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BIA Advisory Committees: Overview of 2016 activity and proposed priorities for 2017

BIA Committee Summit, 24 February 2017

www.bioindustry.org

What's new for 2017

- Synthetic Biology becomes Engineering Biology (EBAC)
- New committee – Science and Innovation (SIAC)
- Communications Committee becomes Communications Forum

Cell and Gene Therapy Advisory Committee

Chair: Sven Kili, VP and Head of Cell
& Gene Therapy Development, GSK

BIA Secretariat: Rachael Mann

Cell and Gene Therapy Advisory Committee 2016

- CGTAC discussed the **NICE mock appraisal** and fed into the BIA's written submission to a **Select Committee inquiry into Regenerative Medicine**. CGTAC members also gave evidence to the Select Committee, representing their organisations (GSK, ReNeuron, Cell and Gene Therapy Catapult).
- The **Accelerated Access Review** was finally published in October 2016; this will be an ongoing priority area in 2017.
- CGTAC members were involved in the work of the **Advanced Therapies Manufacturing Taskforce**.
- BIA signed an **MoU with FIRM**.
- A **document collating information on the Japanese system** was begun, and the committee had representatives from the Japanese Embassy and PMDA (on secondment to EMA) as guests.

Cell and Gene Therapy Advisory Committee 2017

Inform BIA position on relevant policy issues and provide evidence for advocacy:

- **AAR and the NICE ATMP mock appraisal** - work with RAAC to follow up on this from a regulatory and HTA data requirement perspective.
- **ATMP Manufacturing Task Force report** – work with BIA and other Committees to hold Government to account and monitor their response.
- **Regenerative medicine** – awaiting publication of Commons Select Committee inquiry report.
- **Genome editing** – keep watching brief and advise on need to advocate externally.
- **Micro-factories** – keep watching brief and advise on need to advocate externally.

Communicate about the cell and gene therapy sector:

- promote the UK cell and gene therapy environment where appropriate e.g. by contributing to BIA events and publications.
- Continue to facilitate the promotion of UK cell and gene therapy sector and enable opportunities with Japan.

Engineering Biology Advisory Committee

Chair: Dr Tim Fell, CEO, Synthace

BIA Secretariat: Jess Gray

Engineering Biology Advisory Committee 2016

Key activity in 2016:

- Committee members were in strong attendance at SynBioBeta London, and SynbiCITE and BIA represented the UK sector at SynBioBeta San Francisco. Members also attended other events throughout 2016.
- The investor breakfast organised by SynbiCITE to coincide with SBB London was very well attended by both SBAC members and a range of investors from the UK and overseas.

Advocacy:

- The group reviewed and discussed the UK Synthetic Biology Strategic Plan 2016 and its recommendations (including one for industry bodies to lead on developing apprenticeships in synthetic biology)

Pleased to welcome LGC Ltd as a new committee member, following attendance at last year's BIA Committee Summit.

Guest speaker updates from the Royal Society, KTN SynBio Special Interest Group and BrisSynBio.

Engineering Biology Advisory Committee 2017

Communication: Continue to showcase strengths in the UK engineering biology sector, within BIA membership and externally

- The committee agreed to adopt the new title of “Engineering Biology Advisory Committee” from 2017 to better reflect its breadth and relevance, increase accessibility and encourage new members.
- There will be continued committee engagement at SynBioBeta and other conferences, such as the IET/SynbiCITE Engineering Biology Conference and the upcoming Royal Society event.

Advocacy: Input into relevant policy and public affairs activities via the BIA

- If engineering biology principles can be applied to areas identified in the Government’s Industrial Strategy, the committee should work with the BIA team to consider next steps to enable and promote this.

Key aim in 2017: Increase investor awareness of and engagement with UK engineering biology

- Including attendance at the SynbiCITE investor breakfast 2017 and potentially expanding to include involvement at the BIA’s CEO and Investor Forum.

Attract new committee members by promoting the breadth and relevance of engineering biology approaches – combining DNA synthesis, genomics, design for manufacture, digital, automation and more – to full BIA membership and wider bioindustry sector.

Potential guest speakers including Lord Willetts on his proposed fund.

