MINISTERIAL (Bio-Pharmaceutical) INDUSTRY STRATEGY GROUP

26th November 2014, 9.30am – 11:30am

Board Room, Richmond House, Whitehall

Attendees

Government:

George Freeman MP	Minister for Life Sciences

Industry:

Pascal Soriot	CEO, AstraZeneca
John Young	Group President Global Established Pharma Business, Pfizer Inc
Haruo Naito	CEO, Eisai Co Ltd
Jonathan Emms	President of ABPI (Head of Global Innovative Pharma UK & UK Country Manager, Pfizer UK)
Patrick Vallance	President, Pharmaceuticals R&D, GSK
Steve Bates	CEO, BioIndustry Association (BIA)
Sam Williams	Modern Biosciences plc (BIA Board Member)
Stephen Whitehead	Chief Executive, ABPI

Guests:

Dr Tommy Dolan	Vice President, Pfizer Sandwich Site Head & Head of Drug Product Design and Supply
Dr Menelas N Pangalos	EVP, Innovative Medicines & Early Development, AstraZeneca

Officials:

Kevin Baughan	Director of Technology and Innovation, Innovate UK
Professor Sir John Bell	Chair of OSCHR/Life Sciences Champion
Will Cavendish	Director General for Innovation, Growth & Technology, Department of Health
Sir John Chisholm	Chair, Genomics England

Mark Davies	Director, Information and Digital Strategy, Department of Health
Andrew Dillon	Chief Executive, NICE
Sir Malcolm Grant	Chair, NHS England
Dr Ian Hudson	Chief Executive, MHRA
Professor Sir Bruce Keogh	National Medical Director, NHS England
Peter Knight	Deputy Director, Research Contracting, Information Intelligence and Stakeholder Engagement, Department of Health
Abbie Lloyd	Deputy Director, Office for Life Sciences
Dr Nicole Mather	Director for Office for Life Sciences
Jonathan Mogford	Director of Policy, MHRA
Professor Sir Mike Rawlins	Chair, MHRA
Dr Keith Ridge	Chief Pharmaceutical Officer, NHS England
Professor Sir John Savill	CEO, Medical Research Council
Nick Seddon	Prime Minister's Office, No. 10
Dr Mark Treherne	Chief Executive, UKTI
Liz Woodeson	Director, Medicines, Pharmacy & Industry Group, Department of Health

Secretariat:

Sue Middleton	Executive Director, British Pharma Group
David Kullman	Office for Life Sciences

Apologies:

The Rt Hon Jeremy Hunt MP	Secretary of State, Department of Health
Iain Gray	Chief Executive, Innovate UK
Dr Louise Wood	Deputy Director, Head of NHS Research Infrastructure and Growth, Department of Health
Chris Brinsmead	Life Sciences Champion
Professor Dame Sally Davies	CMO/Director General of Research and Development, Department of Health

Lord Deighton	Commercial Secretary, HM Treasury
Flemming Ornskov	CEO, Shire
Rt Hon Greg Clark MP	Minister for Universities and Science
Simon Stevens	Chief Executive, NHS England

Minutes

Welcome

George Freeman welcomed everyone and sent the apologies of Jeremy Hunt who was now unavailable for the meeting. He chaired the meeting in the absence of the Secretary of State. He first expressed pride in being the first Minister for Life Sciences and about the commitment of the Government to make the UK a great place for the life sciences to invest and operate in. He acknowledged that a mature and ageing democracy really needs innovation in healthcare. He expressed the desire to build a landscape that creates a 'push and a pull' approach i.e. sound policies to support R&D and manufacturing couples with policies that support the use of the innovations delivered by industry.

Pascal Soriot thanked the Minister and said that he believes that this country can play a key role on a global basis and make a big difference for patients. We need to harness this with policies, collaborations and systems to create value for patients and for the UK.

The minutes of the meeting in July were agreed.

Use and assessment of medicines in the NHS

Stephen Whitehead explained that industry is increasingly concerned about a policy disconnect between the Government's desire to grow and support the life sciences sector with the needs of the NHS to save money. This is despite the fact that the PPRS agreement provides a relatively safe environment in which to allow the appropriate use of medicines. He recognised that the system is under pressure but flagged concern that the NHS is now essentially the assessor and purchaser of some medicines. He explained the frustration of the industry dealing with a fragmented approach at local level in the NHS, particularly for medicines that NICE chooses not to look at. He proposed a short-life working group to address these issues.

