

**GREATER MANCHESTER HEALTH AND SOCIAL CARE
STRATEGIC PARTNERSHIP BOARD**

5

Date: 24 February 2017

Subject: Pharmaceutical Industry Memorandum of Understanding

Report of: Warren Heppolette and Jon Rouse

PURPOSE OF REPORT:

The purpose of the report is to propose a Memorandum of Understanding (MoU) which demonstrates how a strategic partnership with the Pharmaceutical Industry will support the achievement of Greater Manchester's ambitions in relation to Taking Charge, and the wider Greater Manchester Strategy.

The MOU outlines the shared vision, goals, operating procedures and governance principles for the relationship between Greater Manchester and the Pharmaceutical Industry. It has four shared aims:

- Transformation of the health, wellbeing and wealth of the people of GM,
- Optimisation of care,
- Development and adoption of innovation at pace and scale
- Create an environment for flexibility and opportunity to develop outcomes based pricing methods,

This MoU is one element which will support the wider ambitions and delivery of the medicines enabling workstream, led by the medicines strategy board.

RECOMMENDATIONS:

The Strategic Partnership Board is asked to:

- Approve the signing of the MoU.
- Note the context of the MoU within the wider medicines enabling workstream.
- Support the objectives of the global industry seminar.

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1.0 INTRODUCTION

1.1. On 27th September 2016, a delegation of pharmaceutical industry UK General Managers and ABPI officials met with senior GM leaders from across the sectors to explore challenges and potential opportunities for collaboration. The meeting, co-chaired by Sir Howard Bernstein (CEO, Manchester City Council), Mike Thompson (CEO, Association of the British Pharmaceutical Industry), and Jon Rouse (Chief Officer, GM Health and Social Care Partnership) identified two key areas for development, capitalising on the unique conditions and environment that exist in GM:

- Co-creation of new models of working that include engagement with pharmaceutical companies to provide improved outcomes for people while addressing the clinical and financial sustainability challenges of GMHSCP.
- Development and expansion of a globally competitive 'living lab' based on GM's interconnected data capability, generating real world evidence for research and assessment of value of medicines.

1.2. The meeting concluded with agreement to establish an ongoing working productive relationship between Greater Manchester and the Pharmaceutical Industry. This has been formalised within the attached Memorandum of Understanding (MoU) and associated governance.

1.3. The Greater Manchester Health and Social Care Partnership (GMHSCP) is developing the medicines enabling workstream to support the wider ambitions and delivery of the Greater Manchester transformation programme. This MoU is one element which will support delivery of these programmes.

2.0 ESTABLISHING JOINT WORKING GOVERNANCE

2.1. The GMHSCP and Health Innovation Manchester has been working closely with the trade associations of the pharmaceutical industry on behalf of their members. To develop this MoU. This includes the Association of the British Pharmaceutical Industry (ABPI), Ethical Medicines Industry Group (EMIG) and the British Generic Manufacturers Association (BGMA).

2.2. The lead for this work has been taken by GMHSCP and ABPI, with Jon Rouse and Mike Thompson, the respective Chief officers, jointly chairing the GM and Pharmaceutical Industry Partnership Group. Core members of the partnership group include named representatives from:

- GMHSCP executive
- ABPI
- EMIG
- BGMA
- Health Innovation Manchester (including NWeH & GMAHSN)

- Association of GM CCGs (AGG)
- Greater Manchester Medicines Management Group (GMMMGM) Chairs
- GM Provider Federation Board
- GM Local Pharmaceutical Committee
- GM Combined Authority
- GM Primary Care Advisory Group
- Additional members and expertise may be co-opted as required, e.g. health economic, NHS procurement, senior industry expertise.

2.3. The partnership group has met 3 times within December 2016 and January 2017 to oversee the development of the MoU and will continue to oversee partnership work between GM and Industry on an ongoing basis.

2.4. Health Innovation Manchester (HinM) is developing a coordinating hub through which individual companies, and/or collectives of member companies, will co-develop solutions to healthcare priorities identified by GMHSCP. This hub is intended to be operational from May 2017, iterated in the first 12 months to refine its value for GM and industry.

3.0 ENGAGEMENT TO DATE

3.1. The MoU has been drafted jointly by GMHSCP and ABPI and received input from members of the partnership group.

3.2. It was circulated for comments in early January. Industry comments were sought from ABPI, EMIG and BGMA boards. Within Greater Manchester comments were sought from GMHSCP leaders, GMCA chief executives, GM provider federation Board, Association of GM CCGs, Health Innovation Manchester board and members of the GM Medicines Management Group (GMMMGM).

3.3. We received over 150 comments or edits from 39 individuals or organisations. These were considered by the partnership group on the 23rd January and following consultation with SPBE this final version has been agreed.

4.0 MEDICINES WORKSTREAM AND STRATEGY BOARD

4.1. As indicated at the November Strategic Partnership Board, a medicines enabling workstream is currently being established. The workstream is intended to be operational by April 2017; overseen by the Medicines Strategy Board, chaired by Dr Richard Preece, Executive lead for Quality.

