MHRA Board Meeting – PUBLIC SESSION

12 December 2016

CHIEF EXECUTIVE'S REPORT FOR THE MONTH OF NOVEMBER 2016

1. HEADLINES for November 2016

Memorandum of Understanding with Macedonia - On 24 November, MHRA signed a Memorandum of Collaboration and Capacity Building with the Macedonian Agency of Medicines and Medical Devices (MALMED). The agreement was signed by Director of Inspections, Enforcement and Standards and Dr Marija Darkovska-Serafimovska, Director of MALMED. MALMED was founded in September 2014, and the Memorandum aims to build our relationship with MALMED and support them as they continue to grow and develop effective mechanisms for regulation. Following the signing, discussions were held with the MALMED delegation, and inspections, clinical trials and medical devices were identified as initial areas for collaboration and further engagement.

Environment and Energy Manager - The excellent achievements in energy saving led by the Agency Environment and Energy Manager have been recognised at two events. The Manager was put forward and won the award for the Energy Institute's Energy Manager of the year 2016. In particular the Agency Environment and Energy Manager was praised for successfully engaging staff at all levels of the organisation. In addition, at the Public Sector Energy Managers Association Awards 2016 there was a nomination for the Best Waste & Refuge Project 2016 (NIBSC Waste management work); and she was the winner for the Best Energy Champion / Project 2016 (Government category) and also the Energy Manager of the Year 2016 (Public Sector).

Examples of some of the achievements that have been achieved at NIBSC are:

- 14% reduction in electricity consumption and 20% gas consumption in 2015/16 compared to 2009/10. (The Institute is a large consumer of electricity, and although the unit cost has almost doubled since 2011/12, an overall saving of £963K has still been achieved.)
- The installation of solar panels site wide should lead to a projected saving over the 20 year lifecycle of £2.7M whilst an average saving through less use of the electric grid would be 8%.
- Savings in waste management amount to £85,535 over a 5-year period.
- NIBSC was the first government organisation to use the recycling system Warp-it, with total savings so far of £102,755 - Warp-it have now won a UK-wide government contract.
- The Agency Environment and Energy Manager has been sharing her experiences with a number of government bodies and received very positive feedback.

Another initiative has been joining the Cabinet Office Re-use group, with 85 other government organisations to optimise re-use of free issue furniture. Several loads of furniture had been utilised, including all furniture for a recent refurbishment of the

NIBSC Projects Team area, making a total saving of £78,156. There could likely be advantages in using this scheme in the organisation's move to Canary Wharf.

2. PRODUCT RELATED ISSUES

Medicines issues

Freeze drying of small volume aliquots of reference materials in convenient plastic microtubes - Teams in Technology, Development and Infrastructure (TDI) and Virology Divisions at NIBSC have been collaborating to deliver alternative convenient formats for certain biological reference materials. Most recently this has been used to deliver two recombinant protein reference materials:

- Vp40 antigen - a reference antigen material for Ebola testing – where glass containers were not appropriate for in field testing because of the risk from glass-cuts.
- 14.3.3 protein - a potential marker for certain neurodegenerative disease conditions where only very small amounts of the protein were available and where the tests similarly required little material. This material has been submitted as a CE marked candidate material.

The new format allows trays of 96 plastic tubes, which can be 2-d barcoded for ease of identification, to be dried in a laboratory scale freeze dryer (in batches easily of up to 1200 containers) stoppered in situ and then distributed or stored frozen.

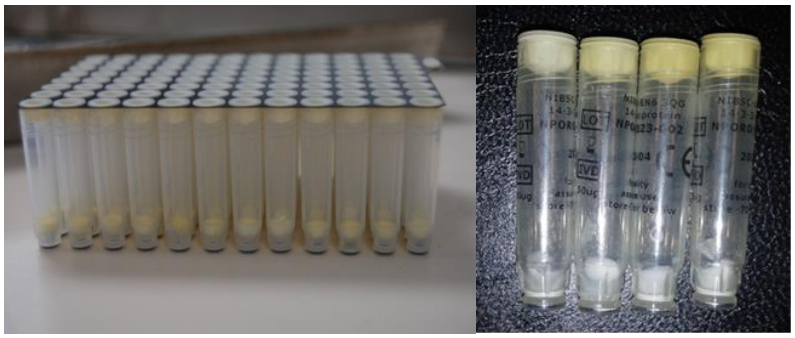
Further work is required to improve the security of the seal, and the headspace gas integrity of the units under prolonged storage, with some technical issues to address with further scale up. This format may not be the future for all of our reference materials, especially when compared to our default format - flame sealed glass ampoules - which have unparalleled storage stability. However, studies on glycan reference materials dried in this format 2 years ago show excellent stability for this particular application and the convenience for use with relatively stable materials required in low (microlitre) volumes is very encouraging.

