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Joint Working: A toolkit for industry and NHS Wales

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Welsh NHS Confederation

The Association of the British Pharmaceutical Industry (ABPI) exists to make the UK the best place in the world to research, develop and use new medicines. We represent companies of all sizes who invest in discovering the medicines of the future.

Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Government and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines. Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK.

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The Welsh NHS Confederation is the only national membership body representing all the organisations making up the NHS in Wales: seven Local Health Boards, three NHS Trusts and Health Education and Improvement Wales (HEIW). We are also part of the NHS Confederation.

Our mission is to be the authentic voice of the NHS leadership in Wales. We aim to support our members in improving the health of the population and the planning and delivery of high-quality health care.

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Introduction

What is Joint Working and when is it appropriate?

Joint Working is a specific type of NHS / pharmaceutical industry collaboration rather than a generic term for all cross-sector collaboration. The ABPI Code of Practice for the Pharmaceutical Industry defines Joint Working as:

> "The Department of Health defines joint working between the NHS and the pharmaceutical industry as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and / or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery.
>
> Each party must make a significant contribution and the outcomes must be measured. Treatments must be in line with nationally accepted clinical guidance where such exists. Joint working between the pharmaceutical industry and the NHS must be conducted in an open and transparent manner. Joint working must be for the benefit of patients but it is expected that the arrangements will also benefit the NHS and the pharmaceutical company or companies involved. Joint working differs from the situation where pharmaceutical companies simply provide funds for a specific event or programme[1]."

A guide to choosing the most appropriate model for cross-sector working can be found on Page 6.

Joint Working projects aim to deliver 'triple wins' in the form of benefits to patients, the NHS and the pharmaceutical company or companies involved and is a key part of the Welsh Government's long-term plan for health and social care, *A Healthier Wales*[2]. As the Minister for Health and Social Services outlines in his introduction,

> "We will need broader and deeper partnerships, new skills and ways of working and we will need people to take more responsibility for their own health and wellbeing."

Both the NHS organisation and the company involved must clearly set out the anticipated benefits in advance and may consider quantifying these as projected returns on investment (ROI) before committing to a Joint Working project.

Potential benefits of Joint Working include:

For patients:

- Care closer to home
- Fewer hospital admissions
- Better information about conditions and treatment options
- Better experience of the healthcare system

For NHS Wales:

- Higher quality care
- Services configured around patient needs
- Better health outcomes
- Better use of resources in line with Value Based Healthcare / Prudent Healthcare agenda
- Lower hospital admissions

1 http://www.pmcpa.org.uk/thecode/InteractiveCode2015/Pages/clause20.aspx
2 https://gov.wales/healthier-wales-long-term-plan-health-and-social-care

For the industry partner:

- Potential expansion of the relevant and eligible patient population as a result of the activity
- Increase in the appropriate use of medicines aligned to local or national guidance
- Better understanding of the challenges faced by the NHS in delivering high-quality patient services and care
- Faster implementation of NHS policy which may be relevant to an organisations' business

All Joint Working projects must be underpinned by a formal Joint Working Agreement[3], an executive summary of which must be made publicly available before the project begins. Agreements must take place at a corporate / organisational level and not with individual health professionals. Agreements must include an exit strategy, contingency arrangements, clear milestones and a commitment to measure, sustain and document outcomes to facilitate replication and scaling across the NHS.

Each party must make a significant and defined contribution to the project, and transfers of value[4] made by companies must be publicly disclosed. Contribution of resources may come in various forms, including people, expertise, equipment, communication channels, information technology and finance.

