NHS England Board meeting

Paper Title:	Medicines Access and Uptake- transforming patient outcomes
Agenda item:	8 (Public session)
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Paper type:	For information and discussion

Organisation Objective:

NHS Mandate from Government	☐	Statutory item	☐
NHS Long Term Plan	☒	Governance	☐
NHS People Plan	☐		

Executive summary:

Medicines- both innovative and established- have the potential to transform patient outcomes, improve population level health, tackle health inequalities and support NHS productivity. They also represent the second highest area of healthcare spend after our workforce.

This paper provides an update on the substantial progress that is being made to drive access and uptake to clinically and cost effective medicines, within a robust framework and programme of action that is delivering value for money for taxpayers and affordability for the NHS.

The proactive, strategic and commercially robust approach we have put in place has helped to transform the lives of hundreds of thousands of people over the last 5 years. The Board's attention and focus on ensuring this progress is maintained over the next five years will be important.

Action required:

The Board is asked to:

- Note the general progress being made to support access to and uptake of clinically and cost effective medicines;
- Reflect on the impact this is having on patient care and outcomes; and,
- Look forward, and consider the principles, opportunities and challenges that should guide our approach so we can ensure progress is maintained over the next five years.

Supporting a Positive Access and Uptake Environment

1. NHS England's proactive and more assertive focus on supporting access and uptake of clinically and cost effective medicines began in 2016 with the reform of the Cancer Drugs Fund. We had inherited administration of a fund that was overspending, undermining the role of NICE and, by late 2015, had had to close its doors to new entrants. Our reforms restored the central role of NICE in appraising cancer drugs and saw the creation of a £340m managed access fund to support

patient access to the most promising new cancer drugs whilst further data could be collected to resolve evidential uncertainties. Working in partnership with NICE, NHSE started entering into commercial access agreements with companies to support them achieving a CDF recommendation from NICE.

2. Building on this success, by the end of 2018, we had established a new Commercial Medicines Directorate (CMD) to enhance our capacity and capability in this area. This function played a critical role throughout the pandemic, ensuring that no hospital in any part of the country ever went without the class of essential medicines it needed to care for patients. It also supported the roll out of dozens of 'COVID friendly' cancer treatments - which required fewer hospital visits or had less of an impact on patients' immune systems.

3. The publication in 2021 of the NHS' first ever commercial framework for new medicines marked a further big step forward. The framework provides clarity to commercial partners on how to best engage with the health service while also setting out new commercial flexibilities that better enable the NHS to fully harness the commercial national buying power of the NHS. A single deal agreed with the NHS provides access to 55 million people in England.

4. Earlier this year, we launched the Innovative Medicines Fund which builds on the success of the Cancer Drugs Fund, providing up to £340m of additional funding to support faster patient access to promising but uncertain non-cancer medicines, particularly in the area of rare diseases.

5. The combined effect of these changes and this focus has allowed the NHS to expand treatment options for hundreds of thousands of patients over the last five years. It is now not uncommon for NHS patients to be the first in Europe or the world to access innovative new pharmaceuticals. Notable examples include two new lung cancer drugs, a peanut allergy treatment, personalised CAR-T therapy for a rare paediatric blood cancer and lifesaving hepatitis C treatments for children aged 3 and older.

6. The development and deployment of the NHS' commercial and adoption capabilities is clearly demonstrated in the pharmaceutical industry's own data. A review of 222 new medicines showed the UK was 3rd globally in the number of medicines commercialised within one year of their first approval.[1] Furthermore, availability of medicines in England is significantly higher than the European average – for every four treatments available in Europe, there is an additional medicine available in England.[2]

7. This positive access and uptake environment is not only benefitting patients, but is contributing to the UK economy as a whole. At the start of the year the UK Bioindustry Association reported record investment into UK biotech and life sciences companies with a 60% jump largely the result of overseas investment, underlining that the UK remains an attractive place for life science investment.

[1] Figures from Patented Medicine Prices Review Board, Canada. National Prescription Drug Utilization Information System (NPDUIS). Meds Entry Watch. 6th Edition. April 2022

[2] Figures from EFPIA Patients W.A.I.T Indicator 2021 Survey, published April 2022. IQVIA.