Teams involved:

CT Yuen (TDI Laboratory of Molecular Structure)

Kataen Ladhani & Jillian Cooper (Virology)

Kiran Malik, Chinwe Duru, Ernest Ezeajughi, Paul Matejtschuk (TDI Standardisation Science)



3. REGULATION AND POLICY

European issues

Implementation of the Clinical Trial Regulation 536/2014 - The EMA informed Member States (MS) that the EU portal and database project is proceeding with some delays but would still be available for independent audit by August 2017. A new service provider started in October 2016 (a consortium called IT4U). If the system gets a green light from the audit, the EU Clinical Trial Regulation will come into effect by October 2018 at the latest.

User Acceptance Testing (UAT) 3 has been completed and all feedback has been analysed. UAT 4 is taking place between the 25 November to 2 December. The UK testers have widened to include colleagues from N Ireland and Scotland for UAT4. This testing is on sponsor-related activities.

Workshops with MS planned to focus on the application programming interface (API) for national IT systems to interact with the EU portal and database. The outputs will be to:

- Define and agree the scope of the API based on the approved requirements
- Define the details (e.g. security, authorisation, entity representation)
- Finalise the specification

A group of NCAs (chaired by BfArm; co-chaired by MHRA) has been created to help the project concerning the design of the API to progress faster. This subgroup will have National Competent Authority (NCA) and EMA representation (business and IT); it will focus on the requirements for the auditable release before working on any post-audit requirements.

HMA accepted a proposal to allow Member States access to information in the portal if not a Concerned Member State. Four countries might have problems with this due to national legislation and they are exploring this further internally.

Process mapping for the UK 'as is' processes is almost complete (MHRA and ethics). The next stage will be to use these to inform the 'to-be' process and develop the UK IT system requirements.

The Health Research Authority (HRA, working with CTU) are in the early stages of piloting the EU-agreed part 1 assessment report template to ensure ethics committees are comfortable using it and it captures everything they need. Part 1 assessment is the responsibility of both organisations whereas part 2 assessment is exclusively ethics.

The overall Communications strategy has been agreed amongst MHRA, HRA, and the Devolved Administrations. The delivery plan and message framework has yet to be agreed.

UK pushed for and joined a special EMA Management Board oversight group established to monitor progress.

SCOPE – the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action Flagship event took place on 23 November at the Royal Society of Medicine. Over the past three years the SCOPE partners have gathered information and reviewed the pharmacovigilance practices from National Competent Authorities across Europe. The SCOPE Flagship event showcased

SCOPE's findings together with the tools and outputs from this unique Joint Action. Our social media campaign to encourage more ADR reporting ran from 7-11 November and was a great success. Our main twitter account (@MHRAgovuk) averaged almost 70,000 impressions each day. We promoted our full animation to targeted audiences and achieved a 33% success rate (of 123,000 impressions our animation was viewed 41,000 times). Including our paid-for Facebook advertising, our animation has been viewed more than 90,000 times. The MHRA version of the animation is available to view at the link:
https://www.youtube.com/watch?v=3et5LdYLc8M

Organically on Facebook our video was shared 44 times by individuals and organisations, and has been seen by more than 5,490 people. Our post on LinkedIn has been seen more than 14,300 times. On YouTube our animation has been viewed more than 980 times.

Key stakeholders helped spread our message including talkhealth (10636 followers) Buckinghamshire CGC (3075 followers) and Healthwatch Cambridge (2309 followers) , Cancer Research UK (280,000 followers), the BMA (82,800 followers), and NHS Choices (196,000 followers). Their support greatly increased the audience for our campaign, at no extra cost.

Medical Devices Directive - The new EU Regulations for medical devices and *in-vitro* diagnostics were substantively agreed in June 2016. However, they are undergoing translation and legal checks, which is providing an opportunity to address any technical points of clarification. We still expect the new Regs to enter into force around April 2017, triggering 3 and 5 year transition periods respectively.
The Brexit 'deep dives' with MedTech stakeholders has highlighted the likely complications from Article 50 negotiations, which are expected to occur during these periods. For now, MHRA is taking a lead role with other European agencies and the Commission to agree priorities for a consistent implementation across Europe, to strengthen and utilise our influence for as long as possible.