Examples of Joint Working projects include but are not limited to:

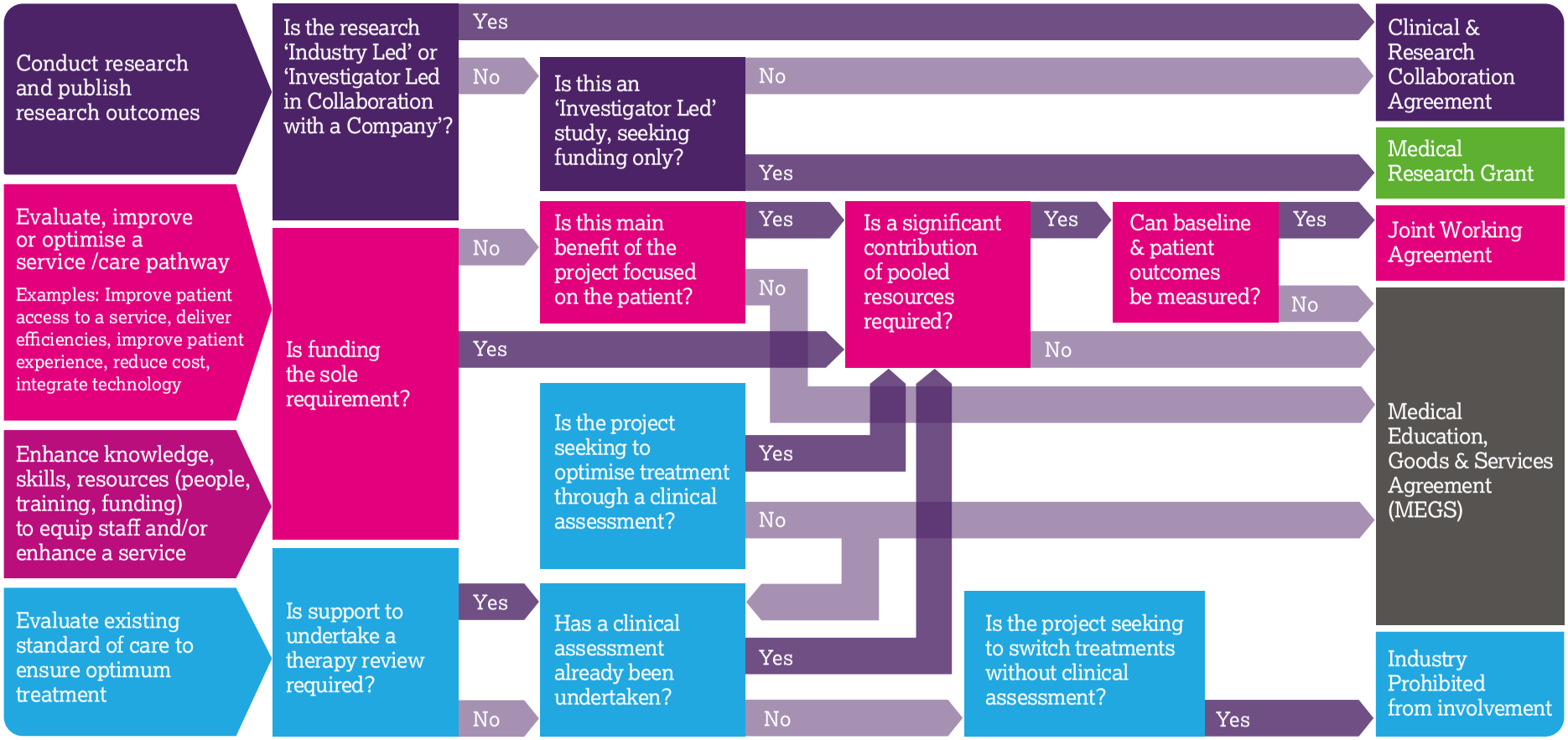
- Facilitation of pathway redesign
- Economic analysis
- Funding of project staff requirements (e.g. provision of administrative, clinical, analytical health, economic and / or management resources by either party)
- Proportionate contribution to nurse services which lead to measurable interventions and outcomes
- Identification of undiagnosed patients
- Reviewing uncontrolled patients
- Improving patient adherence to medicines
- Generating patient experience data
- Increasing system capacity to treat patients

You can further explore Joint Working case studies in Appendix 1 of this document and on ABPI members' own websites. Further governance guidance is also contained in the ABPI Code of Practice and can be explored in interactive form on the Prescription Medicines Code of Practice Authority (PMCPA) website[5].

