

# Memorandum of Understanding between NHS England, the Association of the British Pharmaceutical Industry (ABPI) and the British Generic Manufacturers Association (BGMA)

This Memorandum sets out the nature of the partnership between NHS England, ABPI and BGMA through the Pharmaceutical Industry Sector Partnership, and provides a framework within which all parties can address strategic issues of mutual interest. It sets out our shared ambition, agreed principles for engagement and the Partnership's governance structure and terms of reference. The annexes to the Memorandum set out the respective roles of the partners, and the Partnership's joint priorities.

This Memorandum of Understanding is not legally binding and shall not give rise to any rights or liabilities for any party.

We recognise that further thinking is required to set out the Partnership's work programme and we have identified key priorities on which the Partnership will focus in the first year of this Memorandum. We also recognise that both ABPI and BGMA will have specific priorities and issues that they will want to work on with NHS England.

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## Joint statement

NHS England, ABPI and BGMA share the objectives of facilitating high-quality care for all and improving patient outcomes both now and in the future through the use of medicines that help patients and those who support them (e.g. health care professionals) in providing effective and cost-effective practice.

Medicines play a crucial role in maintaining health, preventing illness, managing chronic conditions and curing disease. In an era of significant economic, demographic and technological challenge it is crucial that patients get the best outcomes from medicines as part of high-quality NHS services. NHS England, ABPI and BGMA will work openly and transparently together, with the ambition that the right patients get the right choice of medicine, at the right time.

All three organisations support the ambition set out in Innovation Health and Wealth 'for an NHS defined by its commitment to innovation, demonstrated both in its support for research and its success in the rapid adoption and diffusion of the best, transformative, most innovative ideas, products, services and clinical practice'.

All three organisations share the ambition that the UK remains an important location for pharmaceutical industry investment in the development and manufacture of all medicines, recognising the industry's contribution to the health and wealth of the UK and its citizens.

## 1. Shared purpose

### 1.1 Ambition and objectives

The NHS needs to be able to deal with challenges ahead, such as an ageing population, a rise in the number of people with long-term conditions, and greater public expectations. Combined with rising costs and constrained financial resources, these trends threaten the long-term sustainability of the health service.

NHS England and the pharmaceutical industry share mutual ambitions in improving health outcomes and quality of care. The transformational change needed across the health system will be delivered more effectively through effective cooperation and collaboration where we all stand to gain.

NHS England and the pharmaceutical industry share objectives to:

- Work together with integrity and probity for the benefit of patients and the public.
- Improve health outcomes through early collaboration and understanding of the future advances in medicines for example, evaluating the potential impact of research pipelines on healthcare system design to maximise the benefits for patients and realise system efficiencies where appropriate.
- To deliver high-quality standards of patient care and improved outcomes, consistently and equitably across the NHS, through optimising and accelerating the pace and scale of access, adoption and diffusion, and safe and effective use of proven established medicines and cost-effective innovative medicines.
- Lead the way in support of clinical research so NHS patients are amongst the first to benefit from medical advances.
- Identify and share opportunities for good practice in transparent and value-for-money partnership arrangements across the NHS.
- Support the development of a safe and sustainable NHS.
- Support the development of economic growth in the UK.

## 1.2 Principles

NHS England, ABPI and BGMA agree to:

- Work together openly, transparently and constructively.
- Cooperate in pursuit of our shared objectives.
- Appropriately reflect the content and the spirit of the Memorandum in each other's business plans and strategies.
- Brief each other on matters of mutual interest and alert each other to emerging issues which may raise concerns in our respective constituencies.
- Subject to reasonable confidentiality restrictions, advise each other of matters of mutual concern.

## 2 Governance and terms of reference for the Pharmaceutical Industry Sector Partnership

The Pharmaceutical Industry Sector Partnership is a sector partnership of the Industry Council. The Partnership provides a forum for parties to progress shared objectives by identifying and tackling key issues of mutual interest. It also provides an opportunity to develop a better mutual understanding and sharing of expertise through knowledge and role exchanges.