UK ISSUES

E-cigarettes – A total of 10,750 individual product notifications were received by the November deadline for existing e-cigarettes and refill containers under the Tobacco and Related Products Regulations 2016. An interim process for processing notifications has been developed and plans are in place to publish a spreadsheet list of notifications in December. Work will also be restarted on development of the IT system to check notifications before the end of the transition period in May 2017.

Falsified Medicines Directive - Work continues on plans for implementation of the 'safety features' element of the Falsified Medicines Directive – due for full implementation by 9 February 2019. November has seen good progress on the impact assessment and our draft position flexibilities Delegated Regulation as we move towards a proposed public consultation in 2017. Final drafting is being made to a joint DH/ MHRA submission which will provide a ministerial update.

The Agency also continues in its supervisory role overseeing the work of SecurMed (the UK repository) who are currently going through a formal tendering process identifying a software provider (out of the original three companies they have now narrowed this down to two).

A different model for assessment of wholesaling pharmacy sites - The volume of new site applications for Wholesale Dealers Authorisations (WDA) has grown year on year which has put considerable pressure on the inspection resources of the Good Distribution Practice (GDP) teams. In an attempt to address the problem a new model of using Office Based Risk Assessments (OBRA) was launched earlier this year with the intention of helping overcome resourcing issues and also reducing the regulatory burden on industry, yet providing good assurance. Since inception the model has been applied to pharmacy collection sites which procure and collect stock for onward transfer to a company main site. The companies submit documentation and data using a questionnaire to allow GDP inspectors to remotely assess the applications for WDAs.

The initial phase of the scheme completed this month for all pharmacy sites that were either originally approved without an inspection or had been previously inspected with a re-inspection date during 2016. The project has involved the completion of 364 successful office based risk assessments, covering eleven companies. The efficiencies are clear when OBRA is compared to the GDP programme for inspections; the latter would have involved over 350 GDP inspector days on site (equivalent to around 5 GDP inspector's workload for a year) compared to 50% of one inspector's time used to carry out the OBRAs. In addition, besides freeing up a large amount of resources for the GDP team the project has also reduced the financial burden on the pharmacy sites involved by charging a reduced fee for the office based assessment.

The OBRA process will be validated during the first quarter of 2017 and will involve conducting physical inspections at a proportion of the sites that have been assessed remotely. Following the validation exercise, and provided the validation is successful, the scheme will be further developed to include other business types holding a WDA. Additionally, if validation is successful, OBRA will have facilitated the management of inspection resources together with a reduction in regulatory burden on the companies involved in the scheme, whilst continuing to maintain regulatory standards.

Several meetings have taken place this month around polio.

- A NIBSC/EDQM OPV transgenic mouse neurovirulence workshop was coordinated at the end of October which was held at NIBSC.
- On 14 November there was a meeting of CH/216 chemical disinfectants and antiseptics group of the British Standards Institute in London.
- On 23 November was a meeting of the UK Panel for the certification of elimination of Polio / UK National Authority for Containment (UKNAC) at PHE, Colindale, London.

4. MINISTERIAL AND PARLIAMENTARY PRIORITIES

Parliamentary Questions (PQs): the target for 2016/17 is to meet DH deadlines in at least 90% of cases. Performance for the month was 100%.
The Agency answered five PQs within deadline in November on:

- Continued access to the EU's rapid alert procedure after the UK leaves the EU.
- Potential costs the Government anticipates for medicines manufacturers in securing separate regulatory approval after the UK leaves the EU.
- Whether an assessment has been made of the possible link between the use of Aspartame and seizures prior to Vim Pat gaining marketing approval
- Sodium valproate and implications from the French compensation scheme.
- Potential for additional costs or complexities for medicines manufacturers in securing separate regulatory approval for the products for the UK and the EU after the UK leaves the EU.

Private Offices Cases (POs): the target for 2016/17 is to meet DH deadlines in at least 90% of cases. Performance for the month was 100%. The Agency led on thirteen responses in November and contributed to a Number 10 case about working with India in the area of pharmaceuticals post Brexit. The subjects covered in the cases on which MHRA led included:

- Two cases about the risk of valproate in pregnancy/the valproate toolkit.
- Use of lactose in medicines.
- Animal testing.
- Two cases about review of Primodos/hormone pregnancy tests.
- Licensing of medicines post Brexit.
- Information provided by suppliers of ileostomy apparatus.
- Use of adrenaline auto-injectors.
- Toxicology testing for e-liquids under the Tobacco Products Directive.
- Brexit and its implications for the UK pharmacovigilance system.
- Packaging of medicines.
- Myodil.