8. The Government's Life Science Vision, published in July 2021, made clear that the 'NHS as an Innovation Partner' is a precondition of the success of the Vision. It set out how new initiatives have accelerated patient access to treatment, noting the role of the Cancer Drugs Fund and the globally leading commercial deals for cutting-edge innovations that have been struck by NHS England, utilising the commercial flexibilities from the NHS Commercial Framework.

9. The infographic at **Annex A** shows just some of the recent commercial access deals NHS England has put in place over the last 12 months- further detail on how these are improving patient care and outcomes is set out below.

Impact of Commercial Access Deals on Patient Care & Outcomes

10. The impact of our commercial medicines activity is being felt across cancer, rare and less common conditions, as well as in much larger patient populations**.**

Improving Cancer Survival

11. Around 50% of all new drugs appraised by NICE are treatments for cancer.

12. **In just over five years, the reformed Cancer Drugs Fund has continued to deliver substantial patient benefit, enabling more than 80,000 people to gain faster access to more than 100 cancer treatments**. In the Summer, a new secondary breast cancer treatment, alpelisib with fulvestrant became the 100th treatment to be funded through the CDF and nearly 18,000 patients have been registered to receive a CDF funded treatment this year alone.

13. **All drugs on the CDF have reached expected uptake levels within three months of a positive NICE recommendation**. Drugs that are commissioned through the CDF are reaching patients, on average, five months earlier than would otherwise be the case and close to eight in 10 drugs (78%) are exiting the CDF with a positive recommendation for routine commissioning.

14. Over the past five years **NHS patients have been amongst the first in Europe to benefit from treatments** like sotorasib (Lumykras®) for lung cancer, which targets the so-called 'death star' mutation and mobocertinib (Exkivity®), which treats a rare and aggressive form of lung cancer, in addition to new personalised CAR-T treatment, tisagenlecleucel (Kymriah®) for childhood cancer. When compared to Europe, based on the latest industry data[3], close to a third more cancer drugs are available in England.

15. In other areas, **new treatments are not just delivering substantial patient benefit in terms of outcomes, but in patient experience too**. For example, the NHS's world leading adoption of the subcutaneous cancer treatment Phesgo® means women can now receive a 'five minute treatment' as an alternative to intravenous administration that requires patients to spend hours in hospital.

16. **The NHS has already made huge strides in harnessing innovation in genomic medicine.** In cancer this has led to NHS patients accessing a new generation of cancer fighting medicines ('tumour agnostic' drugs) while testing available through

[3] Figures from EFPIA Patients W.A.I.T Indicator 2021 Survey, published April 2022. IQVIA.

the NHS Genomic Medicine Service has helped target drugs at those most likely to benefit, improving safety and value. Around 38,000 patients each year that have treatment with fluoropyrimidine-based chemotherapy drugs are now able to have a genomic test for variants in the DPYD gene to identify whether they have a variant which may increase the risk of an adverse drug reaction, preventing significant and life-threatening toxicity to patients receiving chemotherapy.

17. Further summary detail on the clinical impact of the Cancer Drugs Fund (CDF) in improving outcomes for cancer patients can be found at **Annex B**

Transforming the Outlook for Patients with Rare & Devastating Conditions

18. Over the past decade, there has been a dramatic expansion in the number of innovative treatments coming to market for patients with rare, and often previously untreatable, conditions. Although patient numbers are sometimes very small, 1 in 17 people in the UK will develop a rare condition at some point in their lifetime equating to around 3.5 million people. This has, therefore, been an important focus for our commercial activity.

19. **The ability of new medicines to completely transform outcomes for NHS patients with a given condition is well demonstrated with the case of spinal muscular atrophy.** Three managed access agreements (MAAs) for three new treatments (Spinraza®, Zolgensma®, Evrysdi®) for the rare genetic condition, in less than three years, has enabled hundreds of people to benefit from a first-ever treatment, a breakthrough gene therapy, and an oral drug that can be taken at home. These treatments offer prospects for people with Spinal Muscular Atrophy (SMA) Types 1, 2 and 3, including babies and young children, that were previously not possible.