3 http://www.pmcpa.org.uk/thecode/InteractiveCode2016/Pages/Clause20.aspx
4 For a definition of Transfer of Value (ToV) please refer to: https://www.abpi.org.uk/ethics/ethical-responsibility/disclosure-uk/about-disclosure-uk/definitions/
5 http://www.pmcpa.org.uk

Routes to Cross-Sector Working

Choosing the most appropriate model



Further governance Support and guidance Is available from:

Organisations
Conflicts of Interest Guidance

Disclosure UK

ABPI Code of Practice

Further information on clinical trials collaboration, Medical Education Goods and Services (MEGS) projects and working with patient organisations can be found in the appendices and on the ABPI website www.abpi.org.uk

Joint Working

A ten-step process

Step 1: Project Scoping

Potential partner organisations from NHS and industry identify projects and initiatives that will help improve patient care and outcomes.

These projects are often drawn from data analysis or patient feedback which highlight an area of proven patient or clinical need.

Potential partners consider the project's desired benefits and outcomes, in addition to its sustainability and how it could be replicated or scaled if successful.

Once the initial project idea has been generated, the foundation project team is encouraged to review it against the Joint Working criteria checklist set out in Step 2.

At this point, it is also worth investigating if other healthcare organisations have successfully tackled a similar challenge and, if so, whether it may be more appropriate to learn from / replicate / modify their work than to initiate a completely new Joint Working project.

Step 2: Check Joint Working Criteria

Potential partner organisations review the checklist overleaf and satisfy themselves that each criterion will be met under the project.

If the answer to any RED Questions is "NO", the project is NOT a Joint Working arrangement as defined by the ABPI Code of Practice.

Appropriate action will be required to address these areas before proceeding further as a Joint Working project.

If adequate changes to the project cannot be made, then partners should consider a MEGS agreement or alternative approach (see Appendix 3).

A negative response to any AMBER questions signals potential issues that should be addressed to encourage successful and timely project delivery. Some of those previously involved in the foundation project team, and potentially others, reconvene as the final Joint Working Project Team.

Step 3: Gain Stakeholder Alignment

Potential partner organisations check that the project aligns with both organisations' objectives and compliance / legal processes.

A governance committee or Internal Review Committee (IRC) should be in place to review and sign off the project. This group will remain engaged to ensure that the project remains compliant against the criteria set out by the ABPI Code of Practice and any other relevant guidance.

They will:

- Review the principles of the project against the Joint Working Criteria, and
- Ensure that the initial idea has been reviewed by each participating organisations management and experts[6]

The Internal Review Process for an organisation involved in Joint Working usually consists of legal, medical, compliance[7], Joint Working and / or Partnership leads, who have the authority as a panel to sanction each stage of Joint Working projects.

6 NB – As this is a non-promotional draft document, it can be emailed to all parties without needing further approval
7 Industry only

Joint Working

Joint Working Criteria

Red Questions		Yes	No
1	Is the main benefit of the project focussed on the patient?		
2	Do all parties acknowledge that the arrangement may benefit the NHS and company partner(s) involved?		
3	Are any subsequent benefits at an organisational level and not specific to any individual?		
4	Is there a significant contribution of pooled resources from all parties, which may include people, finance and equipment wholly or partly dedicated to the project?		
5	Is there a shared commitment to joint development, implementation and successful delivery of a patient-centred project by all parties involved?		
6	Will anonymised, aggregated, patient outcome data be measured and documented?		
7	Are all partners committed to publishing an executive summary of the Joint Working Agreement?		
8	Are all proposed treatments involved in line with national guidance, where it exists?		
9	Will all activities be conducted in an open and transparent manner?		
10	Has an exit strategy and any contingency arrangements been agreed?		
Amber Questions		**Yes**	**No**
11	Will the project be managed by a Joint Working Team with industry, NHS and any appropriate third-party representation?		
12	Do all parties and their respective organisations have appropriate skills and capabilities in place to manage the project, thus enabling delivery of patient outcomes?		
13	Have all partner organisations got clear procedures in place for reviewing and approving Joint Working projects?		
14	Are all parties aware of and committed to using the Joint Working Agreement template (or similar)?		
15	Are all partners clear on who within their organisation is the signatory to ensure Joint Working Agreements can be certified?		

