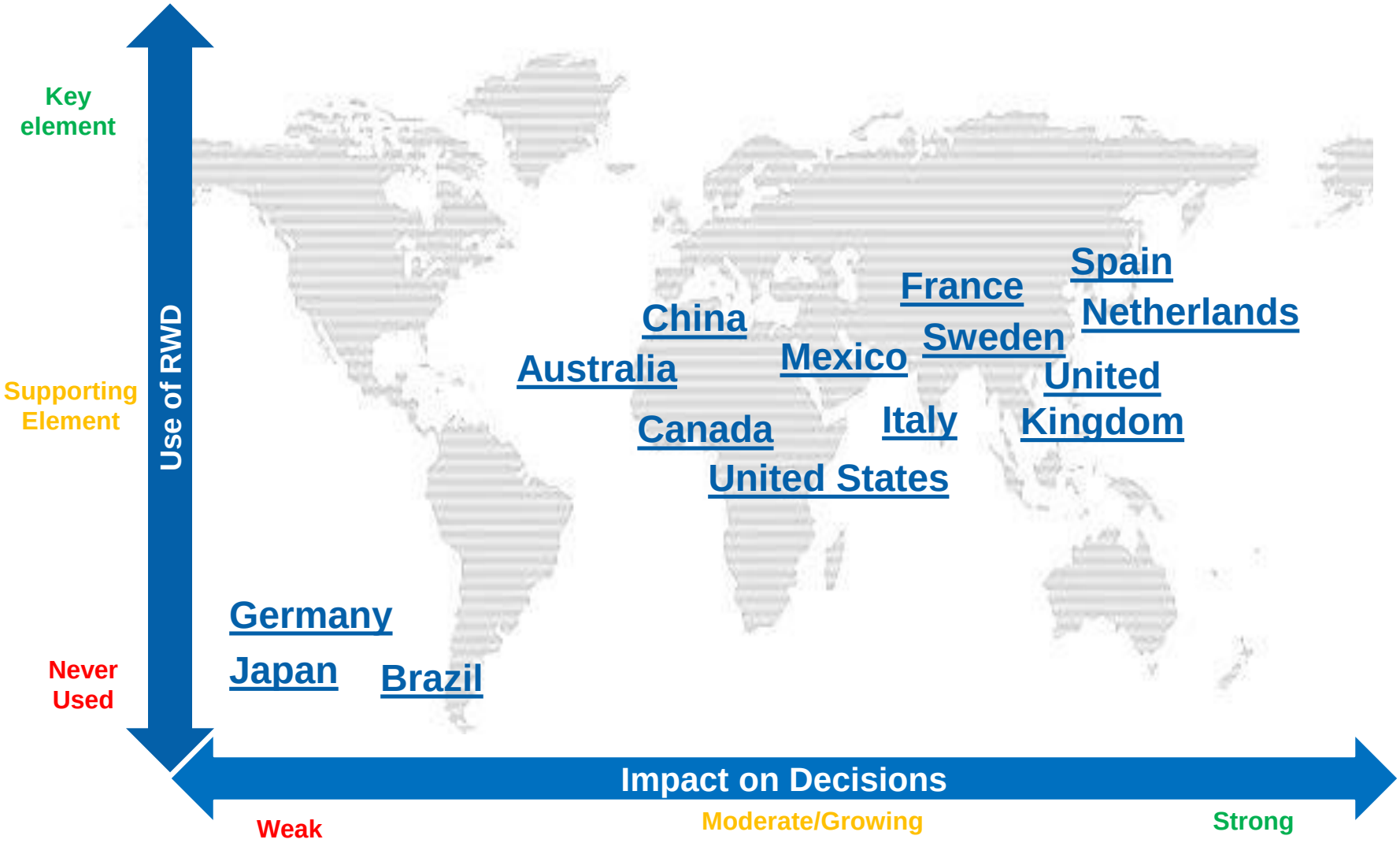
Initial Reimbursement Discussions → Pharmacoeconomic Analysis → Conditional Reimbursement Schemes/Price Renegotiations

	Use of RWD	RWD to inform other parameters and Treatment Effects	Type of RWD source preferred /recommended	Impact of RWD on decision making
Netherlands		RWD accepted after initial advisory meetings. Burden of disease	Local Data Preferred. Registries – a usual recommendation	
Spain		Cost Effectiveness, Budget Impact Model, Epidemiology	Local data Preferred. EU Data (Orphan Diseases)	
United Kingdom		Cost, Resource Utilization	No specific Preference/recommendation. Limitations with RCT data recognized.	
Sweden		Burden of Disease, Cost and Resource Utilization	Local data preferred. National and regional disease registries available.	
France		Epidemiology, Cost and Resource Utilization	Local Data Preferred.	
Italy		Burden of Disease, Cost and Resource Utilization	Local data preferred	
United States		Burden of Disease, Cost and Resource Utilization	Local Data is preferred. Data from other sources accepted in certain circumstances	
Mexico		Burden of disease, Cost, Resource Utilization and Budget Impact Model	No preference for RWD. Local RWD is limited	
Canada		Burden of Disease, Cost and Resource Utilization	Local data preferred	
China		Burden of Disease, Cost and Resource Utilization	Local data preferred	
Australia		Economic Modelling, Cost and Resource Utilization	Administrative data collected by Dept. of Health	
Germany, Japan, Brazil				

Initial Reimbursement Discussions

Pharmacoeconomic Analysis

Conditional Reimbursement Schemes/Price Renegotiations



Initial Reimbursement Discussions | Pharmacoeconomic Analysis | **Conditional Reimbursement Schemes (CRS) / Price Renegotiations (PR)**