FOI Response Time Compliance: the target for 2016/17 is to ensure that 100% of requests receive responses within statutory limits (20 working days; or exceptionally within 40 days where an extension is required to complete a complex public interest test).

as at 31/10/2016	**FOI Requests Received 2016/2017**			
	Q1	**Q2**	**Oct**	**Total**
Received	161	134	59	**354**
Replies sent on time	158	131	58	**347**
Replies not yet due	0	1	1	**2**
Breaches	3	2	0	**5**
Compliance %	98.1%	98.5%	100.0%	**98.6%**

5. COMMUNICATION

The main agency-related issues covered in the press in November are as follows:

Patient and public engagement - Patient Group Consultative Forum (PGCF) – We organised a meeting of the PGCF on 11 November to obtain patient views on the different innovative pathways to regenerative medicine. The meeting was organised in collaboration with the Economic and Social Research Council (ESRC)-funded REGenableMED Project and involved MHRA representatives from the biologicals team, orphan drugs/EAMS, Clinical Trials Unit, Inspectorate, Devices and Policy. It was attended by representatives from 16 different patient groups/research charities including Action on Hearing Loss, Alzheimer's Society, British Heart Foundation, Diabetes UK, Parkinson's UK and the Thalidomide Trust. Outcomes from the meeting include:

- Patient groups are now aware of and better informed about MHRA's regulation of innovative medicines and the role it plays in bringing these safely to market.
- MHRA and the REGenableMED Project gained insights to the patient perspective on the different pathways for the development of Regenerative Medicine, attitudes to risk/benefit and issues concerning access to innovative medicines.
- A report of the main points discussed at the meeting will be circulated to all 80 members of the PGCF, representing between them 47 different patient groups/research charities.
- An emerging new model of pathway (described as 'critical path analysis') was identified through the day's discussions: the larger, better resourced charities, such as Parkinson's UK, go beyond simply supporting researchers elsewhere by undertaking a strategic review of clinical trials design, including how medicines might be repurposed. This will inform the REGenableMED Project final report in May 2017.
- The following charities were recruited into membership of the PGCF as a result of either having attended or been invited to the meeting: Genetic Alliance UK, Leukaemia CARE and The Macular Society. In addition, links were newly established with several others.
- MHRA staff responsible for the regulation of Regenerative Medicine devices will continue to liaise with the REGenableMED Project team in order to increase mutual knowledge and understanding of innovation in this area.
- The PPSE team and Licensing division will hold preliminary discussions around the possibility of a pilot for involving patient groups in EAMS.

MedRegs blog - We have received the green light for launch of the MedRegs blog, following approval from Government Digitals Services. The blog is scheduled to go live on 9 January 2017 featuring posts from Licensing, IPU and VRMM. This follows on from the successful inspectorate blog.

Substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFC) global communications project - We attended the annual meeting of the WHO's Member State Mechanism (MSM) for SSFFC products in Geneva during week of 21 November, where we presented an update in the plenary session of our work to date in 2016 and how this would be used to inform and improve our strategic plan going forward and in particular the work and activity plan for 2017. This was

approved by the Members who in turn were encouraged to join the Communications Working Group (CWG). Several countries including Brazil, Korea, Australia, Japan, India, Mexico and Colombia expressed interest in participating and are being followed up to try and secure their involvement. This will enable CWG to be better representatives of all WHO global regions. We also ran three communications group workshops during the week to further interrogate and validate the outputs of our in-depth research with members of CWG on most valuable contributions to 2017 plan. We intend to use the insights form this pilot to run a mechanism wide piece of research in Q1 2017 which will drill down further to the contextual level of local and regional communication initiatives. Following agreement in Geneva we are also exploring external collaboration and funding opportunities for specific parts of the programme including the role of academia, an initial meeting with Wellcome Foundation in early December, and some early conversations with creative agency groups to determine the likelihood of their providing pro (or low) bono services. Following the MSM meeting, the Communications Project Lead moderated and presented at a communications workshop at ICDRA in conjunction with WHO, embracing contributions from Serbia, Tanzania and Nigeria to demonstrate the breadth of work and thinking that is currently being developed at a country level. The principal intention of our presence here was to spread the work of the SSFFC CWG more widely amongst southern hemisphere countries and lay the groundwork for their further engagement in 2017.

Fake medicines and devices campaign - Our content produced to link the campaign to Halloween and Bonfire Night was very successful, performing well across the agency's social media platforms and causing our target audience to react positively. Web traffic to the campaign pages increased by over 50% in comparison to the previous week and partners who had not previously engaged with the campaign did so, extending the reach of the campaign to new audiences and helping us to achieve our key objective for this stage - to raise awareness of the concept that falsified medical products sold online is an issue.