At this stage, it is vital that good communication between partners is maintained to align and manage expectations, refine the outcomes and objectives of the project and confirm the inputs into the project from each organisation. During this time, it is useful to set realistic timescales and deadlines, and to complete a stakeholder map, communication plan and data collection plan, which will help align all stakeholders within the project.

Step 4: Draft Project Initiation Document (PID)

When the project concept has been approved in principle by both partner organisations, a more detailed plan or Project Initiation Document (PID) is developed.

The PID captures all relevant details of the project and is appended to the Joint Working Agreement (JWA). It includes:

- Aims and objectives
- Benefits to patients / NHS / Pharmaceutical company partner(s)
- Principal activities and accountabilities
- Composition of the steering group and project group
- Timelines and project milestones
- Description of pooled resources
- Plans for monitoring and evaluation
- Communications plan
- Process for project amendment, should this be required
- Defined exit strategy (for all parties)

Step 5: Seeking Approval

Timelines for this stage can vary depending on the complexity of both the project and the organisations concerned.

If an organisation seeking to enter a Joint Working project does not have an established Internal Review Committee (IRC) or similar, it must identify relevant stakeholders with appropriate authority to approve the project.

Step 6: Complete PID

The Joint Working Project Team reconvenes to discuss and implement actions from the IRC's review.

In some instances, the Joint Working Project Team may have to return to their IRCs to gain further comment before completing the Project Initiation Document.

Step 7: Sign the Joint Working Agreement

Once all IRC signatories have approved the PID, all organisations sign the Joint Working Agreement.

The project team produces an executive summary using content from the PID.

The executive summary is published on the respective company(ies) website(s) for the duration of the project at a minimum, with other stakeholders encouraged to do similar. The project CANNOT commence until the executive summary has been published by the industry partner.

Step 8: Project Commences

The project begins AFTER the Joint Working Agreement has been signed by all parties and the executive summary has been published on (at least) the industry partner(s) website(s).

Step 9: Project Monitoring and Delivery

It is critical that baseline measurements and the method and frequency of monitoring progress and outcomes are determined at the outset of the project.

Monitoring of agreed messages begins and may include:

- Increased numbers of appropriately diagnosed or treated patients
- Changes to patient satisfaction / experience levels
- Patient reported outcomes
- Improved patient concordance and adherence to therapy
- Reduced wastage
- System efficiency measures e.g. waiting times, touchpoints which may also link to patient experience indicators
- Market expansion with consequent proportionate increase in the appropriate use of specific medicines, aligned to local or national guidance
- Proxy patient outcomes

Regular review meetings are set up for the duration of the project to monitor progress against objectives and milestones and to ensure that people / resource allocation is fit for purpose.

Timelines are also monitored, and plans put in place if an overrun or delay looks likely. This can be in the form of a letter of amendment or extension.

Step 10: Project Completion

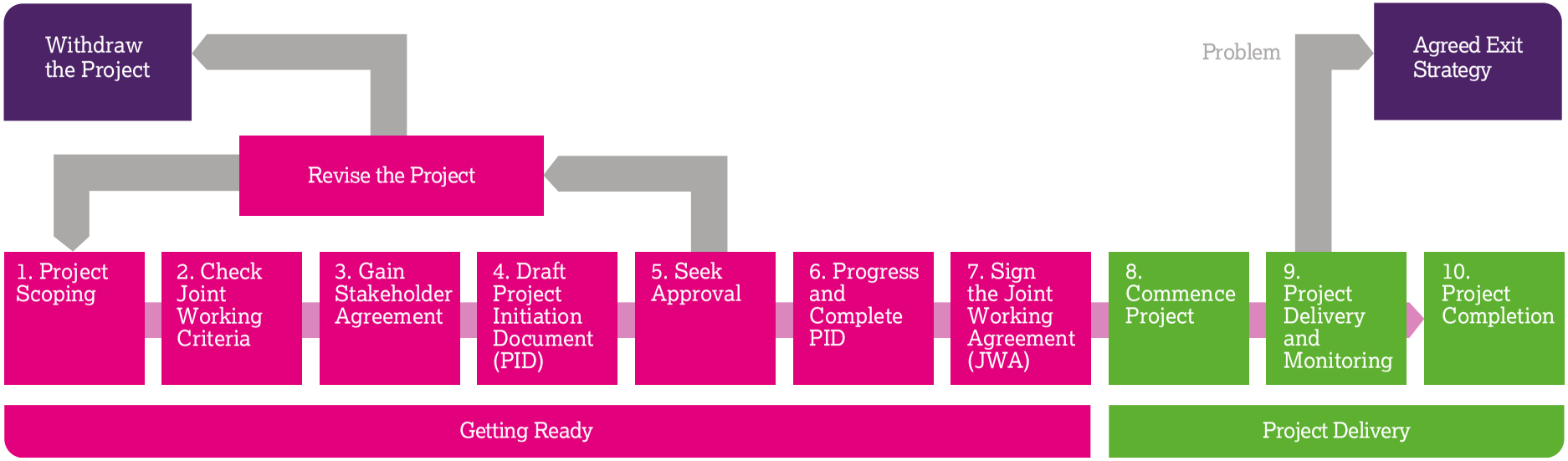
Once completed, the defined outcomes are measured and documented. All parties consider completing a case study write-up of the project to enable others to replicate.

