The impact of the Covid-19 pandemic on the MHRA's Early Access to Medicines Scheme

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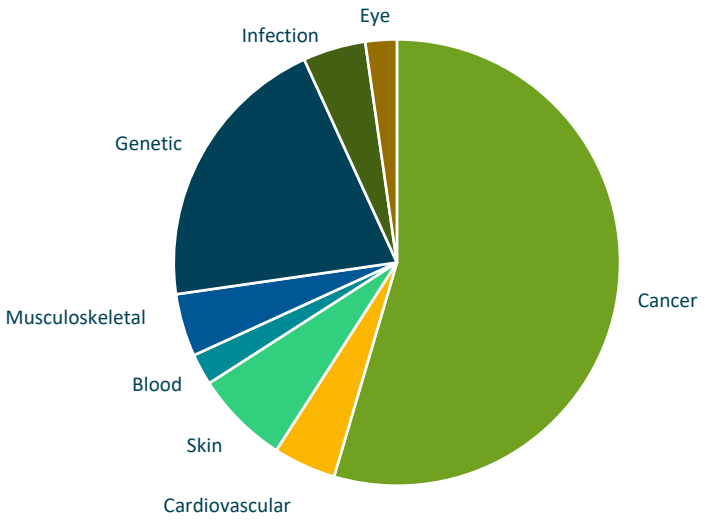
Objectives

To descriptively analyse public assessment reports (PAR) published by the MHRA through their early access to medicines scheme (EAMS) to establish any trends in product characteristics granted a positive scientific opinion (SO), the impact of an SO on subsequent technology assessment (TA) by the National Institute for Health and Care Excellence (NICE), and the impact of the COVID-19 pandemic on the EAMS process.

Methods

All available PARs and NICE TA documents were obtained from their respective websites, and data relating to drug, indication, justifications for positive SO, and NICE recommendation details extracted.

Figure 1. Indications of PARs assessed



Results

EAMS assessments overview (Figure 1)

- The most commonly assessed indications were oncology (n=24, 58.5%) and genetic disorders (n=9, 22%) (Figure 1) and the most frequent drug class reported were monoclonal antibodies (n=19, 46%).
- Of those granted a positive SO, n=27 underwent a NICE TA resulting in n=26 approvals, of which n=4 were recommended for use only within the CDF.
- Of the 26 drugs recommended by NICE, 20 (77%) had a commercial agreement e.g. simple discount patient access scheme.
- One drug received a positive SO but was declined by NICE TA (Tafamidis for ATTR-CM) as it did not meet the acceptable cost effectiveness threshold, insufficient evidence the drug would reduce diagnostic delays, and uncertainty about how long the treatment works after it is stopped.

EAMS and NICE assessments before and during COVID-19 pandemic (Table 1)

- During the COVID-19 pandemic (April 2020-April 2021), 11 drugs were granted a positive SO versus 5 drugs in the previous 12 months (Table 1).
- The most common drug class granted positive SO were monoclonal antibodies (3 [27%] in April 2019-2020 and 2 [40%] in April 2020-2021).
- Of the drugs granted positive SO in during the pandemic (April 2020-2021), 2 (18.2%) were recommended, 7 (63.6%) were in the process of being assessed, and 2 (18.2%) were not submitted for NICE TA. Of the drugs grated positive SO in the year before the pandemic (April 2019-2020), 4 (80%) were recommended and 1 (20%) was not recommended by NICE TA.

Conclusions

- High rates of NICE TA approval (>90%) were observed in products granted a positive SO through EAMS.
- Engaging with the EAMS scheme does not lead to preferential pricing as products were subject to a commercial agreement.
- The COVID-19 pandemic had no clear impact on the EAMS scheme as the number of positive SOs granted during the pandemic was higher than the that of the previous year.
- It was not possible to establish if the COVID-19 pandemic impacted NICE assessment of products with positive SO as many of these products are still in the process of being assessed.

Table 1. EAMS and NICE assessments before and during COVID-19 pandemic

Drug name	Indication	Developer	NICE TA ID	Recommended by NICE	Pricing information
Pre COVID-19 (April 2019-2020), n=5					
Tafamidis	CVD	Pfizer	TA696	No	NA
Atezolizumab	Oncology	Roche	TA638	Yes	PAS
Polatuzumab vedotin	Oncology	Roche	TA649	Yes	PAS
Isatuximab	Oncology	Aventis Pharma	TA658	Yes	CDF
Avelumab + axitinib	Oncology	Merck Serono	TA645	Yes	CDF
During COVID-19 pandemic (April 2020-2021), n=11					
Berotralstat	Blood conditions	BioCryst UK	NA	NA	NA
Nivolumab	Oncology	BMS	TA707	Yes	PAS
Nivolumab + ipilimumab	Oncology	BMS	GID-TA10498	In progress	NA
Lumasiran	Genetic disorder	Alnylam UK	GID-TA10660	In progress	NA
Atezolizumab	Oncology	Roche	TA666	Yes	PAS
Pemigatinib	Oncology	Incyte Biosciences	TA10619	In progress	NA
Risdiplam	MSK	Roche	GID-TA10612	In progress	NA
Abrocitinib	Skin disorder	Pfizer	GID-TA10764	In progress	NA
Avelumab	Oncology	Merck Serono	GID-TA10624	In progress	NA
Remdesivir	Infection	Gilead Sciences	GID-TA10721	In progress	NA
Avalglucosidase alfa	Genetic	Aventis Pharma/Sanofi	NA	NA	NA

CDF, Cancer Drugs Fund; **NA**, not applicable; **PAS**, patient access scheme

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