A new interview has been prepared with Lucy Fallon, the actress whose character on Coronation Street is experiencing side effects with fake slimming pills containing sibutramine purchased online. This will be promoted out and sold to tie in with a crescendo to the storyline in the run up to Christmas and will promote her support for the campaign.

An article with an interview with Lynda Scammell has been sold to Bella, a women's lifestyle magazine, and will be featured in their January print, alongside a wider feature on diet pills and our interview with case study Natalie-Jade.

In response to requests from Universities and healthcare practitioners such as GP's and Pharmacists, we have started to develop some offline collateral in the form of posters for the campaign, which individuals and organisations who seek to support the campaign, but not through social media, can use to drive awareness of our key messages. These campaign resources will be hosted on the campaign webpages and we will be able to monitor downloads as an additional measurement for the campaign. The Council for Responsible Nutrition, campaign partners for the

Slimming Pills wave of the campaign, displayed the first posters at Food Matters Live, a conference that champions the collaboration of food, health and nutrition with over 600 exhibitors and thousands of delegates over a three day period.

We met with two academics from Teeside University who have written a book on Fake Medicines with support from enforcement. They have endorsed our current approach and their research will provide further hooks for the campaign to extend its achievement of objectives. Moving forward they will act as research/strategic advisors for the campaign who can provide support on work in this area and can be tasked with further research projects on a large scale to support. We have linked them up with the Independent's Health Correspondent Siobhan Fenton, who is interested in writing a feature on FakeMeds which ties in with the release of the book and the launch of our improved campaign website.

An ITV documentary on Britain's problems with sleeping carried information about the campaign and the ITV website linked to our safe online purchasing guidance, demonstrating the breadth of the campaign messaging. This created a spike in referrals to the page on the day of the programme as people clicked through That represented our highest web traffic to the campaign guidance pages of the month. We released our diet pills insomnia symptoms animation to tie in with the show which had a good response, especially on Facebook, with 511 views.

We have worked with ITV production company FourTwo media on their ITV programme "The Health Show" who have produced a report on dodgy diet pills, featuring an interview with Danny Lee-Frost, footage of a raid, collateral from the campaign, and advice on how to buy safely. The programme will air in January, and MHRA will receive a copy of the edit to approve in December.

Our social media activity around HIV Self-Test Week led to an approach from BBC show Fake Britain, who want to work on a feature on counterfeit STI Test kits in the coming weeks. We also received 30 retweets for our antibiotic awareness day tweet, which carried a quote from Alastair Jeffrey and reinforced our generic 'know what you're buying' message.

Yellow Card - We issued a press release under embargo on 4 November and we have received coverage online in PMLive, Nursing Times, and the Pharmaceutical Journal. We have been covered in stakeholder blogs Epilepsy Action and TalkHealth.
In the UK ADR reporting via Yellow Card increased by 17% (200 additional reports) over the campaign compared to the same period last year. Over 22 member states took part in this campaign and we are currently evaluating its overall impact. An evaluation report will be available in the New Year.

Competent Authorities for Medical Devices (CAMD)
CAMD communications strategy - A draft communications strategy for CAMD was presented at the CAMD meeting in Bratislava. At the subsequent CAMD Executive Group meeting, the strategy was agreed. Work begins on implementing the various phases of the strategy.

CAMD website development - A number of updates and improvements to the site have been made, following its launch. The site is being updated on an iterative basis with recent improvements including: updates to users' welcome dashboard, new registration process and a wide range of content updates.

Joint Action on Market Surveillance of Medical Devices – following the 39th meeting of the Competent Authorities for Medical Devices in October we launched the Joint Action on Market Surveillance of Medical Devices with a news story and promotion on social media. As part of this we facilitated an exclusive interview with John Wilkinson, MHRA Director of Devices, for the journal Clinica on our role in a European initiative on the market surveillance of medical devices.

Devices

British Society of Interventional Radiology (BSIR) conference 2016 (15-17 November 2016) – Devices colleagues exhibited at this event with the aim to improve reporting of adverse incidents by healthcare professionals with medical devices used in interventional procedures. Surveys featured on iPads to ascertain awareness of MHRA and its activities as this strategy has proved very successful at other exhibitions, providing the division with useful data. This data will be analysed and a summary will be included in the post event report to indicate the return on investment.