Pascal Soriot said that some people believe that there is no link between company investment decisions and the environment for the use of medicines. The industry needs is a comprehensive set of policies to support investment and long term stability in these policies. A key current concern is to get clarity on which body will review which medicine and what data they will need.

Patrick Vallance made the point that historically, it could have been argued that there has been a disconnect between the market and investment. However, in the future, medicines will come to market quicker, with less data with more research being conducted in the post-license phase. A fragmented system that does not take up new medicines quickly is not one where we will be able to do such research.

Haruo Naito said that Eisai is a big investor in the UK and is this afternoon opening a new manufacturing plant. He said that the uncertainty in the environment is causing concern. He is concerned about delisting of medicines from the Cancer Drugs Fund and the fact that it is not yet clear how NICE will evolve to address some of the issues in oncology.

Jon Emms was pleased that the Government understands the need for certainty; industry is concerned about a number of areas that are changing – it is cancer today but what new measures will be announced next year? He also supported the conflict of interest of the NHS being procurer and assessor.

John Young explained that from a US perspective what is wanted is the coherent set of policies that the UK is trying to achieve. We are confused by the sheer complexity of the assessment landscape and believe that the current processes are broken.

George Freeman responded that the Government understands the underlying challenges and drivers that industry is grappling with. He said it is unsustainable to expect industry to spend hundreds of millions to develop a medicine, take through regulatory review only to have it not used. His vision is to put NHS research infrastructure at the heart of the medicines ecosystem to create real benefit in real patients. Working out a 21st Century reimbursement system needs to be part of this. He agreed that we need to create a forum for NICE, the NHS, government and industry to work out what the landscape looks like and what it would take to improve the UK's competitive position.

Malcolm Grant said he was sympathetic to the points made – the NHS has great potential to work with industry to support patients and the economy. He said that industry needs to understand that the NHS is not just a big hospital – it is by nature fragmented and we need to deal with this. He thinks an end to end review is fundamental and will take this away and discuss with Simon Stevens and report back in a couple of months. He feels that the CDF has delivered fantastic benefits but the open-ended commitment has led to big overspends. The interim solution agreed by the Board will have an independent panel assess medicines for CDF funding. In the longer term he hoped to restore the assessment of cancer drugs in a NICE framework.

Will Cavendish felt the biggest opportunity for a short life working group is to look at what happens in the system to medicines that are not reviewed by NICE.

Nicole Mather supported the need for a quick review but wished to avoid the creation of multiple groups. OLS are making good progress in working with NHSE on this topic and there are discussions in the Medicines Access Group to develop a joint approach which we expect will support more rapid results.

Actions

- ***Will Cavendish and Stephen Whitehead to set up a short-life working group to improve how the NHS handles medicines that do not go through NICE.***
- ***Malcolm Grant to report back by the end of February on what can be done to set up a broader discussion between the NHS, NICE, industry and Government on the assessment and use of medicines in the NHS.***

R&D environment

Nicole Mather introduced the paper.

Patrick Vallance thanked her and explained that the UK has a unique globally competitive advantage from harnessing information in medical databases. For this to be effective, it needs to be centrally embedded within the NHS. He explained that there are technologies that allow you to use existing data sets and make them visible and usable immediately without changes to governance or taking the data out of its safe haven. Speed is of the essence and there are obvious things that could be done now. We understand that the NHS is nervous about pilots but this is more about staggered implementation, choosing non-overlapping datasets for a number of disease areas and a number of geographies and getting going; the ultimate aim must be though to join up these local pilots at a national level. Critically we need a single point of leadership that is totally embedded in the NHS.

John Bell agreed and said that the NHS is increasingly effective at collecting data (including secondary care data) but it is not being used yet to change care pathways or for research. He made the case for a sense of urgency.

Mene Pangalos agreed and supported in particular the need for a single point of accountability in the NHS.

John Savill supported and said this is a top priority at MRC. He referenced the investment going into the Farr Institute and said that three things are needed - public trust, (and privacy legislation not to be a blocker), cross institutional data linkage (Scotland and Wales and the BRCs have shown that this can be done) and finally, a shop window to show data that can be accessed. He also spoke of the importance of datasets outside the health and care system, including the UK BioBank and Genomics England Limited.

Ian Hudson said the CPRD is an important piece of the puzzle which must be built upon, and has lots of experience in linking data sets.