4.2. The GM medicines strategy will aim to link all aspects of medicines (and devices, diagnostics, med tech and telemedicine) together in a unique way to improve population health, wealth and wellbeing of the people of Greater Manchester.

4.3. Further details on the governance and draft strategy will be presented to SPB in the coming months. The establishment of this MoU is one element within a significant programme of work to support the transformation of care in Greater Manchester.

5.0 EARLY SUCCESS - GLOBAL INDUSTRY SEMINAR

- 5.1. Greater Manchester is one of the most advanced health economies in the world for research and development with electronic health records.
- 5.2. HinM and ABPI are hosting global industry leaders in Manchester on the afternoon of 24th February, to showcase the real world data evaluation capabilities of Greater Manchester.
- 5.3. Fifteen multinational companies are attending this meeting, to assess the potential for developing research and development relationships with Greater Manchester; building on the success and learnings from the Salford Lung Study.
- 5.4. This is intended to place Greater Manchester as a key UK and global location for the growth of jobs and investment in the thriving life sciences industry; to rival the 'golden triangle' of Cambridge, Oxford and London.

6.0 NEXT STEPS AND OUTLINE TIMESCALES

- 6.1. It is essential to engage with all parts of the system over the coming months to establish this different relationship with the pharmaceutical industry, and ensure it is understood, refined and supported.
- 6.2. The outline timescales are detailed below.

| Work area | Timescales |
|--|---|
| Medicines strategy board | |
| <ul style="list-style-type: none">• Governance drafted and consulted upon• Board established to lead all GM medicines work | Feb - Mar 17 Apr 17 |
| Medicines strategy development | |
| <ul style="list-style-type: none">• Ongoing engagement with stakeholders• Working groups to define work areas• Draft to GM system for consultation• Approval of medicines strategy• Strategy workplan implementation | Dec 16 - Apr 17 Jan - Mar 17 Feb - Apr 17 Apr - May 17 May 17 onwards |
| Global Industry R&D seminar | |
| <ul style="list-style-type: none">• Demonstrate GM real world capabilities• Acquire global R+D partners for GM• Initiate new trials in GM bringing inward investment | 24 th Feb 17 Mar 17 onwards 2017 onwards |

7.0 RECOMMENDATIONS

7.1. The Strategic Partnership Board is asked to:

- Approve the signing of the MoU.
- Note the context of the MoU within the wider medicines enabling workstream.
- Support the objectives of the global industry seminar.

Securing productive partnership working between Greater Manchester and the Pharmaceutical Industry to deliver a transformation in population Health and Wealth

A memorandum of understanding between Greater Manchester and the Pharmaceutical Industry

Partners to the Memorandum of Understanding on behalf of their respective members:

- **Greater Manchester Health and Social Care Partnership**
- **GM Combined Authority**
- **Health Innovation Manchester**
- **Association of the British Pharmaceutical Industry (ABPI)**
- **Ethical Medicines Industry Group (EMIG)**
- **British Generic Manufacturers Association (BGMA)**

Date of agreement: 24th February 2017

Joint Statement

The goal of the Greater Manchester Health and Social Care Partnership (GMHSCP) is:

“To see the greatest and fastest possible improvement to the health, wealth and wellbeing of the 2.8 million people in the towns and cities of Greater Manchester.”

Our best chance of improving lives, population health and wellbeing will be achieved through adopting a systematic approach to the improvement of health in communities; with a focus on self-care, education, and maintenance of health, not just treating ill health.

In combination with other supportive inputs, medicines play a crucial role in maintaining health, preventing illness, managing long-term conditions and curing disease across pathways and whole systems.

In an era of economic, demographic and technological challenge, it is essential that people gain the best possible outcomes from their medicines and the Greater Manchester economy secures the best value from its investment both now and in the future, through effective use of innovative and established medicines.

This Memorandum of Understanding (MoU) demonstrates how delivery of the GMHSCP goal will be supported through a strategic partnership with the Pharmaceutical Industry.

The organisations signing this MoU share the ambition that Greater Manchester (GM) is recognised as a world-leading location in the adoption of clinically- and cost-effective medicines; and an important global site for real world evidence (RWE) generation and development and evaluation of precision medicine. It represents part of GM's response to the challenge of the recent independent Accelerated Access Review that called for clear local routes to get effective products to patients.

1 Background

- 1.1 On 27th September 2016, a delegation of pharmaceutical industry UK General Managers and ABPI officials met with senior GM leaders from across the sectors to explore challenges and potential opportunities for collaboration. The meeting, co-chaired by Sir Howard Bernstein (CEO Manchester City Council), Mike Thompson (CEO ABPI), and Jon Rouse (Chief Officer, GMHSCP) identified two key areas for development, capitalising on the unique conditions and environment that exist in GM:
- Co-creation of new models of working that include engagement with pharmaceutical companies to provide improved outcomes for people while addressing the clinical and financial sustainability challenges of GMHSCP.
 - Development and expansion of a globally competitive 'living lab' based on GM's interconnected data capability, generating real world¹ data for research and assessment of value of medicines.
- 1.2 The meeting concluded with agreement to establish the Greater Manchester and Pharmaceutical Industry Partnership Group (GMPIPG), setting out a framework and principles for collaboration in order to progress these issues.

