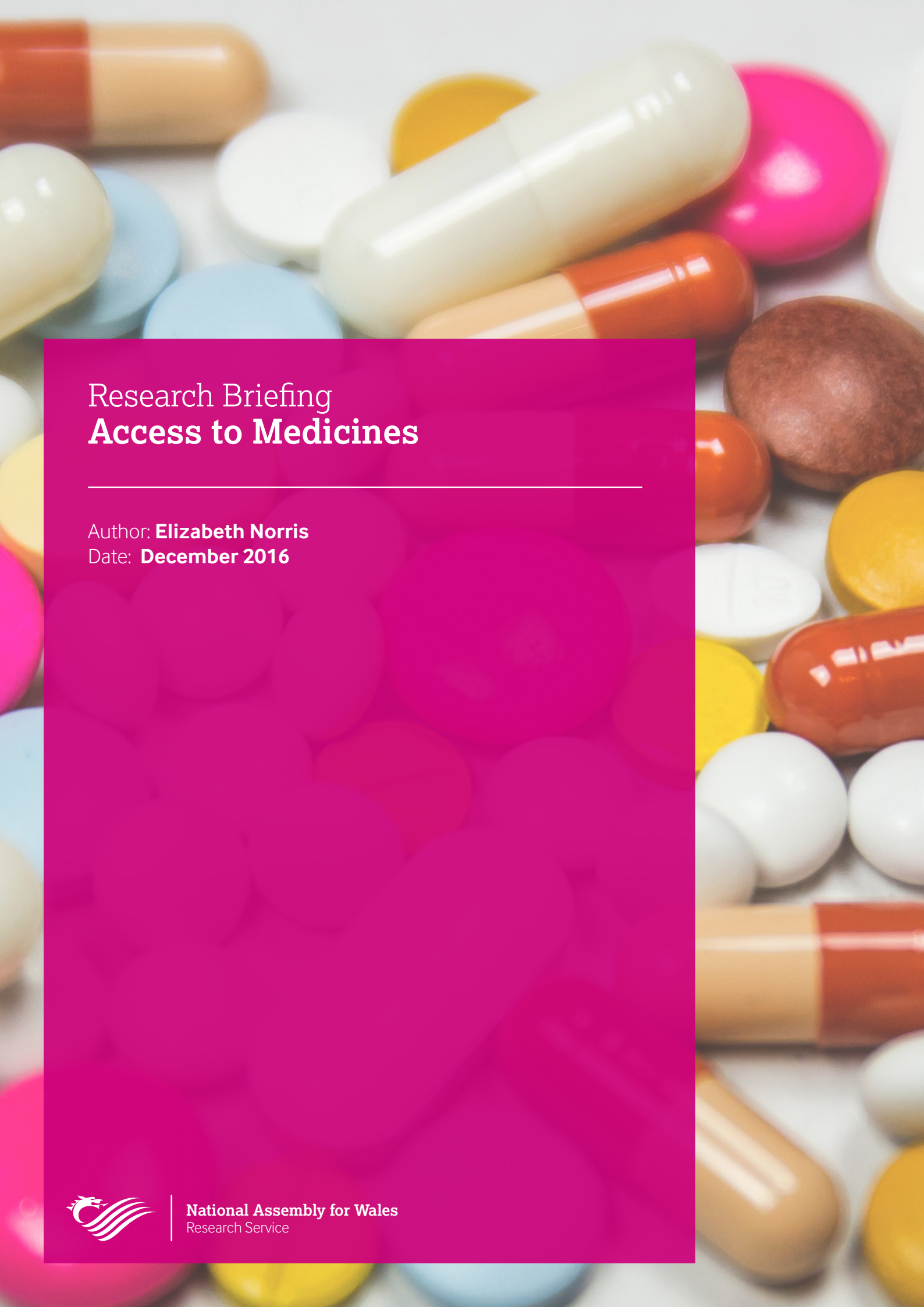

Research Briefing

Access to Medicines

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National Assembly for Wales
Research Service

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Research Briefing

Access to Medicines

This factsheet provides a brief guide to Access to Medicines in Wales. It describes how medicines undergo an appraisal process prior to being made available to patients on the NHS. It also explains some of the ways patients can access medicines which are not routinely available on the NHS and new drugs which may be suitable for advanced or complicated health conditions.

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Appraisal of Medicines

Before new medicines can be routinely used to treat patients in the NHS, they undergo an appraisal process to determine if the benefits of the medicine justify the cost.

For medicines for use within the NHS in Wales, this process is carried out by the **National Institute for Health and Clinical Excellence (NICE)** and the **All Wales Medicines Strategy Group (AWMSG).**

NICE advises the NHS on both the clinical benefits and the cost-effectiveness of the medicine. The All Wales Medicines Strategy Group (AWMSG) appraises new medicines that are not on the NICE work programme. This advice has a statutory basis in England and Wales, and the Health Boards in Wales are legally obliged to fund medicines with a positive recommendation from NICE or AWMSG where these are prescribed.