20. Many of these new treatments involve the introduction of new and **highly complex treatment pathways which NHS England, as the direct commissioner of these services, in partnership with our expert specialised service providers are able to introduce at pace**. For example, following the commercial deal struck for Libmeldy® for the treatment of metachromatic leukodystrophy, a rare and fatal genetic disease, Royal Manchester Children's Hospital is now one of only five centres in Europe with expertise to administer this complex treatment.

21. **In cystic fibrosis we have achieved world beating uptake levels of CFTR modulator therapies** following a portfolio deal struck with the manufacturer which ensured access to their triple therapy, Kaftrio®, could begin on the day it received its European marketing authorisation. In less than six months of securing this access deal, nine in ten people with CF in England (over 7,000 people) were benefitting from a medicine that treats the underlying causes of the condition. Thanks to the uptake of these new treatments, outcomes for people with cystic fibrosis have been transformed – alongside improved lung function and significant reductions in hospital stays, the **latest data shows the number of women with cystic fibrosis who have become pregnant has nearly doubled since the triple-therapy treatment was made universally available**.[4]

[4] Cystic Fibrosis Trust. UK Cystic Fibrosis Registry. 2021 Annual Data Report. September 2022. Accessed November 2022.

22. **We have also concluded deals that secure new treatments for conditions where innovation had stalled. In the past year, the NHS has made a first new treatment for sickle cell disease (SCD) in over 20 years** available and also secured a deal for a first new mesothelioma treatment in nearly 15 years. Both conditions disproportionately affect defined groups – SCD is an hereditary condition much more prevalent among people from African or African-Caribbean origin, while cases of mesothelioma – the UK having the highest prevalence in the World – is mostly linked to occupational exposure among people who worked in manual industries and in the Armed Forces.

23. The launch of the Innovative Medicines Fund will further support our efforts to bring innovative new treatments, including Advance Medicinal Therapeutic Products (ATMPs), to patients in the months and years ahead.

<u>Improving Outcomes & Value in Larger Patient Populations</u>

24. A series of 'smart procurement' agreements demonstrates how NHS England is also using its national buying power to maximise value and provide local systems and NHS healthcare professionals with the tools to deliver significant population and public health improvements, as articulated in the NHS Long Term Plan:

- **On Cardiovascular disease,** sitting alongside innovative new cardiovascular medicines like the cholesterol treatments, inclisiran and bempedoic acid, we are continuing to implement new commissioning recommendations for Direct-acting Oral Anticoagulants (DOACS), that could see more than 600,000 people benefit from effective anticoagulation; taking an opportunity to prevent tens of thousands of potentially fatal atrial fibrillation (AF) related stroke events. We are now seeing uptake of the best value DOAC (edoxaban) increase – the first time we have taken this approach in primary care. Additional patients on DOAC treatment since the launch of the initiative should already lead to the avoidance of nearly 2,000 AF-related strokes and more than 430 deaths prevented, with an opportunity to prevent thousands more potentially fatal strokes as DOAC use continues to increase.

- **On HIV**, where expanding access to antiretroviral treatments, pre-exposure prophylaxis and post-exposure prophylaxis, provide the tools we need to have zero new HIV infections in England by 2030 – and in doing so, make England the first country in the World to have no-new HIV transmissions. A series of national deals struck by the NHS is enabling 87,000 people currently being treated for HIV and 61,000 people considered at high risk of contracting HIV to receive preventative treatment and the latest HIV drugs, wherever they are in England. Effective NHS treatment of people with HIV, and better access to preventative drugs PrEP and PEP have played a major role in helping to reduce HIV transmissions by 34% between 2014 and 2019.

- **On Hepatitis C,** following NHS England delivering its single largest medicines procurement with three pharmaceutical companies in 2018 with a deal worth almost £1 billion over five years, the NHS Hepatitis C Virus (HCV) Elimination Programme has made significant progress to keep the NHS in England on track to eliminate the virus well ahead of the World Health Organisation's (WHO) 2030 target. The WHO target of a 10% reduction in hepatitis C related death by

2020 has already been exceeded three-fold in England. By ensuring all patients can access Direct Acting Antivirals, deaths from HCV, including liver disease and cancer, have fallen by 35%, achieving the global target of reducing HCV related deaths below 2 per 100,000. HCV as a reason for liver transplants has fallen by 52.9%

25. Looking to the future, the NHS continues to take a lead on global challenges, such as in **antimicrobial resistance (AMR)** which, without action, could have a devastating impact on the delivery of care that we currently take for granted. In June of this year, the first two products to utilise a new, world-first 'subscription-style' payment model were purchased. This new model will incentivise companies to invest in this critical area, and help secure a pipeline of future treatment options for NHS patients.