2 The Parties

The MoU sets out the shared commitment of parties to deliver benefits for the people of Greater Manchester, GMHSCP (including Health Innovation Manchester (HInM)), the research-based pharmaceutical companies represented by the ABPI and EMIG, and the generic and biosimilar medicines industry represented by the BGMA. Additional parties may in future join this MoU by mutual agreement.

Further details of the parties are contained within the appendix.

3 Purpose of the MoU

- 3.1 The purpose of this MoU is to set out the shared vision, goals, operating procedures and governance principles for the relationship between Greater Manchester and the Pharmaceutical Industry.

¹ Real World data – healthcare data (near real time) that is collected outside the controlled constraints of conventional randomised clinical trials to evaluate what is happening in normal clinical practice. <http://www.abpi.org.uk/our-work/library/industry/documents/vision-for-real-world-data.pdf>

3.2 The parties to the MoU, and individual companies represented by the parties, will work in partnership on programmes of work that make best use of Greater Manchester data systems and medicines to be adopted and optimised at pace and scale, aligned to the themes of GMHSCP transformation plan to:

- 1 Radically upgrade population health prevention
- 2 Transform community based care and support
- 3 Standardise acute hospital care
- 4 Standardise clinical support and corporate functions
- 5 Enable better care

4 Shared Aims

GMHSCP and the pharmaceutical industry will work in partnership to achieve the following aims to benefit the people of Greater Manchester:

4.1 Transformation of the health, wellbeing and wealth of the people of GM:

- Support social values and the economic development of GM through collaborative arrangements, research, infrastructure, and the sharing of skills, knowledge and expertise to benefit patient care;
- Drive inward investment from the biopharmaceutical industry to the region, utilising health & social care as an economic driver;
- Understand and enhance the value that health & social care in Greater Manchester derives from investment in medicines and technologies;
- Support personalised self-care;
- Reduce health inequalities.

4.2 Optimisation of care,

- Improved person centred outcome measures through effective, trusted partnerships; these could be multi-organisational partnerships as well as a single company projects.
- Quantifiable improvement in effective use of health & social care resources (for further detail see section 7);
- Ensure appropriate use of all medicines, based on consistent application of medicines optimisation principles (appendix 2) in all localities and places of care.
- Ensure the principles, values, pledges, rights and responsibilities within the NHS Constitution are upheld as part of this partnership. Paying regard to decisions from Regional Medicine Optimisation Committees, GMMM and other relevant bodies;
- Identify and support the reduction of unwarranted variation in care and problematic polypharmacy.

4.3 Development and adoption of innovation at pace and scale:

- Innovative use of high quality international evidence and proven best practice to shape services achieve the best outcomes for people in the most cost effective, safe way;
- Sustainable increase of the adoption of medicines innovation at pace and scale across the GM footprint, where patient and population benefits are accrued safely;
- Accelerated discovery, development and delivery of innovative medicines solutions;
- Collaboration to deliver on three strategic enabling priorities identified by HInM: informatics; precision medicine; and initiation of and participation in clinical trials;
- Enhanced contribution of Greater Manchester to the UK's life sciences industrial strategy and development of the Northern Powerhouse and Connected Health Cities programmes; and;
- Accelerated real world evidence generation using the health and care data across the city region; this will to enable Greater Manchester to become a world-leading site for the evaluation of medicines, partner diagnostics and play a greater role with the global pharmaceutical industry.

4.4 Create an environment for flexibility and opportunity to develop outcomes based pricing methods:

- Strive for flexible and fair funding of innovative and established medicines.
- Use of GM real world evidence from health and care data to develop value assessment methods and pay for medicines based on observed outcomes; This may inform National Institute for Health and Care Excellence (NICE), Health Technology Assessments (HTAs), Pharmaceutical Price Regulation Scheme (PPRS) negotiations and other bodies which assess value to develop validated methodologies.
- Exploring the potential of multi-year, multi-agency budgets to enable outcomes based models to be clinically and financially sustainable; and
- Test other incentive models, including those that flow from the national Accelerated Access Review.

5 Ways of working

5.1 The Partnership Group is an 'alliance of the willing'. All parties voluntarily agree to work together to achieve a shared vision of enhancing the health and economic prosperity of Greater Manchester, through appropriate and consistent adoption of medicines innovation that delivers measurably improved patient outcomes and represents best value for health & social care.

5.2 GMHSCP may develop partnerships with individual companies. This MOU is intended to be a framework to enable the success of these partnerships and help reduce any perceived or actual barriers.