In recognition of the clinical needs of patients with rare diseases and acknowledging the potentially high costs of these treatments, the appraisal committee will take broader considerations when appraising orphan and ultra-orphan medicines.

Orphan medicines are defined by the European Medicines Agency (EMA) as medicines for treating conditions which affect no more than five in 10,000 people, this is roughly equivalent to 1,500 patients in Wales. Ultra-orphan medicines are those granted EMA orphan status used to treat conditions with a prevalence of 1 in 50,000 or less in the UK, equating to approximately 60 patients in Wales.

The New Treatment Fund

In July 2016, the Cabinet Secretary for Health, Wellbeing and Sport, Vaughan Gethin AM announced a **New Treatment Fund** to support the early introduction of new medicines which have been recommended by NICE or AWMSG. The role of the New Treatment Fund is to meet the costs of new medicines for a maximum of 12 months, providing Health Boards with time to plan and prioritise funding from within their budgets. The fund should be operational by December 2016.

Individual Patient Funding Requests

If a medicine has not been approved by either NICE or AWMSG but a clinician feels there are exceptional reasons to why a patient should receive the medicine, and medical evidence shows that they will make a difference to the patient's life, a clinician can make an **Individual Patient Funding Request (IPFR)** to the Health Board.

Exceptionality refers to evidence presented of a patient's individual clinical circumstances and takes into account factors such as clinical effectiveness and service and policy implications, economic considerations such as cost effectiveness and an understanding of the resources available. There are also ethical considerations such as the individual impact the treatment will have on the patient.

In September 2016, the Cabinet Secretary for Health, Well-being and Sport announced a review of the IPFR process following recommendations from the **2014 IPFR review**. The review will examine how to improve the IPFR process, the criteria by which they make decisions, such as the clinical exceptionality and how these decisions are communicated to patients. The review will also consider the advantages and disadvantages of retaining the eight IPFR panels or moving to a national IPFR panel.

Top-up Payments

If an IPFR is not granted, but a clinician wishes to prescribe an unfunded medicine, it is possible for a patient to purchase the treatment themselves, these are currently known as 'top-up payments'. In 2011, the **Implementation Group published a report on top-up payments**. This states that when an IPFR is not granted on the grounds of cost effectiveness, private payment may be permitted. It is proposed that the treatment must be shown to have a favourable benefit to harm ratio for the individual patient. The report also states that the top-up treatment will be delivered as an independent episode of care, but the patient will still have access to the NHS services for all other, ongoing care. **Patient information leaflets regarding top-**

up payments are provided by a number of the Health Boards, the information should apply across all health boards in Wales.

One Wales Interim Commissioning

The One Wales Interim Commissioning Process is coordinated by Patient Access to Medicines Service (PAMS) to promote access for clearly defined and specific cohorts of patients to medicines which are not routinely available in the NHS. As stated above, treatments can be funded by IPFR only where 'exceptionality' has been demonstrated. In some circumstances however, it may be that there are additional patients who may also benefit from the treatment. In these cases, IPFR may not be appropriate. For cohorts of patients where there is a clear, unmet, clinical need, the One Wales Interim Commissioning Process creates a pathway whereby conditional approval in relation to licenced treatments can be achieved. The process is utilised rarely and only when there is a strong case for clinical need. Current recommendations of the Interim Pathways Commissioning Group (IPCG) include drugs such as Arsenic Trioxide, which in combination with other treatments, is supported for use as a first like treatment of acute promyelocytic leukaemia.

Early Access to Medicines

The Early Access to Medicines Scheme (EAMS) is a UK initiative, developed by the Medicines and Healthcare Products Regulatory Agency (MHRA), which makes a small number of new medicines available at the earliest stage possible. MHRA is responsible for investigating and advising whether medicines are safe to use, where it is appropriate to do so. The scheme is specifically aimed at medicines which will treat serious situations or life-threatening diseases where there is currently no effective treatment solution.

Once licenced, medicines developed through EAMS will be appraised for routine use by NICE. If EAMS medicines are subsequently recommended through a technology appraisal, it will then be commissioned by the NHS.

The Cancer Research UK website provides useful information on the Early Access to Medicines Scheme. It states that if a patient feels an EAMS drug may be suitable for them, the first step is to discuss this with their doctor. If it is felt appropriate to pursue, the doctor should apply to the Department of Health and Social Services in Wales.

Clinical Trials

Clinical trials may involve new drugs or treatments for patients they may not otherwise have access to through the NHS or through IPFR. Clinical trials may be appropriate for certain patients with specific conditions. Patients can ask their doctors whether they qualify for a trial if they are interested, and doctors may present a trial as an option for patients if they feel it is appropriate and could be of benefit.

Further Information

The Research Service has produced this Constituent Factsheet for the benefit of Assembly Members and their support staff. Authors are available to discuss the contents of these papers with Members and their staff but cannot advise members of the general public.