Looking Forward

26. The pace of innovation continues to accelerate and presents huge opportunities in the years ahead for transforming health outcomes at individual patient and population level. In order to maintain progress on access and uptake, achieve value for money for taxpayers and ensure affordability for the NHS we will need to continue to focus and/or go further in six areas:

- **Maintaining the central role of NICE in determining the clinical and cost-effectiveness of new medicines.** We have transformed the capability and capacity of the NHS to develop commercial solutions that support companies in the value proposition they offer NICE, securing patient access and delivering strong value for the taxpayer. Medicines must continue to benefit from the internationally recognised, robust, and transparent evaluation process led by NICE. It is important to note that unlike any other area of healthcare expenditure, drugs occupy a unique and privileged position in our system. For every positive recommendation made by NICE, the NHS is under an automatic legal requirement to fund that treatment within 90 days. This underlines the importance of managing overall affordability so that there is headroom for discretionary investment in other important areas of healthcare.

- **Carefully managing overall spend on branded medicines to ensure affordability and sustainability for NHS finances**. Underpinning our success in building a positive access and uptake environment is the partnership we forged with the pharmaceutical sector through the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS). The current scheme, which was agreed between industry, Government and NHS England in 2018, places an annual cap of 2% on growth in the branded medicines bill. With the scheme set to end next year, we will work to agree a new voluntary scheme that supports sustainability for NHS finances while continuing to improve patient outcomes.

- **Driving greater value from existing drugs** – The NHS has been incredibly effective in its use of biosimilar and generic medicines, to capitalise on opportunities to deliver savings and to expand access to treatment. Earlier this year, we reported a £1.2bn saving on the NHS medicines bill over three years, achieved by securing better prices for hundreds of hospital medicines, but also

through NHS staff delivering a rapid adoption of biosimilar versions of drugs, including adalimumab (Humira®) that was once the health service's most costly drug. Given the increasing number of high value biologic medicines coming off patent in the coming years, it will be essential for NHS England to support rapid biosimilar market entry and competition.

- **Supporting and embedding medicines optimisation at all levels**. We also continue the 'Transforming and Integrating Medicines Optimisation ' (TIMO) programme to ensure that system prescribers, commissioners and providers have the tools needed to ensure the right medicines are given to the right patient at the right time. Working closely with pharmacists and wider clinical professions, good progress has been made in implementing the recommendations of the independent review of overprescribing – the National Overprescribing Review (NOR). Around one in five hospital admissions in over-65s and around 6.5% of all hospital admissions are caused by the adverse effects of medicines, demonstrating the opportunities for improved patient care and greater utilisation of finite NHS resources. Costs arising from definitely avoidable' adverse drug reactions because of improper use of medicines collectively costs nearly £100 million annually, in addition to the avoidable environmental impact of overtreatment.

- **Taking a proactive approach to ensuring clinical services are ready, willing and able to adopt new, high-impact treatments**. With an enhanced and sophisticated horizon-scanning function the NHS is increasingly able spot and plan for new interventions that can fundamentally change how care is delivered. Where we are the direct commissioner of services, we are already looking ahead with industry and providers to invest in and redesign pathways so patients can access cutting-edge treatments faster. We recognise that there is more that we can do, particularly in primary and community care, to further support the adoption of innovations that offer the greatest value.

- **Continuing to partner with industry on all the above –**the pharmaceutical industry has an important role to play in supporting the health service to deliver on the health challenges of the Long Term Plan and tackling health inequalities. We will continue to support industry bring forward innovations that deliver the greatest benefit to health and care as well as supporting collaborations that help us spread innovation. These commercial partnerships can go much deeper than simply securing access to the latest treatments. For example, the NHS partnership with GRAIL to test the Galleri blood test for the early detection of cancer, through to industry led initiatives and investment to support the NHS in patient case finding in the areas of Hepatitis C and atrial fibrillation highlight the breadth of opportunity.