XII Seminario
Industria Farmacéutica & Medios de Comunicación
Antequera 29 y 30 de Octubre de 2015

European REA: armonización de la evaluación de la eficacia relativa del medicamento en Europa

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farmaindustria

Evaluación de la Eficacia Relativa a nivel Europeo (*EU-REA*)

¿Qué es Eficacia/Efectividad Relativa (*REA, Relative Efficacy/Effectiveness Analysis*)?

- Es la evaluación de los resultados clínicos obtenidos por un fármaco, bien en ensayos clínicos (eficacia), o en la práctica clínica real (efectividad), en comparación con otro medicamento, o con otra intervención sanitaria.
- Esto es, el REA cubre sólo los resultados clínicos de una intervención, sin incluir en el análisis cuestiones económicas o presupuestarias.

¿En qué consiste el REA a nivel europeo (EU-REA)?

- En la actualidad, es la evaluación de la eficacia relativa de un medicamento, llevada a cabo por diferentes agencias europeas de HTA, que trabajan de forma cooperativa, bajo el paraguas de una organización supranacional (EUnetHTA).

¿Por qué un EU-REA?

- Los datos que se obtienen de los ensayos clínicos, tal y como aparecen en el EPAR, son válidos para todos los Estados Miembros de la UE, con lo que el análisis de los aspectos puramente clínicos no debería diferir significativamente entre países.
- Sin embargo, cada agencia europea que realiza una evaluación de un medicamento a nivel local, vuelve a realizar la evaluación de los aspectos clínicos del nuevo producto, lo que resulta en una duplicación de esfuerzos innecesaria e ineficiente.
- A su vez, la cooperación entre Estados Miembros y el análisis conjunto también podría promover una mayor estandarización metodológica y adopción de buenas prácticas.

Una preocupación fundamental

Falta de consistencia entre evaluaciones llevadas a cabo por agencias nacionales

Comparison of Product Evaluations and Reimbursement Price Achieved (launches from 2011-2013)

	G-BA Rating[1]	HAS ASMR Rating
Product #1	Considerable	Moderate
Product #2	Minor	Minor
Product #3	Not Quantifiable	Minor
Product #4	Not Quantifiable	Moderate
Product #5	Considerable	Minor
Product #6	Minor	Minor
Product #7	Not Quantifiable	Moderate
Product #8	Considerable	Minor
Product #9	Considerable	Moderate
Product #10	Minor	No add. benefit
Product #11	Minor	No add. benefit

[1] Rating is the final G-BA rating given after initial IQWiG assessment
Source: IMS Consulting Group analysis, GBA, ASNM

Una preocupación fundamental

Falta de consistencia entre evaluaciones llevadas a cabo por agencias nacionales

Type 2 Diabetes: HTA evaluation

Positive | Positive with limitations | Negative

Country	Producto A	Producto B	Producto C
FRANCE	Negative	Negative	Negative
GERMANY	Negative	Negative	Negative
SWEDEN	Positive	Not reviewed	Not reviewed
UK (NICE)	Positive with limitations	Positive with limitations	Under review
UK (SMC)	Positive with limitations	Positive with limitations	Positive with limitations

Note: synthesis based on interpretation of clinical and economic information provided in manufacturer HTA submissions and published guidance
Abbreviations: SU, sulfonylurea; met, metformin, BP, blood pressure
Source: HTA published guidance, assessments, and reimbursement decisions

Fuente: Farmaindustria, a partir de IMS

Una preocupación fundamental

Falta de consistencia entre evaluaciones llevadas a cabo por agencias nacionales

Multiple Sclerosis: HTA evaluation

Positive | Positive with limitations | Negative

Country	Producto A	Producto B	Producto C	Producto D
FRANCE			Not reviewed	
GERMANY			Not reviewed	
SWEDEN				
UK (NICE)				
UK (SMC)				