### 2.1 Membership

The group will be alternately chaired by the Director of Partnerships, NHS England, the Chief Executive, ABPI and the Director General, BGMA. It will address specific topics and therefore relevant subject matter experts from NHS England, the pharmaceutical industry or wider organisations, such as DH, NICE, MHRA may also attend for specific agenda items.

The Partnership is a decision-making forum where appropriate on agreed policies and work programmes; members need to be of the appropriate level of seniority. The Partnership recognises the governance arrangements of the individual partners, and that some decisions will need to be referred to the respective organisational Boards. Each partner will have a small group of core attendees with additional attendees relevant to specific agenda items.

#### • NHS England

Core membership will be:

Director of Partnerships

Head of Partnerships

Director of Innovation

Head of Commercial and International Innovation

Chief Pharmaceutical Officer with ability for Deputy Chief Pharmaceutical Officer to deputise

Clinical Director, Specialised Commissioning or Pharmacy Lead, Specialised Services or Head of Specialised Services as alternates

Regional Medical Director

Partnerships Manager – Secretariat

Other staff from NHS England may be asked to attend, e.g. finance or commissioning operations colleagues, subject to agenda items and/or specific task and finish group deliverables.

#### • Association of the British Pharmaceutical Industry (ABPI) – ABPI will act as the trade association representing the Bio Industry Association (BIA) and the geographical pharmaceutical groups

Chief Executive Officer

NHS Partnership Director

Value and Access Director

Commercial Director

ABPI/EMG

ABPI/JPG

ABPI/APG

ABPI/BPG

ABPI secretariat

Deputies will be members of the ABPI Board of Management.

- **British Generic Manufacturers Association (BGMA)**

Director General

Technical Director

Economic Manager

Board Chair

Economic and Commercial Chair

Regulatory Chair

Biosimilars Chair

Regulatory Manager & secretariat

Deputies will be vice chairs of working groups.

### Terms of Reference

- To provide a forum for NHS England and the pharmaceutical industry to discuss areas of mutual interest and benefit in a planned and managed approach, which is flexible, strategic and proportionate.
- To share goals and priorities, and provide a channel for raising, discussing and resolving strategic issues specific to the relationship between NHS England and the pharmaceutical industry.
- To support the development of a commissioning system that is ready and capable to rapidly adopt and diffuse proven established medicines and cost-effective innovative medicines for the benefit of patients, in order to drive improved patient outcomes and improved system efficiencies where appropriate, and to reduce unwarranted variation in usage of medicines.
- To undertake work as requested by the Industry Council on pharmaceutical industry specific issues, and to work collaboratively with other Industry Council sector partnerships on cross-cutting issues.
- To provide advice to the Industry Council on pharmaceutical industry specific issues.
- To identify opportunities to improve outcomes for patients through innovative practice and partnerships.
- To agree and confirm areas of common interest and priorities for joint work.
- To support the public, patients and health care professionals in optimising the use of medicines in everyday clinical practice.

## 2.2 Process

### Ways of working

We recognise that most interactions between NHS England, ABPI and BGMA will take place at a national level with three tiers of engagement:

- Industry Council – a cross-industry forum chaired by NHS England and consisting of trade association leads and designated national directors to discuss the opportunities and impact of wider NHS and industry developments on achieving shared objectives, development of joint approaches and strategies, and review issues identified as being of strategic importance to the delivery of mutual goals.
- Bilateral relationships – one-to-one relationships between ABPI, BGMA and NHS England directors to discuss specific issues relating to an individual NHS England work programme or industry issue.
- Sector partnerships – the NHS England/ Pharmaceutical Industry Sector Partnership established by NHS England national directors, ABPI and BGMA to address and develop solutions for specific business, operational or healthcare opportunities and challenges as outlined in this Memorandum.

We also recognise that individual member companies of both ABPI and BGMA will have continued engagement with the NHS at local, regional and national level.

### Governance and management of the sector partnership

The Partnership will typically meet two to three times a year unless agreed otherwise by its membership.

Both NHS England and pharmaceutical industry will commit to ensuring regular attendance from their senior representatives, with deputies attending only by exception.

All members will be able to propose agenda items for discussion. All supporting documentation and agenda items will be circulated to members prior to the meeting giving time to consult with colleagues/ members where required. Papers should normally be prepared by the member organisation proposing the topic, or jointly by all member organisations. All minutes and agreed actions will be circulated in a timely fashion to enable follow up actions to be clearly communicated to all interested stakeholders.

