Matoke Holding Ltd – Supplemetary written evidence (LSI0123)

Correspondence following an oral evidence session with Ian Staples, Chief Executive of Matoke Holdings, on 17 October 2017

About Matoke Holdings Ltd.

- Matoke Holdings Ltd. virtual company. We have built a business model on contracting top specialists into every area to meet its development needs. Every key member of that team are equity holders, investing them in the success of the business.
- MHL already has an approved medical device to address complex soft skin infections, a wound gel which is CE marked by an EU Notified Body. We are now working to develop an antimicrobial pharmaceutical product. Firstly, we will focus on treating complicated Skin and Soft Tissue Infections (SSTIs), the second most common infection in hospitals, but the technology has wider implications for treatment that we intend to explore later.
- MHL is now investing in fast tracking full pharmaceutical regulatory approval involving Phase 2 multi-centre clinical trials, in Britain and Europe, to address multi-resistant, multi-pathogen infected human soft tissue.
- We are now at the point where funding is key to taking our British product through the pharmaceutical process to make a global difference to world health. Grant awards are key to making existing investment go further and accelerate R&D to bring a new treatment to market sooner, and helping patients.

About Antimicrobial Resistance (AMR)

- AMR is widely accepted as one of the major global challenges of the 21st century. AMR currently kills around 700,000 worldwide, 50,000 in the U.S. and Europe alone. Without global action, AMR will kill another 10 million people annually by 2050, according to recent models. Increased death and illness would in turn wipe approximately $8 trillion (€7 trillion) of the world's annual output by 2050.[1]
- The cost of AMR to the NHS is estimated to be in excess of £180 million per annum, resulting in 3,000 deaths a year in the UK alone.[2]

The Life Sciences Strategy and Antimicrobial Innovation

- There is slow progress in bringing forward new innovations to stay ahead of AMR due to funding and regulatory challenges. Given the scale of the AMR threat, public bodies need to do more to try and identify the most promising potential solutions and help to push these forward.
- The costs and timescales involved in completing the regulatory process is a significant barrier to innovation, while the process of randomised control trials (RCTs) required to meet regulatory standards is hugely expensive.

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[1] Lord O'Neil, *Tackling Drug-resistant Infections Globally: Report and final recommendations* (April 2016).

[2] European Centre for Disease Prevention and Control/European Medicines Agency Joint Technical Report: The bacterial challenge: time to react (2009).

The Government's response to the Accelerated Access Review (AAR) should help, but we are still awaiting this.

- Recent research by Boston University has noted that "the antibiotic pipeline does not match health needs because of challenges in discovery and development".[3] Action is required to enlarge the pipeline of new antimicrobials.
- Matoke Holdings was disappointed that the Life Sciences Industrial Strategy did not make concrete recommendations on how the strategy could help develop new innovations to combat AMR.
- Patent life extension for antibiotics may help. British industry should be rewarded but global implementation is essential for commercial success – global cooperation is required.
- SMEs can demonstrate innovation through a superiority study, but it must be rewarded through suitable pricing. Pricing should not just be based on acquisition cost, but put in the context of value and holistic health care budgets – it should consider the return on investment that products can provide by more efficient treatment of patients' ailments.
- There has to be a significant shift in the way antibiotics are perceived – how their development is funded, and the value placed on them so that companies developing antibiotics are properly reimbursed. Antibiotics save lives, and the current funding structure does not recognise this.
- The Government's response to the Life Sciences Industrial Strategy should integrate with existing work such as the Global Antimicrobial Resistance Innovation Fund (GAMRIF). This would create a more holistic approach in providing support to SME's R&D.
- Parts of the Strategy will help, but unless the regulatory, reimbursement and pricing environment improves, few SMEs will enter antimicrobial R&D process and indeed large pharmaceuticals will not either.

Public Grant Funding

- MHL has now worked for over a year trying to get through the complicated grant award landscape. Despite a globally unmet need to address the AMR crisis and an apparent focus on AMR coupled with headline investment of millions. Accessing this money is elusive for SMEs such as Matoke.
- Historical investment by the business owners is not recognised. There is an ongoing requirement for 'matched funding' even though business has already demonstrated significant historical investment.
- Consideration ought to be given to adopting US model of awarding R&D contracts. The UK might look to the US BARDA funding model to get new agents underway – in particular the governmental backing to enter Phase 2 and 3. BARDA supports compounds which may be implicated in bio terrorism, which like AMR, has been identified as a global risk. The model has helped several smaller US companies navigate the regulatory hurdle and reach full development of their innovative technologies.
- Funding criteria should meet the needs of R&D and support the move to commercial exploitation, not the other way around.

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[3] John H. Rex & Kevin Outterson, 'Antibiotic reimbursement in a model delinked from sales: a benchmark0based world-wide approach', Lancet Infect Diseases (2016); 16: 500-05.

- Recent policy for investment in technology innovation has focused on early stage R&D and later stage support to scaling up already established businesses. There is a tendency to declare success too early, leaving many SMEs, although having demonstrated innovative technology solutions, still struggling to grow/. This has a detrimental effect on the UK economy as well as hindering transformational healthcare outcomes.
- Investment strategy should recognise the need for transitional support, especially in the pharmaceutical sector where the complexities and timescales are particularly challenging for SMEs.
- The Industrial Strategy Challenge Fund should be holistic so that funding can better support the whole R&D process. This means the incorporation of clinical, regulatory and other activities should be devised to provide end to end support to SMEs.
- The grant awarding process is not well suited to virtual companies. Whilst most SMEs have a headcount and therefore resource costs, we work with whoever is best for the job. This means that much product R&D is done by academic experts, however business led grants (typically from Innovate UK) restrict the research element to less than 50%.
- There is a number of fragmented funding bodies, each with different funding rules, making the process more complicated. If the creation of UK Research & Innovation (UKRI) leads to simplified and harmonized eligibility criteria and IP rules and the provision of suitable points of contact to offer definitive assistance, this will be a welcome development.
- Government and its agencies need to be active partners in pulling through potentially valuable products to market – 'walking arm in arm' with SMEs'. There should be proactive and practical help for SME's providing clear, joined up development programmes that accelerate the availability of new drugs.
- Some specialists in funding bodies are hard to reach for advice. Whilst the Knowledge Transfer Network (KTN) has been set up to provide advice to business at arms-length from Innovate UK, there are some questions which only Innovate UK themselves can answer and as such they should be more open to engagement with SMEs.

30 October 2017