World Diabetes Day - We tweeted a number of times in support of World Diabetes Day. Our general messages included a reminder for diabetes patients to always check their insulin delivery devices, to read handling instructions before use and to consult a healthcare professional for any questions. In total our tweets were shared 23 times including some key accounts like Roche Diabetes Care UK, Diabetes Research & Wellness Foundation and the Wolfson Diabetes & Endocrine Clinic.

HIV Self-Test Week – To support National HIV Testing Week, we worked with the Terrence Higgins Trust to issue some social media around making sure HIV self-test kits are appropriately CE marked. We issued a number of Tweets and they were re-tweeted by a number of HIV support charities as well as the Terrence Higgins Trust which has over 20,000 followers.

GDP symposium (23 November) – Hilton Glasgow - Due to the significant demand for the GMDP symposium in December, this repeat event was held with a strong number of attendees following intensive promotional activity on social media and through email marketing to the conferences subscriber list. A post event report will include analysis of the area that the attendees are travelling from which will inform the geographical location of this event for next year, ensuring that we are providing the location that is most convenient for future delegates.

VRMM

A Joint Proprietary Association of Great Britain (PAGB)/ MHRA Seminar – Reclassification (17 November) - The Grange Hotel, London - The objective of

the seminar was to help improve the quality, content and structure of reclassification applications. We promoted the event on our website, through social media and via an e-invitation to our conferences subscriber list of c.30,000. We are considering the options for running a similar event independently based on the interest that is shown by non-PAGB members.

Valproate – We have incorporated Royal College of General Practitioner's (RCGP) logo in the valproate video animation and are liaising with the Royal College for inclusion of the video on its website. We began work with the Royal Pharmaceutical Society to develop a version of the video aimed at pharmacists. We have secured commitment from NHS England, ABN, NHS Digital and RCGP to present at a joint project update to the 32 members of the Valproate Stakeholders Network (VSN) in December (although the meeting will now be moved to February).

Ibuprofen – We provided a statement to a number of media outlets including the Daily Mail, Daily Express and BBC News Online in relation to suspected adverse reactions to Galpharm's Junior Ibuprofen. This follows a parent whose child was hospitalised after taking it and is now urging other parents through a Facebook campaign to report any side effects to this medicine.

Scientific Publications - During November, the following scientific paper was published by the NIBSC Flu Group:
Carolyn Nicolson*, Ruth Harvey, Othmar G. Engelhardt, James S. Robertson, 'The Ability of a Non-Egg Adapted (Cell-Like) A(H1N1)pdm09 Virus to Egg-Adapt at HA Loci other than 222 and 223 and its effect on the Yield of Viral Protein' PLoS One. 2016 Nov 18.
http://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0166761&type=printable
The MMR Group published the following:
'Deep sequencing reveals persistence of cell-associated mumps vaccine virus in chronic encephalitis'.
Morfopoulou S, Mee ET, Connaughton SM, Brown JR, Gilmour K, Chong WK, Duprex WP, Ferguson D, Hubank M, Hutchinson C, Kaliakatsos M, McQuaid S, Paine S, Plagnol V, Ruis C, Virasami A, Zhan H, Jacques TS, Schepelmann S, Qasim W, Breuer J. Acta Neuropathol. 2016 Oct 21. [Epub ahead of print]
The first collaborative study for EBOV Ab has been accepted by Vaccine: 'Comparison of platform technologies for assaying antibody to Ebola virus'
Dianna E. Wilkinson, Mark Page, Giada Mattiuzzo, Mark Hassall, Thomas Dougall, Peter Rigsby, Lindsay Stone, Philip Minor.

6. ORGANISATIONAL TOPICS

Meetings:

Medicines Trade Associations – meetings were held with the Association of British Pharmaceutical Industries; the British Generics Manufacturers Association; the Bio Industry Association; the Ethical Medicines Industry Group; and the Proprietary

Association of Great Britain. These are annual meetings held to discuss current and future priorities with the Trade Associations. Key topics discussed included making a success of Brexit, the Trade Association's priorities for 2017/18, and the Accelerated Access Review.

Shirley Norton Lecture – the annual lecture in memory of Shirley Norton took place on 1 November; the lecture was titled "New Medicines, Better Medicines, Better Use of Medicines", delivered by Professor Jayne Lawrence, Professor of Biophysical Pharmaceutics, Institute of Pharmaceutical Science, Kings College London and Chief Scientist at the Royal Pharmaceutical Society.

Departmental meetings – in November the Chairman and the CEO attended meetings with Dame Sally Davies, Chief Medical Officer; with Chris Wormald; and with Tamara Finkelstein. The Chairman and the CEO also met with colleagues from NHS Digital.