5.3 The parties agree that the Greater Manchester and Pharmaceutical Industry Partnership Group will operate by the following principles and values:

- **Trust** – all parties have a stake in striving for the best outcomes for the people of Greater Manchester;
- **Rigour** – partnership work will be evidence-based or evidence generating and underpinned with effective and transparent governance to ensure collaborations have a firm foundation;
- **Respect** – The parties recognise the social and economic value each bring to the people of Greater Manchester. GMHSCP recognises the value of the pharmaceutical industry as an employer of skilled personnel and leader in the life sciences sector; the Industry recognises the stated goals of GMHSCP to deliver the best possible care;
- **Ambition** – A shared goal of enhancing the health and wealth of Greater Manchester. To enhance its life science competitiveness by delivering first-class medicines optimisation. To drive evidence-based innovation into practice; generating globally applicable evidence of the impact of innovation on patient outcomes;
- **Innovation** - opportunity to challenge convention and trial blaze new ways of working that will be a test bed for the UK. To accelerate testing and adoption of new medicines to the benefit of the GM population and improve healthcare, where possible drive down costs.
- **Transparency** – All proceedings undertaken by the Partnership Group will be publically available, and the results of all initiatives and collaborations will be published when complete, (subject to respecting commercial in confidence information).
- **Conflict of interest** - All individuals and organisations have a responsibility to declare interests which the group will manage rigorously; and
- **Fairness** – the partnership group will be conducted with equality of opportunity and access to all participants, companies and organisations.

6 Governance

6.1 Jon Rouse (GMHSCP) and Mike Thompson (ABPI), will jointly chair the GM and Pharmaceutical Industry Partnership Group.

6.2 Core members of the partnership group will include named representatives from:

- GMHSCP executive
- ABPI
- EMIG

- BGMA
 - Health Innovation Manchester (including NWeH & GMAHSN)
 - Association of GM CCGs (AGG)
 - Greater Manchester Medicines Management Group (GMMMGM) Chairs
 - GM Provider Federation Board
 - GM Local Pharmaceutical Committee
 - GM Combined Authority
 - GM Primary Care Advisory Group
- 6.3 Additional members and expertise may be co-opted as required, e.g. health economic, NHS procurement, senior industry expertise.
- 6.4 The Strategic Partnership Group will work flexibly through face-to-face and virtual meetings to maintain momentum and deliver outputs to the agreed milestones.
- 6.5 GMHSCP Board will identify a named lead (sponsor) and effective reporting arrangements to the Board. The sponsor will be accountable for the delivery of GM contribution to the work of the Partnership Group. The sponsor will identify a responsible officer for the delivery of GM contribution to the work and the necessary resource.
- 6.6 ABPI and BGMA will each identify a named lead (sponsor) and effective reporting arrangements to its Board. The sponsor will be accountable for the delivery of ABPI and BGMA contribution to the work of the Partnership Group. The sponsor will identify a responsible officer for the delivery of ABPI and BGMA contribution to the work and the necessary resource.
- 6.7 GMHSCP will be responsible for the meeting management and co-ordination of the Partnership Group in collaboration with ABPI. GMHSCP and ABPI will share meeting costs. Parties will agree a detailed programme and resourcing by 31st March 2017.
- 6.8 All communications from the Partnership Group will be joint and made publically available within one month of interactions taking place and/or agreements being made. If applicable, commercial in confidence information will be removed.

7 Commitments

GMHSCP and HInM will:

- 7.1 Work with all relevant NHS and care organisations to address inappropriate variation in implementation and adoption of evidence-based medicines innovation across the Greater Manchester footprint.
- 7.2 Involve Industry, as individual companies or collaborations of companies, as a strategic partner in designing and delivering innovative new models of care as

set out in the Five Year Forward View and Greater Manchester *Taking Charge* plan, actively incorporating appropriate, consistent and rapid uptake of innovative medicines as a factor in achieving transformation.

- 7.3 All parties recognise Health Innovation Manchester (HInM) as a strategic coordinating hub through which individual companies, and/or collectives of member companies, can co-develop solutions to healthcare priorities identified by GMHSCP and others.
- 7.4 Link areas in Greater Manchester where evidence shows that medicines optimisation principles are variable and outcomes are sub-optimal. Consider co-creating strategic approaches involving Industry to address these issues, where appropriate.
- 7.5 Commit to adopting a whole system value-based approach rather than a perceived cost-minimisation approach to medicines, so that the value of innovation to people and to the entire Health and Social Care system is appropriately calculated and measured.
- 7.6 Aim to create an holistic approach that benefits all people, using appropriate incentives to scale up value propositions within the health & social care system.
- 7.7 Identify prioritisation criteria based on Greater Manchester population needs, to ensure the efforts of the Partnership Group are appropriately directed.
- 7.8 Ensure that when innovative, cost-effective, scalable opportunities are identified and evidenced, dissemination is promoted and implementation encouraged throughout the GM system.
- 7.9 Horizon scan across GM for good practice with innovative treatments, care pathways and approaches to be spread across the wider health and care systems of the UK and internationally.
- 7.10 Exploring the potential of multi-year, multi-agency budgets to enable outcome based models to be clinically and financially sustainable.

