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HEALTH TECHNOLOGY ASSESSMENT POLICY AND GUIDELINE CHANGES IN THE EU-5 DURING THE COVID-19 PANDEMIC ERA : AN INSIGHT INTO TRENDS AND DRIVERS

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Background

- Healthcare provision is subject to policy decisions and is managed more than ever before. [1]
- The global COVID-19 pandemic had unprecedented impacts worldwide on individuals, healthcare systems including health technology assessment (HTA) and the market access of pharmaceuticals.[2]
- The European Medicines Agency (EMA) has been working closely with HTA bodies since 2008.
- Regional and national HTA bodies provide recommendations on medicines and other health technologies that can be financed or reimbursed by the healthcare system in a particular European Union Member State or region.[3]

Figure-1: HTA bodies in EU-5

Objective

The study aimed to highlight recent changes in the health technology assessments' (HTAs) policies and guidelines in the EU-5 nations in the light of COVID-19 situation.

Method

- A surveillance of recent HTA decisions in the EU-5 regions, namely UK, France, Italy, Spain and Germany was done using IQVIA™ 's proprietary platform database '**HTA Accelerator**' from **01/Jan/2020** to **06/June/2022.**
- **HTA Accelerator** is IQVIA™ 's proprietary database platform which allows users to identify HTA information by various entities (molecule, therapeutic area etc.). It also provides other clinical, regulatory, pricing and other information. (https://www.iqvia.com/solutions/real-world-evidence/health-economics-and-value/hta-accelerator)

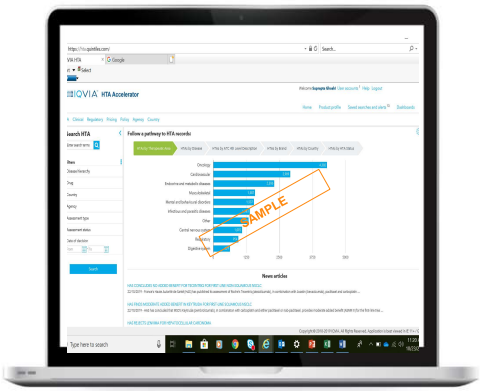
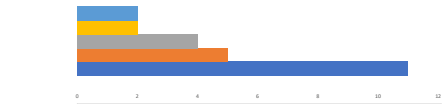


Figure-2: Snapshot of HTA Accelerator dashboard

Result

- Overall, **24 policies and guidelines** were updated during the pandemic period in the EU-5
- **France** had the most number of updates



	1
Italy	2
Spain	2
Germany	4
UK	5
France	11

Figure-3: Total number of policy updates in the EU-5

Highlights of HTA updates in the EU-5

- Updated early dialogue guideline
- Developed a **methodological guide** for **collecting real world evidence (RWE)** for the evaluation of drugs and medical devices
- Contribution of patient and user associations to HAS' evaluation of drugs or medical devices
- Created new department: Department of Assessment and Access to Innovation **(DEAI)**
- Procedures for **early access authorisation** and **compassionate use** schemes
- **CEESP** updated its methodology for **economic evaluations**
- **CEESP** evaluated principles for healthcare products for **pricing** purposes (Doctrine)
- French Ministry of Social Affairs and Health to set maximum price for **hospital medicines**
- *Liste en sus* (list of **T2A exclusions**): ASMR I-IV categories are eligible for inclusion
- CEPS and LEEM sign 2021-2024 **framework agreement** announcing updated pricing rules
- France Adopts **LFSS** for 2022

- G-BA clarifies procedure for **real-world data collection**
- G-BA has announced several proposed changes to its **assessment process** following the introduction of the Law for More Safety in the Supply of Pharmaceuticals (GSAV) in August 2019 and has clarified when **fixed- dose combination drugs** are eligible for benefit assessment.
- **Temporary exemption** from benefit assessment for **COVID-19 drugs**
- On 5 November 2020, Germany's IQWiG **published version 6.0 of its General Methods**.

- Consolidated the use of **RWE in a 'living' framework**
- Published updated **health technology evaluation development manual**
- **EMA** and **EUnetHTA** set priorities for **collaboration**
- EUnetHTA 21 assessments
- The **UK launches** opens a public consultation on selection criteria for contributors to joint clinical **an HTA access tool** as part of its Innovative License and Access Pathway

- Spain announces **new economic regime for orphan drugs** intended to encourage investment in the research, development, and subsequent marketing of orphan drugs.
- Spain announces **a revised HTA process** that includes the creation of a new HTA network and the introduction of health economic evaluations, in support of pricing and reimbursement decision making in Spain.

- Italy's Ministry of Health has **published a decree** with updated criteria for drug reimbursement and pricing negotiations between the Italian Medicines Agency
- The Italian Medicines Agency (AIFA) has published its **guidelines for pricing and reimbursement dossier submissions**.

Conclusion

- In the UK, France and Germany, emphasis on dissemination of RWE data remained mainstay for the updates.
- In Spain and Italy, updates related to pricing and reimbursement decisions were noted.
- Pertaining to the pandemic, specialised delayed dossier submission policy for COVID-19 targeted therapies was also noteworthy.

Abbreviation

- AIFA: Agenzia italiana del farmaco
- ASMR: French High Authority of Health Scale
- CEESP: Commission d'Évaluation Économique et de Santé Publique
- EUnetHTA: European Network for Health Technologies Assessment
- GSAV: Gesetz für mehr Sicherheit in der Arzneimittelversorgung
- IQWiG: Institute for Quality and Efficiency in Health Care
- LFSS: The French Social Security Funding Act (LFSS)
- NICE: National Institute for Health and Care Excellence

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