Note: synthesis based on interpretation of clinical and economic information provided in manufacturer HTA submissions and published guidance
Abbreviations: RRMS, Relapsing-remitting multiple sclerosis; PAS, patient access scheme; IFN-β, beta-interferon
Source: HTA published guidance, assessments, and reimbursement decisions

Fuente: Farmaindustria, a partir de IMS

Agentes relevantes

EUnetHTA

- EUnetHTA es una red de organismos públicos europeos, agencias regionales y organizaciones sin ánimo de lucro que llevan a cabo evaluaciones de tecnologías sanitarias o contribuyen a su desarrollo y que comparten metodologías y resultados.
- En EUnetHTA hay *partners*:

Austria

BIQG/GÖG
Gesundheit Österreich GmbH/Geschäftsbereich
HVB
Hauptverband der Österreichischen Sozialversicherungsträger (Association of Austrian Social Insurance Institutions)
LBI-HTA
Ludwig Boltzmann Institute for Health Technology Assessment

Belgium

KCE
Belgian Health Care Knowledge Centre

Bulgaria

NCPHP
National Center of Public Health Protection
NCPRMP
National Council for Pricing and Reimbursement of the Medicinal Products

Latvia

NHS
National Health Service, NHS

Lithuania

SMCA
State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania
VASPVT
State Health Care Accreditation Agency

Luxembourg

CEM
Cellule d'expertise médicale
CMSS
Administration du Contrôle Médical de la Sécurité Sociale

Malta

MEH
Directorate for Pharmaceutical Affairs, Ministry for Energy and Health

Estonia

UTA
Department of Public Health of the University of Tartu

Finland

FIMEA
Finnish Medicines Agency
THL
National Institute for Health and Welfare

France

HAS
French National Authority for Health (Haute Autorité de Santé)

Romania

NSPH MPD
National School of Public Health, Management and Professional Development

Slovakia

MoH Slovak Republic
Ministry of Health of the Slovak Republic

Slovenia

IER
Institute for Economic Research
NIJZ
National Institute of Public Health of the Republic of Slovenia

Germany

DIMDI
German Institute for Medical Documentation and Information
IQWIG
Institute for Quality and Efficiency in Health Care

Greece

NSPH
National School of Public Health

Hungary

OGYÈI
National Institute of Pharmacy and Nutrition

Ireland

HIQA
Health Information and Quality Authority

Italy

A. Gemelli
University Hospital A. Gemelli
Agenas
Agenzia Nazionale per i Servizi Sanitari Regionali
AIFA
Italian Medicines Agency
ASSR
ASSR Regione Emilia Romagna, Regional Agency for Health and Social Care
Regione del Veneto
Regione del Veneto

Spain

AETSA
Andalusian HTA Agency
AQuAS
Agency for Health Quality and Assessment of Catalonia
AVALIA-t
Galician Agency for HTA
IACS
Aragon Health Sciences Institute
ISC III
Instituto De Salud Carlos III
Osteba
Basque Agency for HTA, Department of Health
SESCS
Evaluation AND Planning Unit - Directorate of the Canary Islands Health Service
UETS
Health Technology Assessments Unit

Sweden

SBU
Swedish Council on Technology Assessment in Health Care

Switzerland

SNHTA
Swiss Network for HTA

United Kingdom

NETSCC
NIHR, Evaluation, Trials and Studies Coordinating Centre, NETSCC
NICE
National Institute for Health and Care Excellence

Agentes relevantes

EUnetHTA

- También hay *asociados*:

Austria

Danube University Krems
Danube University Krems -The University for Continuing Education

UMIT
Private Universität für Gesundheitswissenschaften, Medizinishe Informatik und Technik

Belgium

INAMI
Institut National d'Assurance Maladie-Invalidité

Bulgaria

MU Sofia
Medical University Sofia

Croatia

CHIF
Croatian Health Insurance Fund

Italy

DEDI
Dept. of Economics, Law and Institution (University of Roma Tor Vergata)