Royal Colleges – the Chairman and CEO held an introductory meeting with Louise Silverton (Director for Midwifery), Mervi Jokinen (Practice and Standards Professor Advisor), Carmel Lloyd (Head of Education) and Mandie Forrester (Head of Quality and Standards) at the Royal College of Midwives. A meeting was also held with Sir John Bell of the Academy of Medical Sciences on 22 November.

Regulation and Governance of Health Research – on 1 November the CEO spoke at a forum run by the Academy of Medical Sciences, Cancer Research UK and the Wellcome Trust on Regulation and governance of health research: five years on. The subject of the presentation was on Regulation of Clinical Trials: MHRA perspective, including implementation of the Clinical Trials Regulation.

Heads of Medicines Agencies – over 28-30 November the CEO and other members of MHRA staff attended the Heads of Medicines Agencies (HMA) meeting in Bratislava. At the meeting the UK obtained agreement from HMA to establish a cross medicines and devices advisory group to HMA and CAMD to help with the pan European regulation of borderline and combination products.

Ethical Medicines Industry Group (EMIG) Parliamentary dinner - On 7 November the CEO gave the opening address at the Ethical Medicines Industry Group (EMIG) parliamentary dinner in Westminster.

7. OPERATIONAL PERFORMANCE

ASSESSMENT PERFORMANCE

New UK Marketing Authorisations (MAs) - New Active Substances - 2 new drug substances were assessed in November. The overall average assessment time of new active substances from April 16 to March 17 is 51 working days or 74 calendar days.

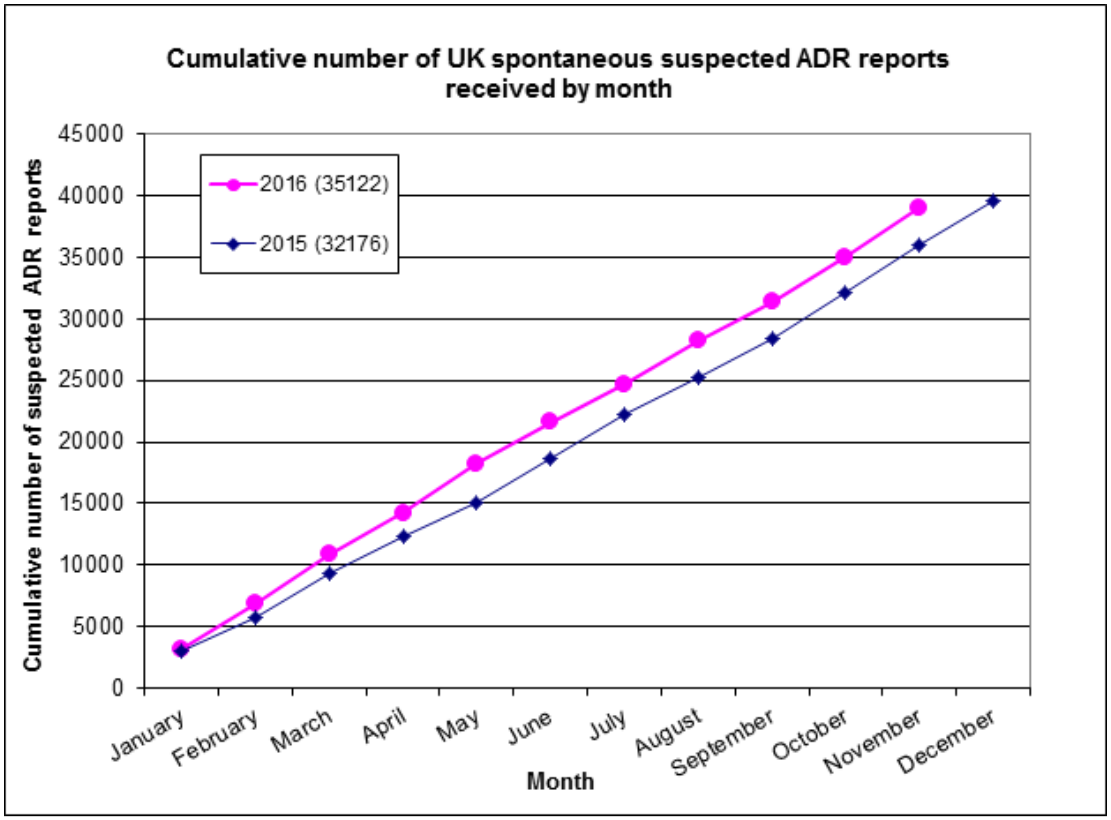
New UK Marketing Authorisations (MAs) - Existing Active Substances - The following tables give the numbers of new Marketing Authorisation applications assessed and determined (granted, refused, and withdrawn) during this month compared to the monthly averages for 2015/16.