Industry will:

- 7.11 Embrace the GM vision, strategic plan and social values and contribute to its delivery of health and wellbeing improvements, financial sustainability and economic development.
- 7.12 Propose scalable solutions that deliver consistent adoption of high quality, evidence-based care and address the financial pressures of GMHSCP.
- 7.13 Recognise Health Innovation Manchester (HInM) as a strategic co-ordinating hub through which individual companies, and/or collectives of member companies, will co-develop solutions to healthcare priorities identified by GMHSCP.

- 7.14 Support GMHSCP in maximising the value and delivery of its real world evidence database by brokering discussions with global experts and potential investors from its membership base.
- 7.15 Working together with GMHSCP to develop and implement solutions to improve the use of medicines and support the people of Greater Manchester to gain best possible outcome from their medicines. Solutions will follow the Medicines Optimisation principles, as shown in Appendix 2, to keep people safe and address challenges of over or under prescribing. Solutions may include supporting implementation of NICE guidelines, reducing problematic polypharmacy, reducing unwarranted variation and reducing use of medicines of known limited clinical value.
- 7.16 Horizon scan UK and worldwide to actively look for opportunities to bring innovative treatments, pathways and approaches to GM using agreed prioritisation criteria.
- 7.17 Work collaboratively with diagnostics, devices and healthcare industries to broaden solutions and maximise opportunities to enhance the health and economic prosperity of Greater Manchester.

8 Roles and responsibilities

- 8.1 The Partnership Group will collectively remain committed to deliver benefits for the people of Greater Manchester, GMHSCP and industry.
- 8.2 All parties will hold each other to account for delivering their agreed actions, share intelligence (subject to confidentiality and anti-trust restrictions), offer solutions and pool resources as appropriate in order to keep delivery of agreed outputs on track.
- 8.3 All parties are committed to mutually beneficial knowledge sharing and will disseminate agreements, outputs, messages and lessons learned with their networks, stakeholders and publish for wider understanding within and beyond GM.
- 8.4 All parties will use the principles agreed in this MoU to facilitate engagement and collaborations with industry, whether as individual companies or as groups of companies working collaboratively.
- 8.5 All parties will work with their networks and stakeholders to address barriers and challenges to implementation. Identified barriers will be discussed within the Partnership Group to find mutually agreeable solutions.
- 8.6 The parties are open to the future extension of the agreement to include other medical and care technologies.

9 Deliverables and milestones

Early implementation plan

- 9.1 The Partnership Group will agree a programme of communication for health & social care and industry **by end March 2017** in order to support the cultural change required for the new collaborative approach.
- 9.2 HInM will report to the partnership group on the progress of selection and execution of both quick wins and strategic projects **from end of March 2017**.
- 9.3 The Partnership Group will continue to work closely with HInM to monitor progress of these 'quick wins' and discuss successes, enablers, barriers and challenges to inform future projects.

Process for identification of projects

- 9.4 HInM will develop an Innovation Access (IA) Pathway for prioritising and routing opportunities, reflecting the shared aims set out in the MoU:
 - Transforming the health, wellbeing and wealth of the people of GM
 - Optimisation of care
 - Clinical and financial sustainability
 - Development and adoption of innovation at pace and scale
 - Create an environment for flexibility and opportunity to develop outcomes based pricing methods and test other incentive models.
- 9.5 The IA Pathway,, when established, will enable a flow of innovations in priority areas via:
 - Calls to industry and the health & care system against specified objectives.
 - Processes to review high impact proposals between calls.

The Innovation Access Pathway

- 9.6 HInM will be accountable for developing, disseminating and managing an Innovation Access Pathway.
- 9.7 The IA Pathway will be open for initial proposals **by end April 2017**. The process will be iterative over time from the initial proposals and closely monitored for the first 12 months
- 9.8 The process will be evaluated and reviewed at least annually or within year as determined by HInM; based on feedback from the partnership group, Industry, GMHSC providers and commissioners and/or other users of the IA Pathway.
First review no later than April 2018
- 9.9 The IA pathway will support and stimulate health innovation and will have clear and transparent processes for the;
 - i) Identification and selection of innovations meeting GM health needs.

- ii) Provision of the appropriate feedback and signposting to organisations submitting proposals that are out of scope.
- iii) Evaluation and the evaluation criteria used for innovations to include guidance to industry on priorities and trial/approval/adoption timescales.

9.10 The process seeks to prioritise specific projects as being most closely aligned to GM priority areas as set out above. It does not seek to preclude the longstanding commitment to undertake collaborative projects between industry partners and Greater Manchester NHS organisations, which aim to improve patient outcomes more generally. We recognise the value of this broader collaborative programme of work.

Health and care data infrastructure and utilisation

9.11 GMHSCP and HInM will work to define the secondary utilisation of GM data for medicines optimisation work, pre and post-licensing evaluation. This will include addressing issues of information governance and information sharing agreements; potentially creating a GM citywide approach for gaining patient consent for utilisation of data for defined groups.