Russian Federation

NCHTA
National Center for Health Technology Assessment

Spain

DGFPS MSPSI
Directorate General for Pharmacy and Health Care Products

MSSSI
Spanish Ministry of Health, Social Services and Equality

Sweden

TLV
Dental and Pharmaceutical Benefits Agency - TLV

Denmark

KORA
Danish Institute for Local and Regional Government Research

Germany

GBA
Gemeinsamer Bundesausschuss

Medical Valley - EMN
Interdisciplinary Centre for Health Technology Assessment (HTA) and Public Health, University of Erlangen-Nuremberg, National BMBF-Cluster of Excellence, Medical Technologies

Ireland

NCPE
National Centre for Pharmacoeconomics, St. James Hospital

Turkey

KDTD
Turkish Evidence-Based Medicine Association

SAGEM
General Directorate of Health Research, Turkey

TÜBİTAK-TÜSSİDE
The Scientific and Technological Research Council of Turkey-Industrial Management Institute

United Kingdom

HIS
Healthcare Improvement Scotland

Agentes relevantes

EUnetHTA

- En EUnetHTA hay también un *foro de stakeholders*:

STAKEHOLDERS

AESGP
The Association of the European Self-Medication Industry (Industry)

AIM
International Association of Mutual Benefit Societies (Payers)

BEUC
The European Consumer Organisation (Patients)

COCIR
The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (Industry)

CPME
The Standing Committee of European Doctors (Providers)

EDMA
The European Diagnostic Manufacturers Association (Industry)

EFPIA
European Federation of Pharmaceutical Industries and Associations (Industry)

EGA
The European Generic Medicines Association

EMSP
European Register for Multiple Sclerosis (Patients)

EPF
The European Patients Forum (Patients)

ESC
European Society of Cardiology (Providers)

ESIP
The European Social Insurance Platform (Payers)

ESMO
The European Society for Medical Oncology (Providers)

Eucomed
Eucomed - Medical Technology (Industry)

EuropaBio
The European Association of Bioindustries (Industry)

EURORDIS
The European Rare Diseases Organisation (Patients)

HIO
Health Insurance Organisation (Payers)

HOPE
The European Hospital and Healthcare Federation (Providers)

Weight Watchers
Weight Watchers (Providers)

Agentes relevantes

EUnetHTA

- Hasta el momento, uno de los principales logros de EUnetHTA ha sido elaborar unas **guidelines metodológicas (HTA Core Model)** para la evaluación de medicamentos y tecnologías sanitarias.
- También la implantación de bases de datos que permiten a las agencias de evaluación integradas en EUnetHTA **compartir información** sobre evaluaciones realizadas o en curso.
- Por otra parte, hasta el momento EUnetHTA ha llevado a cabo 13 evaluaciones conjuntas (***joint assessments***) de tecnologías sanitarias, de las cuales 5 son de medicamentos: Zostavax (septiembre 2013); Canagliflozina (febrero 2014); Sorafenib (marzo 2015); Ramucirumab (mayo 2015); Vorapaxar (junio 2015). En la actualidad EUnetHTA está trabajando en los medicamentos innovadores contra el VHC, pero no está terminado.
- Todas estas evaluaciones se llevaron a cabo a partir de la **decisión voluntaria de los laboratorios** de ofrecer sus productos para que EUnetHTA llevara a cabo el análisis.

Agentes relevantes

EUnetHTA

- Entre las **principales críticas a las evaluaciones** llevadas a cabo por EUnetHTA destacan:

1. Falta de claridad en los objetivos de los pilotos.
2. Incumplimiento de los plazos de la evaluación.
3. Forma de elección de los evaluadores.
4. Falta de input de agentes externos, pacientes, profesionales sanitarios.
5. Falta de *feedback* al laboratorio afectado.
6. Duplicidades con lo que ya ha sido analizado en el EPAR (cuestiones de seguridad).
7. Escaso eco de los pilotos de EUnetHTA en la actividad de las agencias nacionales y regionales de HTA.