Bilateral conversations between the pharmaceutical industry and NHS England should continue to promote active engagement and continue the dialogue outside formal meeting structures to support richer understanding and closer collaboration.

### Duration of the Memorandum of Understanding

The Memorandum, including the terms of reference, membership and work priorities of the group will be kept under review, and the Partnership will formally review it every five years.

### **Priorities and annual work plan for the Pharmaceutical Industry Sector Partnership**

As part of the annual planning cycle, NHS England, ABPI and BGMA will agree a programme of work that sets out mutual expectations for the year, including decision making on, and/or response to, broader health and life sciences policy.

### **Task and finish groups**

Task and finish groups will be based on joint agreement of priorities and set up as required. All member organisations will have the opportunity to join any task and finish groups that are established.

### **Reporting and decision making**

The Partnership has the authority to implement and oversee progress of agreed policies and work programmes. The Partnership recognises that some decisions will need to be referred to the respective organisational Boards. The Partnership also has the remit to contribute to development of new policy. The Partnership will provide an update to the Industry Council at each of their meetings.

NHS England, ABPI and BGMA will keep each other informed about developments in matters in which they share a mutual policy or operational interest.

### **Secretariat**

NHS England will provide the administrative support for the Partnership.

### **Resourcing**

There is not a separate programme budget identified for this Partnership. Respective organisations will be committing people and time to the Partnership and any relevant task and finish groups.

### **2.3 Respecting confidentiality**

Information shared during engagement between industry and members of NHS England could fall within a number of categories and it is important the principles and legal requirements relating to each are strictly adhered to, for example, Freedom of Information legislation, commercial in confidence, academic in confidence. The Partnership will at all times conduct its business so as to comply with UK competition law.

# Annex A: Roles

## NHS England

NHS England is an autonomous non-departmental public body which operates within the wider health and social care system. Its overarching role is to ensure that the NHS delivers continuous improvements in outcomes for patients within the resources available. The Board will fulfil this role through its leadership of the reformed commissioning system. Working in partnership with clinical commissioning groups (CCGs) and a wide range of stakeholders, it will secure better outcomes, as defined by the NHS Outcomes Framework; it will actively promote the rights and standards guaranteed by the NHS Constitution; and will secure financial control and value for money across the commissioning system.

The new system of commissioning for the NHS requires the NHS England to provide national consistency in areas like quality, safety, access and value for money whilst promoting the autonomy of CCGs to make decisions that are in the best interests of their community.

## ABPI

ABPI represents the research-based pharmaceutical industry operating in the UK; including in its capacity as the official negotiating body for the scheme governing the pricing for branded medicines. The ABPI works with the NHS to ensure patients have rapid access to clinically and cost-effective medicines and companies receive the appropriate reward for investment in developing new medicines. The ABPI participates fully in the development and implementation of processes that support the adoption and diffusion of innovative medicines and promotes high-quality participation in those processes by pharmaceutical companies.

In fulfilling this role, ABPI:

- Communicates with a range of stakeholders to raise awareness of the industry and medicines.
- Proactively engages with NICE as a constructive partner.
- Collates and shares with NHS England the views of the research-based pharmaceutical industry in the UK, having respect for the needs of NHS England, the broader NHS, the DH, NICE and other stakeholders.
- Provides insights into the R & D and commercial environments for the research-based pharmaceutical industry and experience of working with multiple partners across the healthcare system – including patients, clinicians, the NHS, commissioners and NICE – to inform policy and decision making.
- Participates in public consultations on NHS England policies, frameworks and processes.

- Represents companies in fora with government including Ministerial Industry Strategy Group, Medicines Access Group, Metrics Oversight Group and Supply Chain Forum.
- Encourages companies to participate effectively in NHS England processes.
- Encourages companies to partner directly with NHS at a national, regional and local level.
- Communicates with companies to ensure a good understanding of NHS England.

