



Medicine Manufacturing Industry Partnership



Advanced Therapies Manufacturing Taskforce

Delivery of the Action Plan

November 2017



I would like to thank everybody involved in the ATMT, we have pushed the agenda and set the foundations for anchoring commercial scale manufacturing in the UK with the health and economic benefits that will follow. We have informed the content of the Life Sciences Industrial Strategy and created opportunities for all medicines manufacturing. We need all the voices across the sector to continue to work together and complete the actions needed to anchor commercial scale ATMPs in the UK.

Ian McCubbin, co chair of the Advanced Therapies Manufacturing Taskforce (ATMT)

Background

The Advanced Therapies Manufacturing Taskforce (ATMT) was formed in January 2016 following a proposal to the Ministerial Industrial Strategy Group (MISG) by the Medicine Manufacturing Industrial Partnership (MMIP). This proposal was that a “task and finish” group should be formed; co-chaired by George Freeman, then the Minister for Life Sciences and Ian McCubbin, Chair of MMIP. This Taskforce was charged with defining the conditions necessary to “anchor” commercial scale manufacturing of ATMP’s in the UK. The Advanced Therapies Manufacturing Action Plan was published in November 2016 with six key actions. Whilst very significant progress has been made with these actions much has still to be done, and one year on, this paper will document the transition of actions from the Taskforce to “business as usual” mechanisms, to ensure that there is secure closure and continuity where necessary as the Taskforce comes to an end. Having limited time available from a minister created a strong focus for both action and engagement from industry, Trade Associations, Government, MHRA, KTN, Catapult and academia (a full list is available in the original Action Plan – <http://bia.me/ATMTplan>).

In August 2017, the Life Sciences Industrial Strategy was published and all the recommendations of the ATMT were accepted.

“Accept in full the recommendations of the Advanced Therapies Manufacturing Action Plan and apply its principles to other life science manufacturing sectors.”

It is imperative now that the ATMT Actions form the basis of a sector deal and that Medicines Manufacturing Industry Partnership becomes engaged in the execution and leadership of sector deals for Medicine Manufacturing.

Transition

ATMT will continue as a workstream within MMIP, led by James Miskin of Oxford BioMedica, and under MMIP Governance to ensure strong leadership and engagement with all the relevant stakeholders and ensure opportunities are taken. This is particularly important in the evolution and delivery of a Life Sciences sector deal.

The transition of actions are:

1. *Strengthen and secure an internationally competitive fiscal landscape to attract investment*

Transition to MMIP Fiscal work group - All the points raised by ATMT in the Action Plan are fully understood. The importance of tax environment that supports growth is recognised and documented in the Life Sciences Industrial Strategy section “Growth and Infrastructure”. MMIP has been working efficiently for some time on this topic and is more than capable of representing the needs of Advanced Therapies under the umbrella of medicines manufacturing.

2. *Target and capture internationally mobile investment through a proactive and simplified process of engagement.*

Transition to OLS/DIT with support from MMIP - This action was also recognised in the Life Sciences Industrial Strategy. “Make support and incentives for manufacturing investment and exporting available to business through a single front door, provide a senior national account manager accountable for delivery and simplify the customer journey”. OLS have appointed a new individual into a role to support this work and DIT are also recruiting. However, in addition to new resources an action plan needs to be drawn up (which industry can support) to simplify engagement and capture new investment in the UK for both existing and new Advanced Therapy Manufacturers.

3. *Maintain science and innovation funding to support industry developing cutting-edge technologies.*

Transition to Innovate UK (UKRI), supported by clear priorities for manufacturing from MMIP - Innovate UK have already supported ATMT Actions with several competitions focused on this area. This has been received very positively by industry and it is encouraging collaborations and advancement of the sector. The ongoing rollout of the Industrial Strategy Challenge Fund offers an additional opportunity for continued funding support for this area.

It is increasingly clear that there are several companies at the “tipping point” of investment in

advance therapy manufacturing on commercial scale, these companies need help/support to make capital investment in GMP facilities and the UK government needs to find a way to support this mechanism. Other countries seem to be able to do this more effectively. The Life Science Industrial Strategy also recognises this need: "Industry suggest 10-15% of the total capital commitment of a project to be internationally competitive".