John Chisholm said it was important to keep focussed on improving patient outcomes through using the UK's data resources; this would drive greater opportunities for research.

Malcolm Grant said he saw the curve of data science overtaking the curve of medical science and thought that harnessing this is the UK's prize to lose. Getting traction in this area is very high on the priority list for NHS England.

George Freeman summarised that he is hearing a big message about a current window of opportunity and the need for a political discourse in a cross party way to deliver collective use of health assets for treatment of disease. He asked that we minute very strong support for the paper and for the next steps to be delivered quickly.

The group endorsed the next steps set out in the paper. Will Cavendish offered to lead the work in partnership with Tim Kelsey, including implementing the pilots. This was agreed.

Action: Will Cavendish and Tim Kelsey to take this programme forward in partnership with industry with the expectation that significant progress will be made by the next meeting.

Manufacturing

Tommy Dolan introduced the paper and gave apologies from Ian McCubbin, Chair of MMIP.

George Freeman thanked the group for really important work, in particular the way industry has worked together in partnership to agree a common agenda.

Ian Hudson said MHRA is pleased to support a new regulatory approach to manufacturing and said that the case studies will show how MHRA can help new processes and new sites be introduced.

Haruo Naito said that he really appreciated this work. And that the UK landscape for manufacturing is getting more competitive. He has lots of requests to invest from Japan, China and India but likes the UK. As most UK manufacturing is for global supply he asked whether MMIP and the Government could consider what incentives might be provided for companies investing in manufacturing for diseases of the developing world. As the UK is higher cost than some developing countries for manufacturing, and coupled with the UK's strong international development agenda, he felt that this might be an area of opportunity to explore to encourage more UK-based investment to support UK priorities in this space through offering incentives for this.

Steve Bates felt that MMIP is flying. He said there is a strong buzz in the biotech community. There is increasing sharing of scientific and technical knowledge for example Novartis working with Oxford Biomedica. He supported the idea of looking at incentives for manufacturing products for neglected diseases, with Ebola being a current challenge.

George Freeman mentioned the Governments strategy to address the UK's overall trade deficit and realise our aspiration to double exports to £1 trillion by 2020.

Mark Treherne gave UKTI's support to the initiative to increase exports and is particularly engaged on supporting increased trade from the UK.

Patrick Vallance said that GSK very much supported the National Centre for Digital Design.

George Freeman said that he is pushing strongly for life sciences in the run up to the Autumn Statement and that he saw a big opportunity to work with the sector to increase exports.

Metrics – Innovation Scorecard & Life Science Competitiveness Indicators

Nicole Mather introduced the paper and said OLS is working closely with industry to agree the vision for scorecard, in advance of publication in May.

Stephen Whitehead supported the good progress made but said it is essential to include simple international comparisons on the use of medicines. He explained that what companies look at are IMS volume and value data.

John Young agreed that it would be incredulous not to include international comparators. He said that we have debated whether uptake in UK is a factor for investment. It is one of the factors thus there must be an international comparator on this.

Steve Bates felt that we have been discussing this for long enough that we either need to agree or agree to disagree, now and move on.

George Freeman summarised by saying that he understood the importance of metrics and that the Innovation Scorecard was much improved but on uptake needed to make sure it was the right metrics in consultation with industry. He asked for resolution by the end of February.

Action: Nicole Mather to work with Stephen Whitehead to agree metrics by the end of February.

AOB

Patent Box

- Pascal Soriot outlined the deep concern in industry about the proposed changes that the UK Government has agreed with the German Government. He said that long term planning is critical for our industry thus our absolute need for predictability on policy. He reminded the group that the Patent Box is a great policy and has potential to grow investment by domestic and foreign companies. He explained that AstraZeneca was about to restructure its global IP towards the UK and that GSK had already done this. To make the Patent Box work going forward he urged the Government to get as close to the original rules as possible in the new Patent Box.
- Sam Williams supported this and explained the unsettling effect this was having on the biotech community. His company is at the forefront of translating academic IP and a key attraction for his investors has been the Patent Box. The current uncertainty is having a negative impact on sentiment.
- George Freeman agreed to pass on concerns to the HMT team.

Papers – to note

- Stephen Whitehead talked through the highlights of the ABPI papers.
- George Freeman very much supported the contribution made by the industry and said that the Ebola crisis is good example of when the world needs it this industry can deliver.

Close

George Freeman closed the meeting.