## BGMA

The BGMA represents the interests of UK-based manufacturers and suppliers of generic and biosimilar medicines and promotes the development of the generic and biosimilar medicines industry in the United Kingdom. The BGMA represents the views and interests of its members and the generic and biosimilar medicines industry generally to the UK government, the devolved administrations, regulators, other relevant third parties, including where appropriate the institutions of the European Union.

The BGMA operates through a series of expert working groups that cover Regulatory Affairs, Economic and Commercial (Pricing, Reimbursement, Market Access, etc), Secondary Care, Sustainability and Biosimilar medicines. As part of this work, the BGMA:

- Is the industry body designated by the Secretary of State under section 266(6) of the National Health Service Act 2006 to represent manufacturers and suppliers of generic medicines.
- Works continuously with the DH to ensure the effective implementation of the Scheme M voluntary agreement on long-term arrangements for reimbursement of generic medicines and to ensure efficient take up of new generic medicines in the interests of maximising patient access to medicines and the efficiency of the NHS.
- Has agreed with ministers a joint review of the sustainability of the generic and biosimilar medicines industry in the UK to ensure the industry's ability to continue to supply high-quality, cost-effective medicines to the NHS.
- Promotes the positive market environment for biosimilar medicines to ensure that the NHS is able to take advantage of increased affordability and accessibility to biopharmaceutical medicines.
- Works with relevant NHS and DH bodies to review the effectiveness of the secondary care generic and biosimilar medicines market.
- Works to create the most cost-effective UK regulatory environment possible and promote the quality of generic medicines.

# Annex B: Joint priorities for NHS England, ABPI and BGMA

The Partnership will need to identify and establish a work programme of joint areas of common interest and priorities. Objectives, timescales, approach, measures, resources and outputs will also need to be agreed in partnership. The work programme will be kept under review.

The work programmes of each sector partnership will be kept under review to avoid duplication and/or to identify any gaps. Task and finish groups may be set up drawing members from across sector partnerships when necessary on cross-cutting issues.

## 1. Joint priorities

### 1.1. Medicines optimisation

Medicines optimisation is a patient-focused, holistic approach to getting the best outcomes from investment in and use of medicines. It requires an enhanced level of patient-centred professionalism, including partnership in decision making between a clinical professional and a patient.

NHS England, ABPI and BGMA commit to working together with other stakeholders effectively to communicate, promote and implement medicines optimisation throughout the NHS to achieve the best outcomes at a local level.

*Medicines Optimisation: Helping patients to make the most of medicines. Good practice guidance for healthcare professionals in England, May 2013* defines medicines optimisation and sets out four guiding principles describing medicines optimisation in practice.

### 1.2. Information and planning

NHS England, ABPI and BGMA recognise the unique opportunity presented by the availability of unprecedented levels of electronic health data. This opportunity will be jointly harnessed to improve patient outcomes, reduce health inequalities, increase NHS cost effectiveness and enhance efficient research value for the UK pharmaceutical industry.

This will involve collaboration on several fronts such as:

- Raise awareness of 'big data' and building of a shared understanding of how it can be used to derive insight and value for the benefit of patients.
- Horizon scanning (e.g. through Pharmascan) for new medicines and other relevant innovative technologies and therapies.

### 1.3. Research and innovation

NHS England, ABPI and BGMA recognise the importance of embedding a culture of research and innovation within the NHS. All partners will continue

to engage with existing stakeholders such as National Institute for Health Research, Health Research Authority and the Ministerial Industry Strategy Group to work towards:

- The UK remaining a destination of choice for global clinical trials.
- The UK strengthening capabilities in running 'real world data' studies.
- Stratified medicines and personalised healthcare approaches are adopted appropriately and consistently and quickly within the NHS.
- Beneficial innovation in medicines regulation is embraced in the UK.
- A shared commitment to transparency in research findings taking into account patient and commercial confidentiality.

### 1.4. Patient safety

NHS England, ABPI and BGMA commit to working together to improve patient safety by:

- Improving collection of relevant NHS data such as medication errors and collaborate to determine best use of the data to improve NHS patient safety and medicines optimisation.
- Investigating developments in new technology such as eHealth/informatics and point of dispensing scanning where undertaken to improve NHS patient safety.
- Supporting and communicating the aims and objectives of the UK Antimicrobial Resistance Strategy.
- Improving understanding within the NHS implications of European pharmacovigilance legislation.
- Considering how patients can best receive the right information so that they can take informed decisions about their medicines consumption.