9.12 Industry will work with HInM and relevant Greater Manchester organisations associated with health data, to support the development and marketing of the 'offer' from Greater Manchester to the global pharmaceutical industry.

9.13 ABPI will facilitate industry engagement of a group of global experts drawn from its member companies as well as relevant experts in assessing the value of medicines, NHS Digital and HTA specialists to work with HInM and North West e-Health (NWeH) to ensure GM data is generalisable and fit for purpose in a global context. A first meeting of this working group is expected **by end March 2017**.

Outcomes based models

9.14 The Partnership Group will define and agree a common language between industry and GMHSCP for outcomes-based and risk-sharing models of care delivery. This common language is to be disseminated across the health & social care system and industry to enable these models to be developed and adopted.

9.15 HInM will work with NWeH and Industry partners (subject to confidentiality and anti-trust restrictions) to establish a proof of concept for an outcome based funding model using GM health and care data.

9.16 The Partnership Group will agree a structured implementation plan to scale any successful proofs of concept and replicate the process with other interventions.

10 Measurement

10.1 The Partnership Group will be consulted on the development of interim & proxy measures to assess our overall success against this MoU (not individual projects). Measures may include;

- Improvements in patient outcomes using appropriate health economic measures, such as QALY;
- Evaluation of savings delivered for the GM health and social care system over 3 to 5 years
- Investments required to achieve improved outcomes and/or savings;
- Quantifiable improvements in economic, social value and health outcomes for GM people and the GM city region;
- Increased life sciences investment in the GM region;
- Reducing variation in care;
- Reducing inequalities;
- Number of 'quick win' projects that have started within 12 months;
- Number of 'quick win' projects that have started in multiple locations;
- Number of 'quick win' projects that have achieved adoption into standard care within three years;
- Number of proposals that have been evaluated by the 'Innovation Access Pathway' and an audit of the outcome of the process;
- Number of outcome based funding models piloted within 2 years;
- Number of outcome based funding models adopted into standard care within 3 years;

10.2 Individual projects should agree measures appropriate to that project to measure success. These should be able to show a contribution towards the overall partnership measures above.

10.3 The Partnership Group will commission an independent review of the effectiveness of the partnership after minimum period of 18 months including:

- Contribution to changing culture, behaviours and outcomes from partnership working.
- Ensure innovative opportunities identified and work to disseminate and adopt through the system.
- Analysis of project or aspects, which have not been as successful as anticipated, ensuring system learning.

11 Code of practice and conflicts of Interest

11.1 Greater Manchester bodies will use the NHS England Conflicts of Interest and business conduct policies as their default.

11.2 GM members of the partnership group will be governed by the respective codes of business conduct and conflicts of interest policies of their employing

organisations. Any declarations must be made to their employing organisation in accordance with prevailing policies.

- 11.3 Industry members will be governed by the ABPI Code of Practice and their own internal policies. If the ABPI Code does not apply, Industry Members will comply with their respective association code.

12 Relevant legislation

- 12.1 All partnership agreements will be in accordance with relevant UK and EU legislation.
- 12.2 Nothing in this MOU is intended to, or shall be deemed to, establish any partnership or joint venture between the parties, constitute any party as an agent of another party, nor authorise any of the parties to make or enter into any commitments for or on behalf of the other parties.
- 12.3 This MOU is not intended to be legally binding on the parties, but rather an expression of how the parties intend to work in the furtherance of commonly agreed objectives. The content of this MOU is not intended to be confidential.

13 Intellectual Property

Projects approved across Greater Manchester may generate intellectual property (IP). Each project should consider if IP may be generated at initiation and clearly state in project documentation how any IP will be owned, managed and used.

14 Confidentiality and information governance

- 14.1 It is expected that all discussions between GMHSCP and Industry partners are open, honest and transparent, to achieve the aims of this MoU and individual projects. Financial and non-financial support from industry partners for this MOU and individual projects will be declared in accordance with the ABPI Code of Practice or other appropriate applicable codes.
- 14.2 There may be occasions where information is shared as commercial in confidence, all parties agree to respect this and not share beyond necessary parties. The Parties acknowledge that antitrust restrictions must be respected in relation to the sharing of information between industry parties.
- 14.3 Treatment of patient and other personal confidential data (PCD) will be within a robust and compliant Information Governance framework, voice We will use GM Connect² to support the Partnership in ensuring that data is handled correctly at all times with the necessary consents in place.

² Overseeing body for data sharing and governance across GM

15 Review period

MoU to be reviewed annually.