	Use of RWD	CRS/ PR	Use of RWD in CRS Aims	CRS Procedure	Involvement in collection of RWD	Impact of RWD on decision making
France		CRS	Cost Effectiveness and Budget Impact	• Identify evidence gaps. • Consult on study design. • Result based decision	No Involvement	
Netherlands		CRS	Cost Effectiveness and Effectiveness	• Identify evidence gaps. • Consult on study design. • Result based decision	No Involvement	
Italy-Sweden		CRS and PR	Cost Effectiveness	No consultation	Initiates its own product or disease registry	
Australia		PR	N/A	N/A	No Involvement	
Germany		PR	N/A	N/A	No Involvement	
United Kingdom Spain, United States, Canada, China, Mexico, Japan, Brazil						

Initial Reimbursement Discussions

Pharmacoeconomic Analysis

Conditional Reimbursement Schemes / Price Renegotiations

Conditional Reimbursement

- A new technology is reimbursed for a given period of time under the condition to collect additional evidence (RWD on costs, appropriate use and effectiveness), from pre-specified study, to support continued, expanded, or withdrawal of reimbursement
- Insufficient evidence at product launch or time of reimbursement decision
- **Payer Benefit:**
  - ✓ Provides access while generating additional evidence to support future coverage decision

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The Challenge of Conditional Reimbursement: Stopping Reimbursement Can Be More Difficult Than Not Starting in the First Place!

E.J. van de Wetering, PhD[1], Job van Exel, PhD[2,*], Werner B.F. Brouwer, PhD[1]

[1]Institute of Health Policy and Management, Erasmus University Rotterdam, Rotterdam, The Netherlands; [2]Erasmus School of Economics, Erasmus University Rotterdam, The Netherlands

Conditional Reimbursement

- Only few initiatives have been reviewed from the countries that have implemented CRS
- Majority of countries have issues with the evaluation procedure
- Reassessment is a politically sensitive procedure
- Gathering additional evidence seems to be challenging
- Policymakers seems to adopt a passive role in withdrawing reimbursement
- **Conclusions of the study**: stopping reimbursement seems more difficult than not starting reimbursement in the first place

Swedish follow-up study to maintain reimbursement of Entresto®

Aims

- Describe **patient population initiated on Entresto®** and **assess long-term effect** of Entresto® compared with a concomitant HF population on standard treatment

Method

- **Retrospective analysis** using national **HF quality register centers**, linked with **national registries** (including: Swedish Patient Registry, Swedish Prescription Registry, Cause of Death Registry)

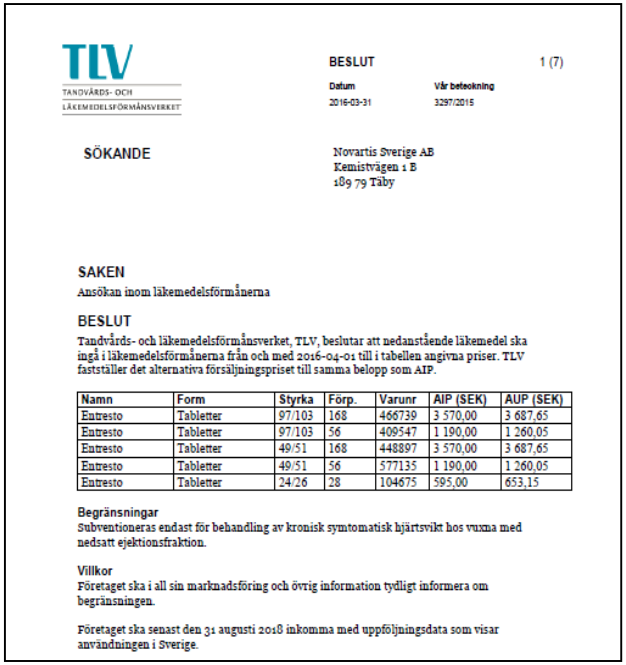
Results

- Patients on Entresto® were **younger males** than the general HFrEF population

Market access use

- Understanding patient profile using Entresto® and quality of treatment management
- **Required data to maintain reimbursement**

HF, heart failure; HFrEF, heart failure with reduced ejection fraction;



TLV
TANDVÅRDS- OCH LÄKEMEDELSFÖRMÅNSVERKET

BESLUT 1 (7)

Datum 2016-03-31
Vår beteckning 3257/2015

SÖKANDE

Novartis Sverige AB
Kemistvägen 1 B
183 79 Täby

SAKEN
Ansökan inom läkemedelsförmånerna

BESLUT
Tandvårds- och läkemedelsförmånsverket, TLV, beslutar att nedanstående läkemedel ska ingå i läkemedelsförmånerna från och med 2016-04-01 till i tabellen angivna priser. TLV fastställer det alternativa försäljningspriset till samma belopp som AIP.

Namn	Form	Styrka	Förp.	Varunr	AIP (SEK)	AUP (SEK)
Entresto	Tabletter	97/103	168	466739	3 570,00	3 687,65
Entresto	Tabletter	97/103	56	409547	1 190,00	1 260,05
Entresto	Tabletter	49/51	168	448897	3 570,00	3 687,65
Entresto	Tabletter	49/51	56	577135	1 190,00	1 260,05
Entresto	Tabletter	24/26	28	104675	595,00	653,15

Begränsningar
Subventioneras endast för behandling av kronisk symtomatisk hjärtsvikt hos vuxna med nedsatt ejektionsfraktion.

Villkor
Företaget ska i all sin marknadsföring och övrig information tydligt informera om begränsningen.

Företaget ska senast den 31 augusti 2018 inkomma med uppföljningsdata som visar användningen i Sverige.

Entresto® reimbursement decision, with mandatory follow-up requirement August 31, 2018

Thank You