Finance and Tax Advisory Committee

Chair: Colin Hailey, Partner and
Founder, Confluence Tax

BIA Secretariat: Martin Turner

Finance and Tax Advisory Committee 2016

- **Brexit:** Provided advice to the BIA and attended Transition Programme workshops
- **Patent Box:** Inputted into Finance Bill 2016 consultation and attended HMT meetings to discuss implementation and cost-sharing arrangements
- **EIS/SEIS:** Prepared a BIA briefing note explaining impact of the changes introduced in 2015 (TBC), represented the BIA at the newly established VC Stakeholder Forum, and responded to Government consultation on Replacement Capital.
- **Post CSR environment:** provided comment to BIA on impact of Autumn 2015 CSR, including grants to loans issue
- **Business tax roadmap:** Helped shape BIA's input to this, alongside input to **March 2016 budget** and **2016 Autumn Statement**.
- **R&D tax credits:** Made these the core policy focus of Autumn Statement submission, achieving a new Government review.

Finance and Tax Advisory Committee 2017

- **Brexit and Industrial Strategy:** participate in BIA and Government-industry workshops and provide advice to the BIA. Customs and trade likely to become a focus.
- **R&D Tax credits:** will be a focus in 2017; wider BIA member engagement will be sought to build up an evidence base for policy calls.
- **Venture Capital Schemes:** represent the BIA at VC Stakeholder Forum and advise the BIA on new policy development.
- **Consultations:** Input into BIA's responses to R&D tax credit and patient capital reviews, and Budget and Autumn Statement submissions.
- **Patent Box:** Monitor implementation and ensure BIA members are kept updated.
- **Membership:** FTAC will recruit new members and reviewing progress on priorities will be a standing agenda item at meetings.
- **Wider outreach:** build on contacts made in 2016 through AMRC and City work to broaden reach of the Committee.

Intellectual Property Advisory Committee

Chair: John Murphy, General Counsel
and Company Secretary, SkyePharma
Plc

BIA Secretariat: Martin Turner

Intellectual Property Advisory Committee 2016

- **Brexit:** Established a sub-group, provided advice to the BIA and attended Transition Programme workshops
- **US case law and patentable subject matter:** Led international *amicus brief* submission to US Supreme Court on Sequenom v Ariosa case.
- Tracked major IP issues at UK and EU level (**UP, UPC and Nagoya**), providing advice to BIA and Government and facilitating wider BIA member engagement where appropriate.
- **Supplementary Protection Certificates:** tracked emerging developments from Europe, particularly around proposals for **unitary SPC** and **possible SPC manufacturing waiver** – the EC has not progressed this agenda much in 2016
- Supported the BIA UK Bioscience Forum with IP session
- Hosted **summer drinks** and a **Christmas lunch** after Q4 meeting.

Intellectual Property Advisory Committee 2017

- **Brexit:** Advise the BIA on IP opportunities and challenges and participate in Government-industry workshops
- **Unitary Patent and Unified Patent Court:** Track implementation of the UPC and input into Government planning for UK's future involvement or exit
- **US case law and patentable subject matter:** Monitor developments and provide comment where appropriate
- **Nagoya Protocol and Access and Benefit Sharing:** Represent BIA members as guidance is developed and ensure BIA members are aware of how they might be impacted
- Maintain a watching brief on various issues, involving attendance at stakeholder meetings, including **grace periods**, **Biotech Directive** and **Supplementary Protection Certificates (SPCs)**.
- Deliver **IP Hot Topics** session at the BIA UK Bioscience Forum.
- Host **summer drinks** and **Christmas lunch**.

Manufacturing Advisory Committee

Chair: Dr Stephen Ward, COO, Cell
and Gene Therapy Catapult

BIA Secretariat: Netty England

Manufacturing Advisory Committee 2016

- Key functional delivery role within **Medicines Manufacturing Industry Partnership**
 - Secretariat and full workstream engagement for AT Manufacturing Taskforce
 - fiscal environment (Patent Box support)
 - regulatory (paper on flexible manufacturing for MHRA)
- Creating next generation of **bioproduction leadership**
 - Scoped and initiated programme for individuals from 11 BIA member companies – to educate and build a network based on site visits
- Delivered a hugely successful programme for the 2016 **bioProcessUK conference**
- Represented BIA at the **MHRA** GMP/GDP consultative committee meetings and shape policy discussion
- **Networking** – summer drinks for committee plus connecting through the KTN