Agentes relevantes

EUnetHTA

- En la Joint Action 3 que acaba de empezar, EUnetHTA llevará a cabo **nuevas evaluaciones** y desde la industria se plantean **recomendaciones para mejorar su calidad**. A continuación se muestran algunas de las más importantes:

1. Iniciar sólo pilotos en los que sea posible cumplir los plazos de la evaluación.
2. Elección del autor principal por su experiencia; a su vez, debe estar directamente implicado en procesos nacionales de HTA.
3. Incluir pacientes y profesionales sanitarios en el proceso de evaluación.
4. Dar feedback al laboratorio titular del producto evaluado.
5. Preservar la metodología EUnetHTA como un modelo de buena práctica y no como una recopilación de metodologías seguidas por distintas agencias HTA
6. Continuar el proceso de mejora de las guidelines, incluyendo la necesidad de justificar situaciones en las que los autores se separen de las mismas.
7. Perseguir como objetivo la reutilización de resultados de la evaluación en países europeos.
8. Comprometer a todos los agentes con la reutilización y analizar si se reducen duplicidades.
9. Analizar si es posible reemplazar elementos de las evaluaciones nacionales, a fin de mejorar la eficiencia del proceso evaluador en Europa.

Agentes relevantes

EUnetHTA

- EUnetHTA es la entidad que se ha constituido como el mecanismo de cooperación técnico-científica de la HTA Network hasta el final de 2015

List of participating members

The HTA Network met for the first time in October 2013. All Member States have appointed a representative. The list of HTA Network member organisations is available below.

According to the Implementing Decision (714 KB), the HTA Network "shall be supported by a scientific and technical cooperation mechanism". This function will be performed by Joint Action EUnetHTA until the end of 2015.

Agentes relevantes

HTA Network

- Red de autoridades nacionales responsables de la evaluación de tecnologías sanitarias (HTA), cuyo objetivo es la cooperación y el intercambio de información sobre HTA.

Agentes relevantes

HTA Network

- Participación voluntaria

Members:

Austria – Ministry of Health	Italy - Ministry of Health
Belgium - Belgium Health Care Knowledge Centre (KCE)	Latvia - Ministry of Health
Bulgaria - National Center for Public Health and Analyses (NCPHA)	Lithuania - State Health Care Accreditation Agency
Croatia – Agency for Quality and Accreditation in Health Care and Social Welfare	Luxembourg - Inspection générale de la sécurité sociale (IGSS)
Cyprus - Ministry of Health Services	Malta - Ministry of Health
Czech Republic - State Institute for Drug Control (SUKL)	Netherlands - Zorginstituut Nederland
Denmark - Ministry of Health	Poland - Ministry of Health
Estonia - Ministry of Social Affairs	Portugal - Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)
Finland - Ministry of Social Affairs and Health	Romania - Ministry of Health
France – Ministry of Health	Slovakia - Ministry of Health
Germany - Ministry of Health	Slovenia - National Institute of Public Health
Greece - National Organization for Medicines	Spain - Ministry of Health
Hungary - Ministry of Human Resources	Sweden - Swedish Council on Health Technology Assessment (SBU)
Ireland - Health Information and Quality Authority	United Kingdom – Department of Health

Agentes relevantes

HTA Network

- Su inicio se remonta a la directiva de sanidad transfronteriza (marzo de 2011)

Article 15

Cooperation on health technology assessment

1. The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. The Member States shall communicate their names and contact details to the Commission. The members of such a health technology assessment network shall participate in, and contribute to, the network's activities in accordance with the legislation of the Member State where they are established. That network shall be based on the

4. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.

