The Impact of the Patient Access Schemes on Appraisals for the Innovative Medicines in Scotland 2011-2020

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Background and objective

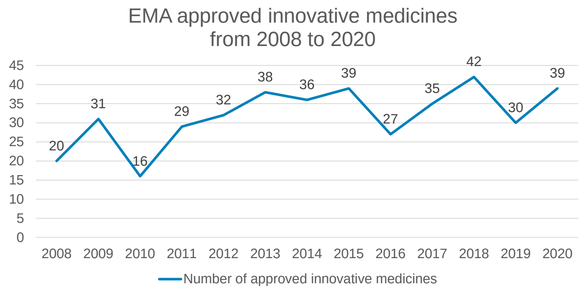
- The patient access scheme (PAS) has been implemented as a formal part of the pricing and reimbursement environment in the United Kingdom (UK) since 2009. [1]
- PAS, usually with confidential discount, is an innovative pricing agreement proposed by pharmaceutical companies, which aims to improve cost-effectiveness and enable patients to gain access to high-cost drugs and treatments. [2]
- PAS operated via two main mechanisms: "Price discount schemes" and "Manual managed discount schemes". [3]

Main mechanisms for PAS	
"Price discount schemes"	The pharmaceutical company passes on a straightforward discount of X% on the price of the drug. This will be the price invoiced to the organisation and no new internal processes/mechanisms require implementation.
"Manual managed discount schemes"	An internal process/mechanism has to be implemented in order to allow the potential cost avoidance to be realised. This may be resource-intensive and involve multiple departments within the organisation.

- The Patient Access Scheme Assessment Group (PASAG) reviews and advises NHSScotland on the feasibility of proposed schemes for implementation. It operates separately from the Scottish Medicines Consortium (SMC) to maintain the integrity of the assessment process. [4]
- Innovative medicines were defined by the European Medicines Agency (EMA) as the medicines that contained an active substance or a combination of active substances that had not been authorised before. [5]
- Innovative medicines are promising with the potential for incurable diseases or diseases without satisfactory treatments.
- How to reimburse and price of these drugs is a big challenge for decision-makers in HTA agencies as these drugs are usually costly and uncertain in terms of clinical and economic evidence.
- This study was to investigate the impact of the PAS on the appraisals for the innovative medicines in SMC between 2011 and 2020.

Method

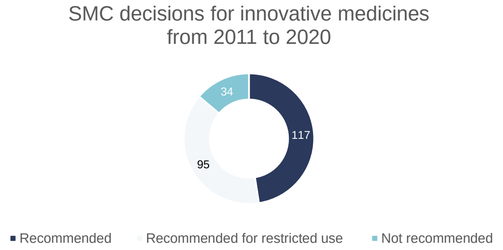
- The list of approved innovative medicines was obtained the from EMA website.
- Considering the delay between EMA approvals and reimbursement decisions, the approved innovative medicines by EMA from 2008 to 2020 were used to check the decisions in SMC from 2011 to 2020.
- A total of 414 innovative medicines were approved by EMA from 2008 to 2020.
  - The number of approvals fluctuated between 16 in 2010 and 42 in 2018.



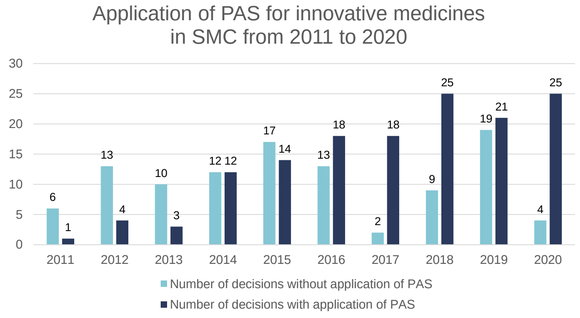
- The following information was extracted for each SMC decision for innovative medicines:
  - Publication year: the SMC decision publication year
  - SMC decision: recommended, recommended with restricted use or not recommended
  - PAS: application of PAS or not
- The extraction was conducted by two researchers independently.
- All statistical analyses were conducted using Excel software.

Result

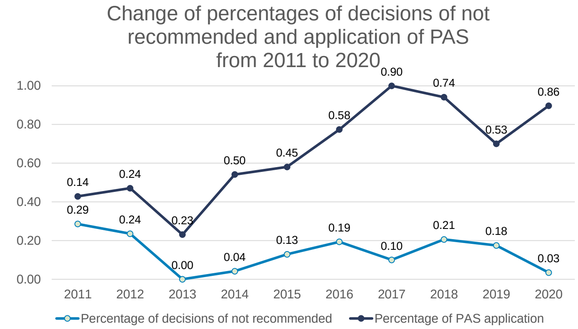
- A total of 246 decisions for innovative drugs were made by SMC between 2011 and 2020, among which, 117 (47.6%) were recommended, 95 (38.6%) were recommended for restricted use and 34 (13.8%) were not recommended.



- Among 246 decisions, 141 decisions applied for the PAS and 105 decisions did not apply for the PAS.
- The application rates of PAS increased dramatically since 2014, from 23.1% in 2013 to 50.0% in 2014.
- In 2020, the application rate of PAS reached 86.2% and only 4 of 29 appraisals did not apply the PAS.



- Of 141 decisions that applied for the PAS, 78 (55.3%) were recommended, 61 (43.3%) were recommended for restricted use and 2 (1.4%) were not recommended.
- Of 105 decisions that did not apply for the PAS, 39 (37.1%) were recommended, 34 (32.4%) were recommended for restricted use and 32 (30.5%) were not recommended.
- The percentage of decisions of 'not recommended' decreased with an increased percentage of PAS applications.



CONCLUSIONS

The application of PAS has become a popular trend for innovative medicines in Scotland, which could significantly decrease the rates of 'not recommended' decisions in SMC when PAS is applied.

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