Manufacturing Advisory Committee 2017

- Key functional delivery role within **MMIP**
 - Major role in delivering asks from the **Advanced Therapy Manufacturing Taskforce Action Plan**
 - **Regulatory workstream** - deliver and keep live an evolving regulatory flexibility paper
 - **Technology & Innovation workstream** – support and encourage biologics initiatives that come out of HVM roadmap refresh
- Deliver another successful programme for the 2017 **bioProcessUK conference**
- Deliver a session at the 2017 **UK Bioscience Forum** in partnership with CGTAC
- Deliver **BIA sessions at other external events** if required
- Deliver next generation of **bioproduction leadership** programme
- Represent BIA at the **MHRA** GMP/GDP consultative committee meetings
- **Network** through committee summer drinks and continued engagement with KTN

People Advisory Committee

Chair: Helen Hughes, HR Director,
Allergan Biologics

BIA Secretariat: Nick Gardiner and
Vicky Triplow

People Advisory Committee 2016

- The key activity for PAC was to tackle the industry's talent agenda and the challenges laid out in the *Vision* document published in 2015. Refining and developing the proposal around mentoring and any associated events, publications or activities.
- Publication of the document ***Growing the next generation of UK management talent*** building on the work being done in talent development.
- **Examples of best practice** were given from organisations which could sign-post and give templates for successful mentoring/talent development.
- **The Apprenticeship Levy** and how this legislation would affect companies working in our industry was a key issue and discussed.
- **Predicting present and future skill sets** needed across the industry and how best to react to these, specific input was given by the Skills Stream of the MMIP group.
- **Advising on key people topics**, the group continued to discuss and share confidential HR information and issues.
- **Referendum Implications** – the group began to develop key People concerns and implications which may arise from the decision to leave the EU.

People Advisory Committee 2017

- Talent Development – **Update the *Management Talent Report*** with a focus on mentoring. Publicise the report at Committee Summit and via mailshot.
- Outgoing CEOs/Board members – **enable and facilitate the sharing of their knowledge within the industry** – particularly important with the age profile of these people.
- Consider how to Influence **excellent board standards** and practice in our industry (consider the topic for a summit, or workshops, or additions to the Management Talent Report.
- **Diversity** – Generate a paper for gender reporting and also keep wider diversity topic on the agenda – links to item on recruiting diverse board members.
- **STEM – link with other Advisory Committees** – see how PAC can support their priorities from an HR and skills perspective.
- **Apprenticeships** – younger talent, explore and influence the schemes being developed.
- **Brexit impact** – retaining and attracting people, recruitment cost implications and issues of documentation and general people movement as plans become clearer.

Regulatory Affairs Advisory Committee

Chair: Alan Morrison, Vice President
Regulatory Affairs International, MSD

BIA Secretariat: Christiane Abouzeid

Regulatory Affairs Advisory Committee 2016

- **BIA and Brexit:** Leading (in collaboration with ABPI) the development of the post-Brexit regulatory environment to ensure that the UK remains competitive in Life Sciences.
- **Successful BIA/MHRA conference:** Accelerated Development and Access to Innovative Medicines for Patients, attended by 170 delegates across the life sciences sector.
- **Continued positive engagement with MHRA, NIBSC and NICE:** Guest speakers at Committee meetings, and members forming delegation to bilateral BIA/MHRA meeting.
- **Key discussions:** Improving regulatory pathways and access to innovative medicines – adaptive pathways, PRIME scheme and Accelerated Access Review (AAR).
- **New members:** BioMarin, GSK, Tusk Therapeutics, Vertex.
- Networking drinks after Q4 meeting.

Regulatory Affairs Advisory Committee 2017

- **BIA and Brexit:** Provide regulatory support to help shape BIA's input into Government negotiating position on the future of medicines regulation.
- **Advocate and provide BIA unique insights for a supportive regulatory environment for R&D and innovation in the UK and EU:** This includes strong support for implementation of the EU CTR and maintaining UK alignment with EU and International standards.
- **Deliver joint conference programme with MHRA:** Focus on innovation in life sciences in a changing and dynamic environment.
- **Maintain strong relationships with key UK and EU regulators:** Host guest speakers, e.g. senior EMA officials.
- **Improve access to innovative medicines:** Share experience and contribute as EAMS and PRIME schemes are reviewed; AAR; collaborate with MHRA and NICE on alignment of regulatory and HTA assessment; address challenges for transformative, curative treatments.