The creation of UKRI also affords an opportunity to enhance the support given by Innovate UK and support this sector further. The recently announced Innovation Loans could assist and be effective

4. Set out an end to end talent management plan to secure the relevant skills for emerging manufacturing technologies.

Transition to BIA Manufacturing Advisory Committee supported by MMIP skills - Real progress has been made with this action thanks to interim funding from the Gatsby Foundation. The BIA MAC is best placed to continue this action under the MMIP governance. This will ensure industry gets what it needs and that the community can be fully engaged. Innovate UK has also been supporting this workstream and continues to do so.

5. Clearly set out a swift, predictable and viable route to market for these innovative products and give industry confidence that the UK is a progressive hub.

Transition to ABPI and BIA - Limited progress has been made though several fruitful sessions have taken place. The "thorny" issue of uptake and use is being addressed through the Accelerated Access Review. The complexity of this issue applies across the range of existing and novel treatments of which Advanced Therapies are part. The implications of change are very significant which in part has created a lack of progress. The Treatment Centre concept does in part address this area in at least a physical sense of creating facilities. It is also at the heart of the concept of the Life Sciences Industrial Strategy that NHS and Industry need to work more effectively together. ABPI as the Government nominated representative

for the biopharmaceutical industry on pricing and coverage negotiations as well as BIA with its community of SME's are a vital part of this interaction, and will be leading the future actions on this particular item, in line with their member and strategic priorities. Although the ATMT will no longer be leading on this action, both trade bodies will make sure that appropriate links are in place for regular updates on progress to the ATMT.

6. Develop a long-term regulatory strategy and plan for the MHRA to lead in global standards supporting scientific activities and international outreach of NIBSC.

Transition to MHRA with support clarified via BIA Cell & Gene Therapy Advisory Committee (CGTAC) and ABPI regulatory groups. MHRA, NIBSC and BP are working together actively in this field. With the support of CGTAC and ABPI, appropriate industry representatives from biopharma and SME's can help ensure that the UK continues to have innovative and supportive regulatory framework to be industry leaders on a global basis. Support can be provided by the MMIP Regulatory workstream to assist MHRA as and when required.

ATMT Community within MMIP

The ATMT has created an effective community for industry (large and small), academia, catapult, regulators, suppliers to the industry, Innovate UK, KTN as well as ABPI and BIA. We have been very fortunate to have had the willing support and energy of all participants.

This strong community has enabled positive influence with government, and supported infrastructure which has enabled policy to support the growth of this sector.

Two of the existing organisations for this sector are within the BIA: Manufacturing Advisory Committee and the Cell and Gene Therapy Advisory Committee. These committees contain a strong representation of large and small companies, the Cell and Gene Therapy Catapult and have the capability to continue to grow the advanced therapy community. These committees will work closely with ABPI under the MMIP Governance to avoid any duplication of effort and ensure that MMIP is the focal voice into government for medicine manufacturing.

Conclusion

When the ATMT Action Plan was published urgency of action was key. This has not changed. Advanced therapies are moving toward use very quickly, an increasing number of companies have formed and the UK remains a leader in this area.

There is much to be done to integrate the UK Community, build on the strong science base in the UK and the infrastructure created by Innovate UK investments in the Catapults. It will become increasingly important that as products are incubated and mature in such organisations, that they ultimately remain in the UK for the long-term, for the benefit of not just the economy, but also to our patients and health service.

This is time critical and competition from other countries is fierce. The focus and visibility of the ATMT Actions has been strongly enhanced through the Life Science Industrial Strategy and is expected to feature strongly in a Sector Deal.

It is imperative that actions are agreed and accelerated through sector deals and that MMIP and ATMT are fully involved in this process.

The Life Sciences Industrial Strategy currently targets ten large and ten smaller capital investments. When the ATMT actions are delivered, the UK can “bank” a majority of these smaller investments. Once these are made they will provide the basis of a new Life Sciences Industry in the UK with all the associated benefits.

This segment of the industry is moving rapidly on a global basis. The community must remain nimble and active to ensure that the UK becomes one of the foremost global hubs for industrialisation of advanced therapies.

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Medicine Manufacturing
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