### 1.5. Biosimilars

NHS England, BGMA and ABPI recognise that biosimilar medicines offer potential benefits for both the NHS and patients. All partners will work together on the appropriately managed uptake of biosimilars across the NHS:

- Reflecting advice from the relevant regulatory authorities and clinical standard setting bodies, and
- Providing appropriate information and guidance to stakeholders across the NHS including clinicians about biosimilars medicines.

## 1.6. A Call to Action

NHS England and the pharmaceutical industry will work together to discuss and address the strategic issues set out in *A call to action* to deliver a safe and sustainable NHS. *A call to action* can be found at [http://www.england.nhs.uk/wp-content/uploads/2013/07/nhs\\_belongs.pdf](http://www.england.nhs.uk/wp-content/uploads/2013/07/nhs_belongs.pdf)

## 2. Individual priorities for ABPI and BGMA

We recognise that both ABPI and BGMA will have specific priorities and issues that they will want to work with NHS England on bilaterally; the Memorandum therefore also sets our specific work programme priorities for both individual organisations:

### ABPI

NHS England and ABPI recognise their mutual interest and respective responsibilities in encouraging adoption and diffusion of innovation that enables the research-based pharmaceutical industry to deliver new and improved medicines for the benefit of NHS patients.

### 2.1. Access, adoption and diffusion of innovative medicines (Innovation, Health and Wealth IHW)

DH is the sponsor of the pharmaceutical industry within Government, and has responsibility through its participation in the joint Office for Life Sciences' programme to promote the creation of an environment in which life sciences innovation can flourish. This role is underpinned by the Pharmaceutical Price Regulation System (PPRS).

The PPRS 2014 negotiated between the Department of Health and the ABPI on behalf of industry came into force on 1 January 2014. Chapter 4 of the PPRS which is relevant to access, adoption and diffusion of innovative medicines can be found here [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/282523/Pharmaceutical\\_Price\\_Regulation.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282523/Pharmaceutical_Price_Regulation.pdf) and it is an objective of both parties to work diligently towards the full implementation of the measures identified in the PPRS and to achieve the overarching objectives set out in Chapter 1 of the PPRS. The measures include (but are not limited to) implementation of IHW, NIC, automatic inclusion on formulary, scorecard, NICE Good Practice Guide, AHSNs and commitments within NHS Mandate and NHS Constitution.

NHS England and ABPI both support the implementation of IHW. Implementation of IHW may be addressed both in the Pharmaceutical Industry Sector Partnership and in the IHW Board. The work programmes of each sector Partnership will be kept under review to avoid duplication and/or to identify any gaps.

NHS England and ABPI will work together to review and align incentives and levers to support the adoption and diffusion of innovation including the use of innovative medicines and improve quality and healthcare outcomes.

### 2.2. Specialised commissioning

The establishment of NHS England Specialised Services National Clinical Reference Groups (CRG) offers a real opportunity to develop new partnership ways of working between those designing future services and industry, building capability and products for the delivery of healthcare. The compact agreement agreed between NHS England and ABPI can be found here <http://www.england.nhs.uk/tag/compact-agreement/> and provides a framework for staff in the NHS and industry to look ahead to new ways of working.

NHS England and ABPI will work together within the compact agreement framework to improve patient outcomes, through ensuring patients receive high quality care and have access to appropriate medicines.

NHS England Specialised Commissioning team and ABPI will collaborate on the development of the specialised services five year strategy.

### BGMA

Through the use of a range of measures including information, incentives and guidance, the NHS has been able to support appropriate prescribing and dispensing of generic medicines, thereby ensuring value for money and supporting investment in other services. The Partnership allows the opportunity for industry and NHS England to work together to support optimal use of medicines, by encouraging and supporting the use of generic medicines where available and clinically appropriate, and ensuring that patients are supported to get the most from the generic medicines they are prescribed.

This objective complements the Scheme M Agreement between the DH and the BGMA, and their joint work stream on the sustainability of the generic medicines industry in the UK.