Next review date February 2018

16 Signatories to the MoU

Greater Manchester:

Greater Manchester Health and Social Care Partnership

Lord Peter Smith, Chair

Jon Rouse, Chief Officer

Health Innovation Manchester

Rowena Burns, Executive Chair

Greater Manchester Combined Authority

Sir Howard Bernstein

Pharmaceutical Industry:

Association of the British Pharmaceutical Industry (ABPI)

Mike Thompson, Chief Executive

Ethical Medicines Industry Group (EMIG)

Leslie Galloway, Chairman

British Generics Manufacturers Association (BGMA)

Warwick Smith, Director General

Document Control:

| Version | Date | Changes made |
|----------------|-------------|---|
| 0.3.1 | 05.12.16 | Draft produced by C Goldrick, H Lewis, A White, W Heppolette, presented to Partnership group 12.12.16 |
| 0.4 | 20.12.16 | Changes proposed by partnership group on 12.12.16 |
| 0.5 | 09.01.17 | Changes made after meeting on 3.1.17 |
| 0.6 | 19.01.17 | Changes following initial feedback from ABPI board members and GMHSCP leaders |
| 0.7 | 24.01.17 | Revisions following: <ul style="list-style-type: none"> • 102 comments from 34 industry and GM commentators, • Partnership group comments and decisions on feedback received 23.01.17 • Additional comments and edits from BGMA 25/01/17 |
| 0.8 | 26.01.17 | Final draft for SPBE following review by Jon Rouse and Mike Thompson |
| 0.9 | 15.02.17 | Updated following SPBE feedback |
| 1.0 | 16.02.17 | Final signed version |

Appendix 1 - Partners to the MoU

1. Greater Manchester Health and Social Care Partnership – GMHSCP

- 1.1 The high level ambition for Greater Manchester is to become a financially self-sustaining city region, sitting at the heart of the Northern Powerhouse with the size, assets, skilled and healthy population, and political and economic influence to rival any global city.
- 1.2 The GMHSCP vision is: ‘to deliver the fastest and greatest possible improvement in the health and wellbeing’ of the 2.8 million people living across GM. This requires the delivery of an ambitious transformation programme, which will:
1. Radically upgrade population health prevention,
 2. Transform community base care and support,
 3. Standardise acute hospital care,
 4. Standardise clinical support and corporate functions and
 5. Enable better care.
- 1.3 Greater Manchester wants to be the safest most effective place to receive medicines. Crucial to achieving this will be a cultural shift to considering medicines as an investment in improving patient, community and population outcomes. This will be achieved through the better use of medicines and the explicit disinvestment in unnecessary medicines, to invest in other areas more effective at achieving outcomes.
- 1.4 Health Innovation Manchester (HInM)
- Health Innovation Manchester, an integrated health-care delivery system covering every single stage of the translational health pathway from discovery science through to health services commissioning and real world evaluation.
 - HInM’s objectives, and added value as a partnership is to create a “one team” approach to tackling GM’s health challenges, by:
 - Providing a single industry-facing brand for GM’s work on health innovation
 - Resolving activity overlaps between organisations which sap energy, create tensions, are inefficient, and confusing for the industry
 - Engaging all partners in defining a clear and shared set of health improvement goals where innovation is both necessary and possible;
 - Supporting the shift toward a holistic approach to innovations across the entire population health, social care, primary and secondary care systems;
 - Providing a robust, transparent, agile and system wide processes to support innovators in accessing the GM health ecosystem.

- Health Innovation Manchester is signing on behalf of its partner HEIs in Greater Manchester.
- HInM will work through the GM H&SCP MoU with the Voluntary, Community and Social Enterprise Sector and GM Healthwatch to ensure that the partnership with industry is fully engaged as appropriate with residents and service users

2.5 Further information available at: www.gmhsc.org.uk and www.healthinnovationmanchester.com

2. The Association of the British Pharmaceutical Industry – ABPI

2.1 The ABPI represents innovative research-based biopharmaceutical companies. The research-based pharmaceutical industry is a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to people.

2.2 ABPI represent companies who are researching and developing the majority of the current medicines pipeline, ensuring that the UK remains at the forefront of helping people prevent and overcome diseases.

2.3 The ABPI and its members recognise the financial and demographic challenges in this current time and are committed to working with Greater Manchester to develop sustainable and robust mechanisms to:

- enable the adoption of innovative medicines;
- enable the effective and efficient use of new and established medicines
- address issues associated with waste and inappropriate use of medicines;
- secure flexible and fair funding for innovative medicines ;
- identify, agree and support reduction in unwarranted variation in medicine usage;
- support the development of data assets identified in Greater Manchester for global value.

2.4 Further information available at: www.abpi.org.uk

3. The Ethical Medicines Industry Group – EMIG

3.1 EMIG is the research based representative body for small to medium biopharmaceutical companies and also membership from, patient charities, research policy organisations, universities and AHSNs.

3.2 The primary aim for EMIG is to ensure that people have equal access to all health technologies. This means that EMIG must work closely with government, regulators, the NHS and academic research establishments at all levels to create an environment, in which:

- The Government encourages pharmaceutical research and development (R&D) in the UK;

- Pharmaceutical companies can operate effectively in delivering health technologies which have been proven safe and effective;
- The decision to prescribe a technology is based on clinical need.