Review of lessons learned between all parties.

Best practice: within three months of completion, the organisations involved in the Joint Working project should publish a short summary of outcomes and lessons learned.

Joint Working

A summary guide to the ten steps involved in Joint Working



1: Scoping:

Partners involved, often Healthcare Professionals and Industry Representatives, scope the concepts that will help improve patient care and outcomes.

2. Check Joint Working Criteria:

Each party reviews the proposed project against the Joint Working Criteria to ensure that these will be met.

3. Gain Stakeholder Alignment:

Each party involved reviews the project idea to check it aligns with their respective objectives and compliance processes.

4. Draft Project Initiation Document (PID):

A more detailed plan or 'Project Initiation Document' (PID) can be developed.

5. Seek Approval:

Representatives from each organisation submit the PID for review through their own internal governance structure.

6. Progress and Complete PID:

The Joint Working Project team convenes to finalise the PID, taking into account any feedback. This may involve resubmission for final approval.

7. Sign the Joint Working Agreement:

Once the PID is approved, each party signs the Joint Working Agreement and an Executive Summary is published on (at least) the company website.

8. Commence Project:

The Project can only start after the Joint Working Agreement has been signed and the Executive Summary has been published.

9. Project Delivery & Monitoring:

The Project Team deliver the agreed activities and monitor progress in accordance with the Joint Working Agreement.

10. Project Completion:

Defined outcomes are documented and consideration is given to producing a case study to share learning.

Legal Considerations Regarding Joint Working

Data Protection:

All parties to a Joint Working arrangement will need to comply with Data Protection legislation including, but not limited to, the General Data Protection Regulation (EU) 2016/679 ("GDPR") and any national implementing laws, regulation(s) and secondary legislation as may transpose the GDPR into the domestic law of all or any part of the United Kingdom (including, without limitation, the Data Protection Act 2018), in each case as such law(s) may be replaced, supplemented, substituted or amended from time to time.

Under the ABPI Code of Practice (hereafter referred to as ABPI Code), neither a pharmaceutical company nor its medical / generic representatives may be given access to data / records that could identify or could be linked to particular patients. This does not preclude individual employees from accessing patient-identifiable information provided they are an appropriately qualified person (e.g. a healthcare professional, statistician) and not employed in a promotional role.

Given that Joint Working will involve NHS patients, it would be preferable to make clear in the Joint Working agreement (and / or secondment / NHS honorary contract) that the NHS organisation is the "data controller", i.e. the person or entity that determines the purpose and the means of any data processing. The data controller is ultimately responsible for ensuring that patient confidentiality and / or privacy are adequately protected.

Anti-Bribery and Corruption:

Care must be taken if an individual physician or NHS employee could benefit personally from any Joint Working arrangements. This is because UK corruption laws (including, but not limited to, the Bribery Act 2010) and comparable legislation in the United States (the Foreign Corrupt Practices Act), prohibit the offering, promising or giving of a financial or other advantage to public officials for the purpose of obtaining any improper business advantage.

