# Free of charge medicine schemes in the NHS. A local and regional Drug and Therapeutic Committees (DTC) experience.

Simon O'Callaghan[1], Robin Ferner[2], Andrew Barron[1], Katherine Saxby[1], and Reecha Sofat (CURRENTLY UNAVAILABLE)[3]

[1]University College London Hospitals NHS Foundation Trust
[2]City Hospital
[3]University College London

July 11, 2021

## Abstract

Introduction: Free-of-charge (FoC) medicine schemes are increasingly available and allow access to investigational treatments outside clinical trials or in advance of licensing or NHS commissioning. Methods: We retrospectively reviewed FoC medicine schemes evaluated between 2013 and 2019 by a single NHS trust and a regional drug and therapeutics committee (DTC). The details of each locally reviewed FoC scheme, and any nationally available MHRA Early Access to Medicines Scheme (MHRA EAMS) in the same period, were recorded and categorised. Results: Most FoC schemes (95%) allowed access to medicines intended to address an unmet clinical need. Over 7 years, 90% were company-FoC schemes and 10% were MHRA EAMS that were locally reviewed. Phase 3 clinical trial data were available for 44% of FoC schemes; 37% had phase 2 data; and 19% were supported only by phase 1, retrospective observational studies, or pre-clinical data. Utilisation of company-FoC schemes increased on average by 50% per year, while MHRA EAMS showed little growth. Conclusion: Company-FoC medicine schemes are increasingly common. This may indicate a preference for pharmaceutical companies to independently co-ordinate schemes. Motivations for company-FoC schemes remain unclear and many provide access to treatments that are yet to be evaluated in appropriately conducted clinical trials, and whose efficacy and risk of harm remain uncertain. There is no standardisation of this practice and there is no regulatory oversight. Moreover, no standardised data collection framework is in place that could demonstrate the utility of such programmes in addressing unmet clinical need or allow generation of further evidence.

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