BGMA – Commercial Task & Finish Group

Meeting held on 3rd May 2023

Notes

Chaired by John Niland and Mark Samuel

Following the VPAS Roundtable in January, in order to further strengthen engagement and partnership working on a sub-national basis with the NHS, it was proposed that two task & finish groups (T&F) should be created to focus on further developing the commercial and clinical partnership offer.

Conclusio will work with the BGMA to agree Terms of Reference and work plans for each group and oversee the delivery of each.

These are the notes of the first meeting of the Commercial T&F Group.

Purpose

- Agree ToR.
- Achieve more equitable VPAS alternative successor scheme.
- Understand and articulate the fullest outlook on key issues.
- Identify where opportunities exist for equitable VPAS model to demonstrate value in supporting a population health proposition through branded generics/biosimilar industry partnership with NHS.

Draft outline ToR

- Each TF Group will be jointly chaired by a senior NHS Leader and a member of the BGMA Leadership Team.
- Each T&F will comprise a membership that includes senior NHS and Industry stakeholders who wish to work closely with industry partners.
- The Commercial T&F Group will develop a partnership strategy for each area and generate a range of proof points and case studies, which both demonstrate the impact of medicine as part of a population health approach and the implications of a reduction in medicines supply.
- It is anticipated that the Commercial T&F Group will meet once in-person and twice virtually. The aim is to have a joint in-person meeting of both the Clinical and Commercial T&F Groups where recommendations and supporting information will be presented to a senior meeting of the BGMA and its core members.

Discussion themes

NHS external affairs, landscape and perspective

- Key challenge is that DHSC appraises value based on cost.
- The case for generics is commercial also.
- Uncertainty over the extent to which feedback from ICBs will resonate with Treasury.
- Uncertainty about the level of appreciation of the unintended business, financial and market implications of an inequitable VPAS held at both strategic and operational levels in the NHS.

Key factors in developing the issue and engagement narrative.

- Important to amplify generic sector voice. BGMA needs to show its clear authority and credibility for being involved in the VPAS negotiations. Founded on:
  - Disproportionate impact of VPAS on sector.
  - Population health and supply consequences for the UK.
  - Strong market stimulates new products, innovation in the off-patent sector and market competition which lowers medicines acquisition costs.
- NHS and health narrative dominated by patented sector and doesn't give enough space to importance of branded generics and biosimilars.
- Clinical benefits of branded generics and biosimilars for patients.
- When we engage on this, we are not necessarily engaging with people that are acutely informed on this issue.
- A pro-competitive approach in the market is an advantage in stimulating new meds and developing local offers.

Key commercial considerations

- It was also noted that we should also consider any additional areas of redress from a legal and procurement perspective.
- There was a need for a compelling commercial argument which demonstrates both the impact of the levy but also the opportunity of enhanced medicines optimisation, delivery of population health benefits and the reduction in health inequalities brings.
- It was noted that alongside the work of this group there is a clinical task and finish group which is focusing on a number of pathway examples such as asthma and ulcerative colitis (Biosimilar); it will develop a framework that emphasise the role of medicine in terms of optimising patients' outcomes and the risk and issues associated with restricting prescribing and reducing overall supply.
- It is important that we develop a transformational case for change and vision for the future, beyond the transactional realities, which could inform any successor scheme and demonstrate how the industry can work in partnership with the NHS on a sub national basis. This will be critical in terms of credible clinical engagement and to an extent "winning hearts and minds" and stressing that rather than putting prices up and the BGMA and its membership will focus instead on demonstrating the population wide value that medicines Optimisation brings.
- It was also recognised as critical that this work provides an NHS wide opportunity to position and repurpose existing and impactful BGMA messages and impact reports such as that developed by the LSE.

NHS realities – an overview from John Leslie

John Leslie is an experienced NHS Director, and he gave an overview of the challenges facing the NHS:

- That whilst the system" broke even "last year the next five years will see a significant increase in financial pressures and ICSs will have to be a lot more transformational in their outlook and embed system wide approaches to pathway delivery.
- That in some specialty areas we may see a return to payment by results and tariff-based delivery and performance management.
- The level of elective backlog is significant and will take circa 5 years to clear. At the same time the majority of patients (85%) on an elective waiting list have yet to receive a first outpatient appointment. This may present more opportunities for community-based care and medicine-based care for patients with long term conditions. The level of avoidable harm is significant in this regard.

BGMA Update

Mark provided an overview of some of the key factors from a BGMA perspective and updated on the judicial review process. In addition, he highlighted:

- All savings flow directly to the treasury and not to the front line for the benefit of the patients.
- Potentially cost pressure of VPAS for each ICS is circa £43 million.
- Direct and indirect Cost of companies withdrawing from the UK Market.
- NHS already have the lowest generic prices in Europe.
- The realities of a finite supply can't be underestimated, and global organisations make rational decisions about where they supply medicines stock to. The UK could lose out in this regard.
- Real consequence of price increases/restricted choice and considerable impact on the population health aims and objectives of the NHS.

Legal considerations

In addition to the Judicial Review, further consideration should be given to

- Any redress with the Competition and Market Authority (CMA) given that what is being suggested is against the core of the 1998 Competitions Act.
- Engaging with Monitor given that VPAS restricts parent choice and increase costs.
- Considered engagement with NHS procurement experts.
- Engagement with a wider range of government departments with competing priorities who are likely to be materially impacted by the VPAS decision i.e., FCO / Business and Trade given that many of BGMA's members are multinational and make significant investment in the U.K. and contribute to the balance of payments.

John Niland in response highlighted:

- Need to look at the options in relation to a levy on profits rather than turnover.
- Take a different approach product where there is competition and where there is not.
- Ensure economic argument and health outcome argument are aligned.
- That there is a potential to offset against what is already a significant R & D investment.
- Consider the offsets in a range of areas such as balance of payments/ trade/employment.

- Supply chain sustainability.

Commercial Business Case

Jeremy Hooper presented a framework for the business case which is attached which looks at the wider value of branded generics and biosimilars in 3 areas;

- Value in the medicine, linking with the clinical task and finish group and demonstrating the benefits of maintaining patient adherence to medicines in terms of reduced exacerbations or reduction in the need for elective surgery.
- Value in Research & Development which companies need to do to bring branded generic or biosimilar products to market once the originator company patent has expired or to show the value in extending use of the medicine to more patients.
- Value to the wider economy in terms of jobs and exports for UK manufactured products.

Ultimately looking to present a case for a reformed VPAS which maintains sustainable access to effective medicines while incentivizing the pharmaceutical industry to support NHS priorities.

Key points of discussion included.

- Ensuring the case is aligned with current methodology the NHS understands.
- The importance of referencing and repurposing NHS Data.
- Need to Demonstrate the broader benefits beyond the product (demonstrate broader transactional opportunities) and link to a range of high-volume pathway and prescribing examples (this is being taken towards by the Clinical T&F)
- That the value of increasing access to common medicines to the population at large is recognized and that there is an emphasis on the potential impact on quality adjusted life years for a large number of lives through enhancing access to simple, long-established therapies. It was noted that comparing this with the cost of bringing one novel specialist agent to market would be useful.