5. Arrangements for granting the aid, the conditions to which it may be subject and the amount of the aid, shall be adopted in accordance with the regulatory procedure referred to in Article 16(2). Only those authorities and bodies in the network designated as beneficiaries by the participating Member States shall be eligible for Union aid.

L 88/64 EN Official Journal of the European Union 4.4.2011

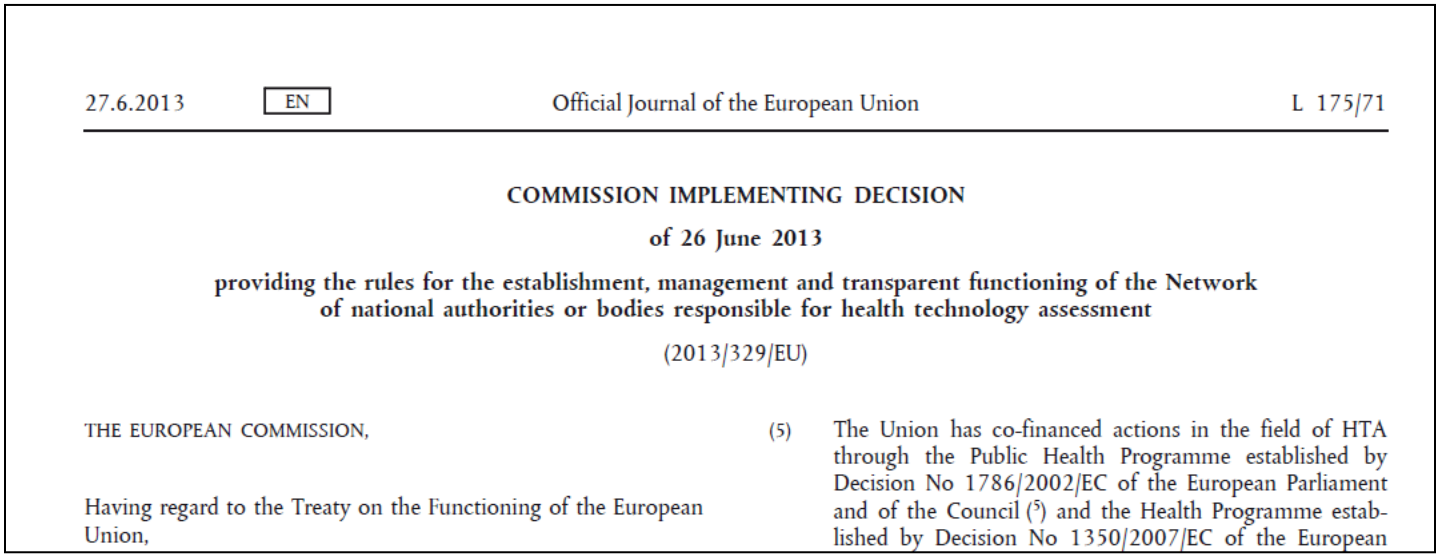
6. The appropriations required for measures provided for in this Article shall be decided each year as part of the budgetary procedure.

power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

Agentes relevantes

HTA Network

- En junio de 2013 se establecen las reglas de funcionamiento de esta red



27.6.2013 EN Official Journal of the European Union L 175/71

COMMISSION IMPLEMENTING DECISION

of 26 June 2013

providing the rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment

(2013/329/EU)