Procedure	MAA Assessed This Month	MAA Assessed 2015/16 Average per month
National, UK-only	43	24
Decentralised, UK=RMS	28	28
Decentralised and MR, UK=CMS	43	45
Total	114	97

Procedure	MAA Determined This Month	MAA Determined 2015/16 Average per month
National, UK-only	17	19
Decentralised, UK=RMS	20	26
Decentralised and MR, UK=CMS	54	48
Total	91	93

The number (volume) of new MA applications assessed in November has increased compared to October's volume driven mainly by National assessments. The total volume of assessments for November is higher than the average number of assessments completed 2015/16. The numbers of new MA applications determined in November was slightly higher compared with the average monthly figures for 2015/16.

Pharmacovigilance Adverse Drug Reactions (ADRs) – During November the Division continued to meet all Agency targets related to the capture of ADR reports and signal detection. A total of 4023 UK ADR reports were received in November 2016, of which 783 were received from patients, parents and carers. A further 24527 non-UK reports were received in the month. Results against key performance measures for fatal and serious reports were both 100%.
100% of UK spontaneous serious ADRs were sent to EMA and MAHs within the High Level Target of 11 days



Devices adverse incidents - 1,625 Adverse Incident reports received in November (which compares with 1,508 for the same month last year), an increase of 7.8%. Cumulative total for 2016 is 15,687, which compares with 15,315 in 2015, an increase of 2.4%.

Device clinical investigations - 100% of clinical investigations have been completed within 60 days and the average review time for the year to date is 49 days. 5 clinical investigations were completed in November and 43 have been completed year to date.

Parallel imports (PLPIs) – In In November, 81 PLPI initial submissions were received, 117 were assessed and 132 were determined (67, 94 and 130 respectively in October).
Median time from submission to grant was 4.8 months (4.7 months in October). 642 PLPI variation applications were received, 840 were assessed and 851 were determined (1131, 1287 and 1263 respectively in October).
Average time from submission to grant was 2.0 months (1.8 months in October).

Public Assessment Reports (PARs) - • 100.0% of UK Public Assessment Reports and Lay Summaries (25/25) completed in November 2016 were published within the 60-day high-level target time from grant of the marketing authorisation. There were three updates to PARs (Type II Medical) with non-safety variations of clinical importance completed in November 2016, all completed on time.

Clinical Trial Authorisations (CTAs) - There were **10** Phase 1 applications processed in an average time of **13.4** days with **10/10 (100%)** within the 30 day

target. In the year to date there have been **99** Phase 1 applications processed in an average time of **12.6** days. Of all other CTAs, **61** were processed with an average time of **25.2** days and **61/61 (100%)** within the 30 day target. In the year to date there have been **538** non-Phase 1 CTA applications processed in an average time of **24.2** days.

Biologics batch release – Test release certificates for vaccines and blood products were issued for 191 product batches in November, 34 batches up from last month. 173 plasma pool batches were issued, down from 208 in previous month.
The review around the target for timeliness of product testing being missed on several batches is still ongoing as the figures need to be assessed by the Control Programme Board.

8. OTHER INTERNATIONAL TOPICS

Staff from NIBSC attended and facilitated a WHO workshop on implementation of recommendations to assure the quality, safety and efficacy of recombinant HPV vaccines, 15-17 Nov 2016, in Xiamen, China. She gave presentations on the European perspective of the batch release of HPV Vaccines and the production and use of International Standards and secondary standards. She also presented a National Control Lab case study on implementing a programme of work for the batch release of a new HPV Vaccine. The meeting was well received by participants who represented labs, regulators and manufacturers from Asian countries.
NIBSC colleagues attended the Coalition for Epidemic Preparedness Innovations first meeting of the Joint Coordination Group in Geneva on November 18th. The CEPI's mission is to prioritize, stimulate, finance and co-ordinate vaccine development against emerging infections with epidemic potential, especially in cases where market incentives alone do not achieve this.
NIBSC colleagues also travelled to Trinidad to establish contact with the Caribbean Public Health Agency to process samples in order to make reference materials - serum samples from Zika and Dengue patients were collected. The intention is to now work together to access their materials in the future which they normally discard after 5 years. A MoU will be set up to cover these activities.

Dr Ian Hudson
Chief Executive