Although the NHS as an organisation may benefit from Joint Working projects, this is unlikely to breach Anti-Bribery and Anti-Corruption laws unless one or more public body officials (e.g. an individual NHS healthcare professional or NHS employee) is offered, promised or given a direct or indirect personal benefit from a particular Joint Working project. This is why it is preferable to agree primary care Joint Working projects at Health Board / Trust level or above.

Competition and Commercial in Confidence Issues:

Joint Working projects may involve more than one pharmaceutical company, so Competition and Commercial in Confidence issues may arise. Anticompetitive agreements, decisions or concerted practices between companies (e.g. agreeing prices or discount schemes with competitors) are illegal. Each company should seek its own advice to ensure that it complies with competition law in force at the relevant time and enters into appropriate confidentiality agreements and other safeguards to keep its commercially sensitive information confidential.

Where competing companies need to discuss setting up a Joint Working project, they should consider taking the following steps:

- Establish a written understanding of the purpose and scope of the discussions to ensure that they remain consistent with the parties' objectives and do not stray into areas that could raise competition law issues (e.g. pricing, market practices)
- Create a written agenda for meetings which can be approved in advance
- Limit participation to appropriate personnel who are briefed about the potential competition concerns and the importance of keeping to the approved agenda

Legal Considerations Regarding Joint Working

Consider whether legal counsel from at least one of the companies should be present at the meetings.

Take detailed minutes of all meetings which are then reviewed by legal counsel and retained.

Do not disclose or discuss confidential or commercially sensitive information. In particular do not discuss or disclose confidential information or enter into agreements in the following areas:

- The pricing of products or commercial strategies of any of the companies
- Individual company cost components or structures, or the relationship between cost and price in the industry generally
- Allocation of markets or market practices, either in relation to particular customers or geographical regions
- Actual or potential company-specific customer relationships
- Actual or potential bidding opportunities, and each other's responses to such opportunities
- Individual company or industry production levels, capacities, or inventories, or individual company market shares, or research and development activities or results

Appendices

Appendix 1

Joint Working Case Studies

AstraZeneca and Leeds Teaching Hospitals NHS Trust collaborated on the 'Re-engineering the Post-Myocardial Infarction Medicines Optimisation Pathway' Joint Working project. The project provided a comprehensive medicines review for patients with cardiovascular disease who have recently suffered a myocardial infarction (MI) and assessed if this intervention improved patient outcomes. The project adopted a patient-centred approach and shared decision-making strategies to enable the establishment of true medicines partnership and has been NICE Quality Assured as an example of Shared Learning. https://www.nice.org.uk/sharedlearning/re-engineering-thepost-myocardial-infarction-medicines-optimisationpathway

Bayer's 'Don't Wait to Anticoagulate' collaboration with West of England AHSN delivered a project aimed at helping prevent strokes amongst patients with atrial fibrillation (AF) by optimising medicines management in primary care. 13 strokes have been avoided through Joint Working, reducing the overall burden of care to the NHS and saving significant sums of money. http://www.dontwaittoanticoagulate.com/

Janssen UK, Welsh Government, NHS Wales and Myeloma UK have partnered to co-create and implement an All Wales Haematological Malignancy Data Solution, which will capture Real World Evidence for improving patient outcomes and facilitating a value-based healthcare environment. https://www.janssen.com/uk/collaboration/joint-working-declarations

MSD worked with Aylesbury Vale and Chiltern CCGs to improve the quality of their diabetes service, by looking at innovative ways to address population health challenges and to standardise the approach across all the practices involved. The programme aimed to better support patients to manage their diabetes by providing a greater understanding of their condition and the treatment options available to them, thus supporting self-care, leading to improved management and quality of life. https://www.msd-uk.com/partnerships/joint-working.xhtml

Novartis and Chelsea and Westminster Hospital NHS Foundation Trust's collaboration in heart failure (HF) aims to improve detection and treatment of HF in primary and secondary care as well as educate patients on how to manage their condition at home. The expected outcome of the project is optimisation of care for HF patients irrespective of the care setting. https://www.novartis.co.uk/partnerships/partnering-with-the-nhs/joint-working

Appendix 2

Clinical Trials Collaboration

Collaboration between NHS and commercial organisations on clinical trials is essential to the development of new medicines. The ABPI has produced a guidance series to support this critical process. All parts of the guidance are under regular review to ensure they are consistent with the latest regulations.