THE EUROPEAN COMMISSION,

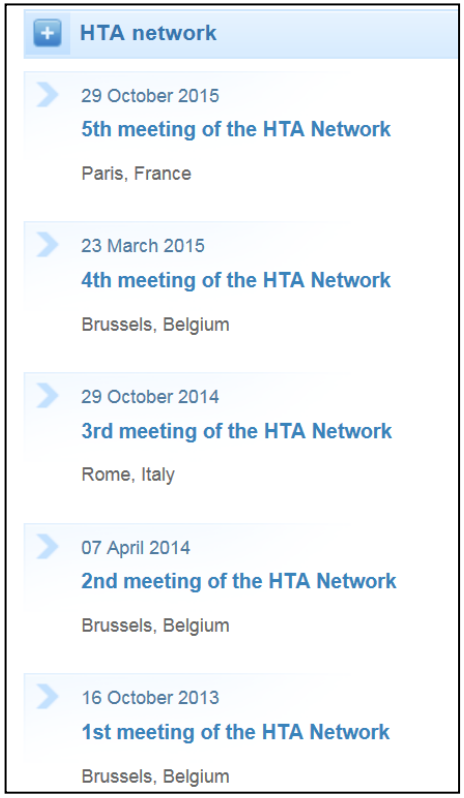
Having regard to the Treaty on the Functioning of the European Union,

(5) The Union has co-financed actions in the field of HTA through the Public Health Programme established by Decision No 1786/2002/EC of the European Parliament and of the Council (5) and the Health Programme established by Decision No 1350/2007/EC of the European

Agentes relevantes

HTA Network

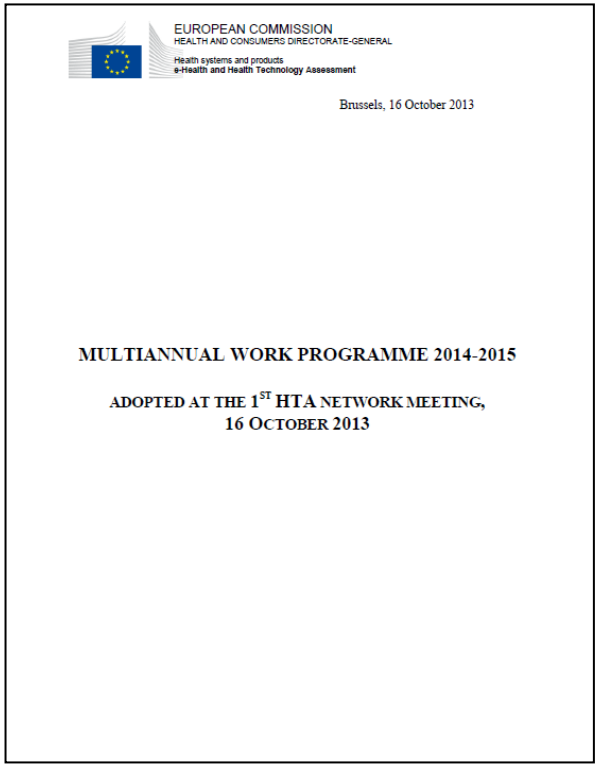
- Desde su establecimiento se ha reunido en 5 ocasiones



Agentes relevantes

HTA Network

- Y ha publicado 3 documentos


EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Health systems and products
e-Health and Health Technology Assessment

Brussels, 16 October 2013

MULTIANNUAL WORK PROGRAMME 2014-2015

ADOPTED AT THE 1ST HTA NETWORK MEETING,
16 OCTOBER 2013


Ref. Ares(2015)1982600 - 11/05/2015

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Health systems and products
e-Health and Health Technology Assessment

Brussels, 15 April, 2015

HTA NETWORK REFLECTION PAPER ON
"REUSE OF JOINT WORK IN NATIONAL HTA
ACTIVITIES"

ADOPTED BY THE HTA NETWORK, APRIL 2015

Agentes relevantes

HTA Network

- La agenda de la reunión que este organismo celebró ayer muestra claramente cuáles son sus cometidos inmediatos

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
e-Health and Health Technology Assessment

Brussels, 18 September 2015

HTA NETWORK
DRAFT AGENDA

5TH MEETING
29 OCTOBER 2015, PARIS, HAUTE AUTORITÉ DE SANTÉ

9.30 **Registration**

10.00 **Opening**

10.30 **Topic 1: Preparation of EUnetHTA Joint Action 3**
Lessons learnt from EUnetHTA JA2
Preparation on EUnetHTA JA3: reporting and strategic discussion on scope of the work

