HEADS OF AGREEMENT SUMMARY

The 2019 Voluntary Scheme for Branded Medicines Pricing and Access (Voluntary Scheme) is a non-contractual voluntary agreement between DHSC and ABPI - the representative body of the pharmaceutical industry in the UK – that aims to provide stability and predictability for all parties in terms of the UK's branded medicines expenditure and the medicines pricing and access environment for the period 2019-2023. The scheme aims to achieve a balance between patient access, affordability and supporting the development of innovative new medicines, including support for small companies.

The Heads of Agreement sets out the key terms of the agreement reached between the parties on the Voluntary Scheme, and represents their commitment to continue to work together to reach the full agreement.

In summary, the Heads of Agreement outlines the following:

- **Uptake, access and outcomes**
  - NHS England to provide more proactive uptake support and implementation planning for innovative, cost-effective medicines which provide a significant health gain; including committing to the objective of reaching the upper quartile of uptake for five highest health gain categories.
  - Government, NHS and industry to continue developing data infrastructure, including developing the Innovation Scorecard.
- **Value assessment**
  - More and faster NICE appraisals for new medicines including speeding up appraisal of non-cancer medicines to be in line with cancer medicine appraisals. Cost-effective new medicines will be available faster for patients, and come with guaranteed funding.
  - NICE basic cost-effectiveness threshold to be retained at the current range (£20,000 - £30,000 per QALY) for the duration of the scheme.
  - NICE committed to scoping and, where appropriate, initiating a review of technology appraisal methods.
- **Routes to market**
  - Single, shared approach to horizon scanning to support better financial and service planning
  - Opportunity for companies to engage earlier with the NHS/government through a single route, including case management where appropriate.
- **Commercial arrangements**
  - Opportunities for greater commercial flexibility for those companies who offer the best value new medicines, negotiated with NHS England. NHS England, with input from NICE and ABPI, committed to develop and publish a 'commercial framework' which will set out further operational detail once the Voluntary Scheme is in place.

    - Confidential sharing of commercial arrangements across the UK with all four countries to reduce duplication and work towards comparable commercial arrangements.
- **Affordability mechanism**
    - Industry agree to contribute to NHS financial sustainability through an overall cap on growth on NHS branded medicines sales at a nominal rate of 2.0% p.a., with member companies making payments based on net sales.
    - A new cap mechanism to improve 'stability' which takes into account overall branded medicine sales across the Voluntary and Statutory Schemes and parallel imports, although scheme members only pay for the voluntary scheme share.
    - Support for innovation through a rolling 36 month exemption from payments for new active substances and a significantly improved exemption for smaller companies.
    - The payment rate for 2019 is set at 9.6%, with subsequent years' payments to be determined by actual sales growth.
- **Scheme operation**
    - Continued support for innovative medicines in the first 3 years post-licensing including freedom of list pricing for new active substances and immediate line extensions.
    - Reduced bureaucracy for companies with routine Annual Financial Reviews (AFRs) no longer being required other than to support applications for price increases, and offering the option of a one-off settlement for historic cash payments.
    - Discontinuation of modulation, although existing modulated prices can remain.
    - Price increases will continue to need approval from DHSC, with a new provision for price increase approvals if there is evidence that a medicine is no longer economic to supply and where discontinuation would have a negative impact on patient health.