Phase 1 guidelines

The 2018 edition of the ABPI guidelines reflects the current EU legislation for the performance of Phase I clinical research as set down in the EU Clinical Trials Directive. Until the Clinical Trials Regulation EU No 536/2014 becomes applicable, all clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive. In addition to regulatory changes, this new edition now also incorporates the previous ABPI First in Human Studies guidelines[8].

Model Clinical Trial Agreement (mCTA)

The ABPI has worked with the four home nations to develop a model Clinical Trial Agreement for commercial clinical research. We continue to work together to keep this single template agreement up to date. This collaboration also develops guidance to assist understanding of the template agreement[9].

Clinical Trial Compensation

The ABPI also produces guidelines on clinical trial compensation for use in clinical trials in the UK[10].

Appendix 3

Medical and Educational Goods and Services (MEGS) guidance

The research-based pharmaceutical industry is committed to supporting healthcare and research organisations to drive improvements in patient care and help achieve the best results for patients and the NHS.

One of the ways to do this is by providing Medical and Educational Goods and Services (MEGS) to organisations comprised of health professionals and/or organisations which provide healthcare or conduct research.

MEGS are often provided in the form of financial grants or services delivered by an industry partner or a third-party supplier engaged by a pharmaceutical company. MEGS are intended to either enhance patient care or benefit the NHS and maintain patient care.

Involvement of a pharmaceutical company is strictly limited to the provision or delivery of the MEGS grant or service. Companies receive no direct benefit in return.

8 https://www.abpi.org.uk/publications/guidelines-for-phase-i-clinical-trials-2018-edition
9 https://www.ukcrc.org/regulation-governance/model-agreements/
10 http://www.abpi.org.uk/publications/ct-compensation

MEGS do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

Examples of MEGS agreements include (but are not restricted to):

- Donations
- Grants
- 'Benefits in Kind' (for example: secondments, people, education)

Common goals of MEGS agreements are often to:

- Improve patient access to a service
- Deliver efficiencies in the pathway
- Improve patient experience
- Reduce service costs
- Integrate technology to improve efficiencies or experience

Information on MEGS is contained within the ABPI Code of Practice and can be explored in interactive form on the Prescription Medicines Code of Practice Authority (PMCPA) website[11].

Appendix 4

Working with Patient Organisations

The ABPI has produced guidance entitled Working with Patients and Patient Organisations: A Sourcebook for Industry to support pharmaceutical companies in working successfully and collaboratively with patients and patient organisations. We want to support relationships that are in the interests of patients and within the law and the ABPI Code of Practice. We also hope that the sourcebook will be helpful to patient organisations as they build partnerships with industry.

Many people have asked for a simple declaration that the ABPI, and its Code of Practice, support industry and patient organisations working together. The Introduction to the ABPI Code has always referred to this, and the 2019 edition, in the principles and overview of self-regulation, states that:

"Working with patients and patient organisations can bring significant public health benefits."

While this new Sourcebook provides informal guidance, following it does not guarantee compliance. Companies need to ensure they comply with the ABPI Code.

The Sourcebook has been produced in response to suggestions from industry and patient organisations. There is a great deal of useful and thoughtful guidance available already from national and international organisations, in addition to the ABPI Code, and we are not seeking to replicate or replace what already exists. Rather, our aim has been to collate practical tools and tips and to provide pointers to sources of information.

The ideas you will find in the Sourcebook constitute a framework for thinking and deciding on how best to engage with patient organisations. One size does not fit all, so inevitably there is not one template that can be applied to every situation. But we hope that you will find enough advice to help guide your way.

You can download a copy of the Sourcebook from the ABPI website www.abpi.org.uk

11 http://www.pmcpa.org.uk

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