12.00 **Topic 2: EU HTA cooperation answering national needs**
Reuse of EUnetHTA deliverables, including joint work: experiences, challenges, barriers and benefits from the perspectives of a national HTA body, a decision maker and three ministries of health

13.00 **Lunch break**

14.00 **Topic 3: Multiannual work programmes 2014-2015 and from 2016**
Implementation of the work programme 2014-2015
Preliminary discussion for a work programme from 2016
- Nomination of a subgroup and rapporteur for the next MWP
- Nomination of a sub-group and rapporteur for the reflection paper on interaction between regulatory and HTA issues

14.30 **Topic 4: Recommendation on the use of PARENT joint action deliverables on patient registries**
The Network gives input and comments to the eHealth Network on a recommendation on the use of PARENT deliverables on patient registries.

15.30 **Topic 5: HTA and market access issues for a complex intervention**
Presentation of the business case for a remote monitoring service for chronic heart failure patients

16.30 **Topic 6: Hospital HTA**
Answering the needs of hospital managers: joint procurement of medical devices

Closing session

17.30 **Finish**

Agentes relevantes

Parlamento Europeo

STUDY

Abstract

This study, produced for the ENVI Committee by Policy Department A, investigates the possibility of a harmonised EU approach concerning the assessment of the added therapeutic value (ATV) of medicinal products. It reviews the current EU legal and policy framework and looks at the state-of-play within all 28 Member States. In addition, it presents the results of an in-depth analysis on the use of ATV in six selected EU countries. The study closes with policy recommendations on how a possible European harmonisation of the ATV assessment might be taken forward within the current legal framework.

Conclusion

Added therapeutic value provides patients and physicians with crucial information on the expected benefits of a new treatment. This type of information is relevant on its own, regardless of economic considerations.

While there are differences in how ATV is assessed and defined across the EU Member States, the underlying principles are not fundamentally incompatible and share the same goals and concepts. Agreeing on a shared definition of ATV is a desirable and logical next step following the HLPF's endorsed definition of relative effectiveness and efficacy. It should be possible for the Member States to agree on a shared definition and assessment methodology, as long as this is based on clinical criteria, rather than social and economic considerations. The HLPF and the Joint Action Program have already paved the way through their achievements in the field of relative efficacy and effectiveness.

A shared definition and methodology to determine ATV would facilitate communication between all stakeholders, allow Member States to build on each other's expertise and make joint assessments easier. Joint assessments, which have already been conducted through HTA Joint Action 1 and 2, tend to have the added benefit of concentrating expertise that is not usually found within a single national agency and, once there is an agreement on their methodology, saving time. Moreover, the existence of a shared methodology would reduce

Aspectos positivos del EU-REA

Principales Ventajas

- **Evitar duplicidades** ineficientes a la hora de evaluar la aportación incremental relativa de los nuevos medicamentos en sus aspectos puramente clínicos.
- **Evitar discrepancias** difíciles de explicar en los resultados de las evaluaciones de los aspectos clínicos de los nuevos fármacos llevadas a cabo por distintas agencias nacionales.
- Impulsar la elaboración y adopción de **guías metodológicas que fomenten las mejores prácticas** en materia de evaluación de medicamentos.
- Un **acceso más rápido y equitativo** a las innovaciones farmacéuticas por parte de los pacientes europeos.
- Evaluaciones llevadas a cabo por parte de los **mejores organismos / profesionales / expertos**.
- No obstante, la consecución de las ventajas anteriores **dependerá** de que la evaluación de la eficacia relativa a nivel europeo consiga:
  - La **eliminación real de las duplicidades** a nivel de estados miembros.
  - La **adopción real de los resultados** de las evaluaciones a nivel nacional, regional y local.
  - La implantación de un **procedimiento rápido** de evaluación que no obstaculice el acceso de los pacientes a las innovaciones

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