Science and Innovation Advisory Committee

Chair: Mark Carver

BIA Secretariat: Netty England

Science and Innovation Advisory Committee High Level Objectives

- To identify and build on evolving science trends that can give the UK biotech industry competitive advantage
- To influence the policy of government and funders of UK science and technology to the benefit of UK life science companies. It will particularly seek to engage at an early stage to influence funding decisions before they are made, and will aim to facilitate understanding and uptake of the funding opportunities by BIA members as they emerge.
- To improve translational science through more effective interaction between the academic research community, TTOs and BIA members
- To encourage active networking between BIA member companies to facilitate communication, collaboration and sharing of best practice for mutual benefit
- To address the identified science skills shortage in UK life sciences
- Represent BIA at sector events

SIAC will focus on delivering a small number of working objectives well and will actively champion these.

Science and Innovation Advisory Committee 2017

- Define **SIAC's distinct role** and purpose within BIA ensuring engagement with priority stakeholders
- Build active relationships with funders (e.g. UKRI, BBSRC, EPSRC, MRC)
- Ensure **SIAC is effectively marketed** to the CSO/CMO BIA community to increase awareness and improve engagement
- Develop and run **two events** focused on the scientific community
- Making the UK a destination for translational research and early phase trials (supports the vision) – CMO Forum
- A science focused session at UK Bioscience Forum – share latest technologies in drug development?
- Build links with **TTOs** and identify mechanisms to improve knowledge and engagement with BIA members
- **Represent the BIA** at Scientific Events as required by the Exec team
- Deliver BIA's science & innovation **webinar series** in 2017

Communications Advisory Committee 2016

2016 Achievements

EU Referendum Thought Process:

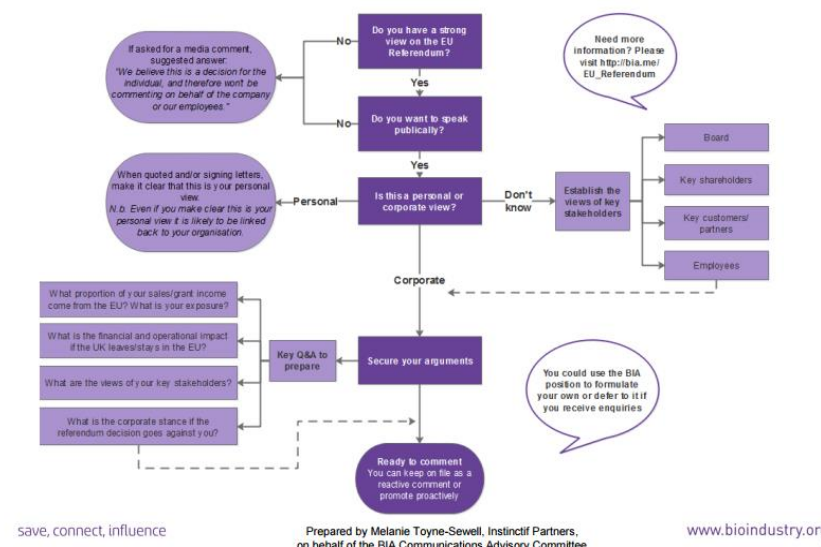
Produced to help members address questions in the build up to and after the referendum.

Communications Guide:

Aimed primarily at SMEs and start-ups, the aim is to introduce various communications concepts and show how they can be applied to drive positive outcomes for your organisation.

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EU Referendum thought process



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Communications
Committee



Communications
Forum

Goals:

- Share and develop knowledge and best practice
- Develop network for communicators and SMEs
- Continue as 'critical friend' to BIA

Steering Group

- **Chris Gardner**, Consilium Strategic Communications
- **Chris Sampson**, BTG
- **Melanie Toyne-Sewell**, Instinctif
- **Rob Winder**, FTI Consulting

BIA Secretariat: Ed Sexton

Communications Forum

2017 Agenda

- **Thursday 2 March** at the Chartered Institute of Public Relations
Peter Evans, Sunday Times
- **Thursday 8 June** at Instinctif
- **Thursday 7 September** at BTG
- **Thursday 7 December** at FTI
- Possible future topics: City relations, social media, internal communications, crisis management

We are at the forefront of UK bioscience, connecting individuals and organisations, helping to shape the future of the UK sector

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