3.3 Further information available at: <http://www.emig.org.uk/>

4. The British Generic Manufacturers Association (BGMA)

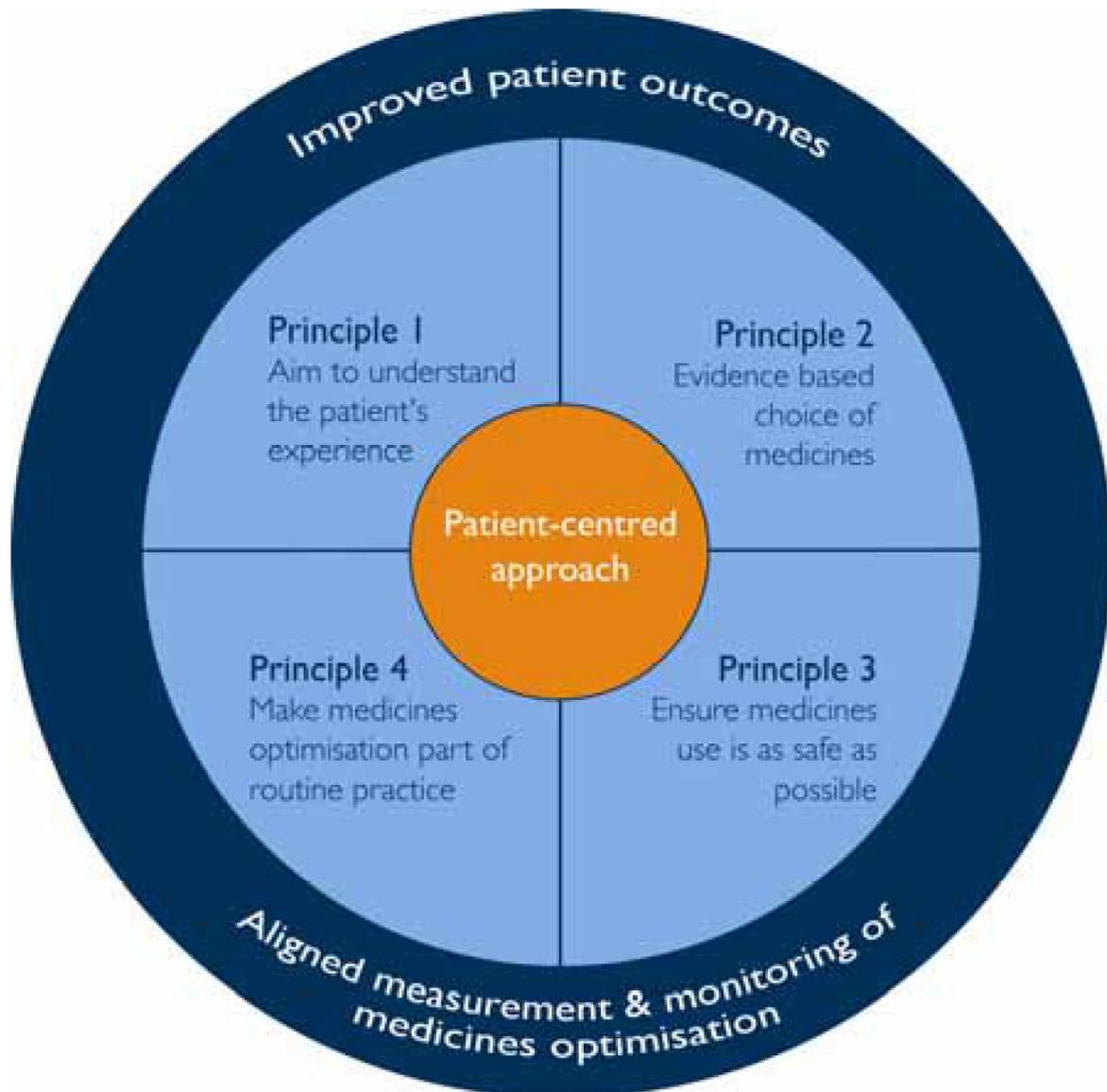
4.1 The BGMA represents the interests of UK based manufacturers and suppliers of generic medicines and promotes the development of the generic medicines industry in the United Kingdom.

4.2 The BGMA specifically:

- Encourages a positive market environment for generic and biosimilar medicines to ensure that the NHS is able to take advantage of increased affordability and accessibility to medicines.
- Works continuously with the Department of Health and the NHS to ensure the effective and efficient take up of new generic and biosimilar medicines in the interests of maximising patient access to medicines and the efficiency of the NHS.
- Works with relevant NHS and DH bodies to promote the effectiveness of the secondary care generic and biosimilar medicines markets.
- Works to create the most cost-effective UK regulatory environment possible and promote the quality of generic medicines.

4.3 More information at www.britishgenerics.co.uk.

Appendix 2 – Medicines Optimisation principles



Medicines Optimisation: Helping patients to make the most of medicines
Good practice guidance for healthcare professionals in England, May 2013
www.rpharms.com/promoting-pharmacy-pdfs/helping-patients-make-the-most-of-their-medicines.pdf