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Recent health technology assessment scenario across the EU-5 - a focus on multiple sclerosis

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Background

- Multiple sclerosis (MS) is a demyelinating disease in which the insulating covers of nerve cells in the brain and spinal cord are damaged.[1]
- This damage disrupts the ability of parts of the nervous system to communicate, resulting in a range of signs and symptoms, including physical, mental, and sometimes psychiatric problems.[2,3]
- The disease modifying therapies (DMTs) for MS are expensive and a burden on healthcare systems.[4]
- Decisions driving the reimbursement of currently available DMTs can help prepare appropriate strategies for pricing and reimbursement submissions in future.
- Future biological biomarkers could help identifying patients at early stages of MS, helping physicians develop a tailor-made therapeutic approach that could have a positive impact in economic terms.[4]

Objective

The objective of this analysis was to understand recent health technology assessments (HTAs) for MS therapies in EU-5 nations and identify the factors driving their reimbursement decisions.

Methods

- European Commission (EC)-approved drugs for Multiple Sclerosis were identified via European public assessment reports.
- A surveillance of recent HTA decisions in the EU-5 regions, namely UK (NICE, SMC, AWMSG), France (HAS), Italy (AIFA), Spain (AEMPS, AETSA) and Germany (G-BA, IQWiG) was done using IQVIA™ 's proprietary platform database '**HTA Accelerator**' from **01/Jan/2015** to **01/June/2019.**
- **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)
  - which accelerates knowledge of trends, decision-drivers and emerging themes in payer assessments
  - One can have direct insight into payer decisions and requirements and advanced analytic capabilities to guide market access strategy from research to launch to market expansion.
  - Which shows payer requirements by market, disease or product category.
  - provides near real-time data on recent product submissions

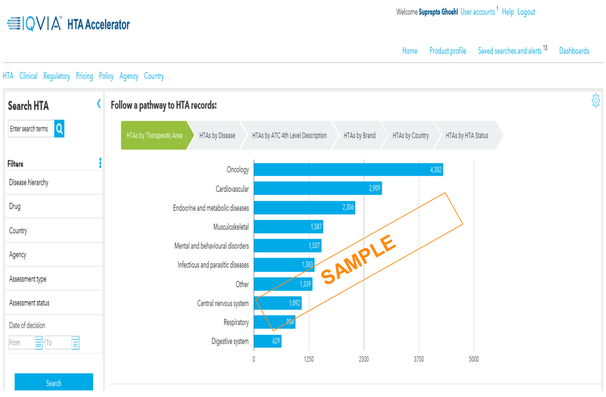

Figure : Snapshot of HTA Accelerator dashboard

Results

- **Fourteen** MS-specific DMTs have received EC approvals **01/Jan/2015** to **01/June/2019;** out of which daclizumab was voluntarily withdrawn post-approval for various safety reasons by the innovator. (**Fig.1**)

Name of the drug	Name of Molecule	Market Authorization Holder	Market status	HTA Appraisals
Gilenya	Fingolimod hydrochloride (fingolimod)	Novartis Europharm Limited	Authorised	SMC 1; IQWiG 3; G-BA 2; HAS 4; AWMSG 1; **Total = 11**
Plegridy	Peginterferon beta-1a	Biogen Netherlands B.V.		AEMPS 1; AWMSG 1; HAS 1; **Total = 3**
Aubagio	Teriflunomide	Sanofi-aventis groupe		AEMPS 1; HAS 1; **Total = 2**
Tecfidera	Dimethyl fumarate	Biogen Netherlands B.V.		**None**
Ocrevus	Ocrelizumab	Roche Registration GmbH		NICE 2; AEMPS 1; SMC 2; AIFA 1; G-BA 1; HAS 2; IQWiG 1; **Total = 10**
Lemtrada	Alemtuzumab	Sanofi Belgium		AEMPS 1; HAS 3; **Total = 4**
Rebif	Interferon beta-1a	Merck Europe B.V.		HAS 1; **Total = 1**
Betaferon	Interferon beta-1b	Bayer AG		**None**
Avonex	Interferon beta-1a	Biogen Netherlands B.V.		HAS 1; **Total = 1**
Tysabri	Natalizumab	Biogen Netherlands B.V.		HAS 2; **Total = 2**
Fampyra	Fampridine	Biogen Netherlands B.V.		HAS 2; SMC 2; AWMSG 1; **Total = 5**
Mavenclad	Cladribine	Merck Europe B.V.		NICE 1; SMC 1; IQWiG 1; G-BA 1; AEMPS 1; HAS 1; **Total = 6**
Extavia	Interferon beta-1b	Novartis Europharm Ltd		**None**
Zinbryta	Daclizumab	Biogen Idec Ltd	**Withdrawn**	AETSA 1; HAS 2; SMC 1; **Total = 4**

Figure 1: Enlists the 14 MS-specific drugs with their EC-approval status and HTA appraisals with the index period

- **Forty-nine** single drug assessments (SDAs) were carried out for these 14 drugs since 2015 (**Fig 1**).
- Of these, the highest number of SDAs were for fingolimod (22.4%; n= 11) and ocrelizumab (20.4%; n= 10). (**Fig.2**)

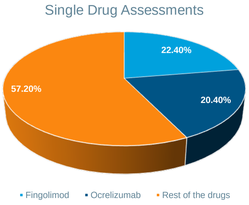

Figure 2: Shows the highest number of SDAs were for Fingolimod & Ocrelizumab

- Among the recently published 49 HTA decisions (SDAs), it was found that **5 negative recommendations** were received for 3 DMTs in EU-5 [**fingolimod** (1 for G-BA), **cladribine** (1 for HAS and 1 for G-BA) and **fampridine** (1 for SMC and 1 for AWMSG)] owing to insufficient evidence justifying high cost or inability to demonstrate sufficient clinical effectiveness against the comparators.

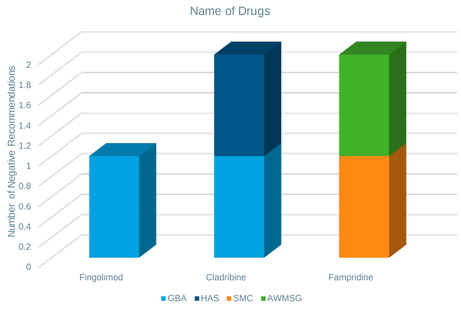

Figure 3: Shows five negative recommendations that were received for three DMTs in EU-5 in the index period

Conclusion

Despite approval of several DMTs for MS in the EU-5 region, DMTs have confronted negative recommendations from HTA agencies for not being able to justify their high cost against comparators. Hence, further emphasis on robust economic analyses justifying price vis-à-vis clinical benefits are warranted to drive positive HTA recommendations. Emerging biologics and other biomarker based therapies may pose competition to these DMTs and alter the economic scenario thereafter.

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Abbreviations (not mentioned in the body):
UK: United Kingdom; NICE: National institute of health and care excellence; SMC: Scottish medicine consortium; AWMSG: All wales medicines strategy group; HAS: Haute autorité de santé; AIFA: Agenzia italiana del farmaco; AEMPS: Agencia española de medicamentos y productos sanitarios; AETSA: Andalusian health technology assessment department; G-BA: Gemeinsamer bundesausschuss; IQWiG: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

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