Medicines and Healthcare products Regulatory Agency

15 December 2017

CHIEF EXECUTIVE'S REPORT FOR THE MONTH NOVEMBER 2017

1. HEADLINES for NOVEMBER 2017

Brexit - During November, preparatory work on Brexit continued as we potentially move towards future relationship negotiations with the EU. We have moved more clearly into the operational planning phase of our work with the Agency Task Force agreeing an increasing number of policy issues to present to the Corporate Executive Team. We have scoped out the framework of a change impact analysis to explore in more depth the implications for Agency procedures – and different parts of the Agency – of different scenarios.

EMA relocates to Amsterdam: Following the vote to relocate the EMA to Amsterdam, the EMA put out a statement from Guido Rasi welcoming the decision and thanking the member states for taking their requirements into consideration. Previous surveys of staff had shown that a large number of EMA staff would be willing to relocate to Amsterdam. The EMA and the Netherlands will establish a joint governance structure to steer and oversee the relocation project and in early December, the Agency will place a monitoring chart on its website that will track the progress made.
Stakeholders have congratulated Amsterdam and many have called for this to mark the start of attention turning to ensuring patient safety and access to treatments. The Association for Medical Research Charities (AMRC) reiterated the importance of continuing EU-wide regulatory frameworks for rare diseases and special populations and argued that a single authorisation for the EU can make distribution of medicines more effective. The Association of British Pharmaceutical Industries (APBI) called on both the UK and EU to ensure 'that securing a comprehensive agreement to cooperate on medicines safety, regulation and supply is an urgent negotiating priority'. Both the British Generic Manufacturers Association (BGMA) and BioIndustry Association (BIA) urged the government to provide certainty to ensure the supply chain of medical isn't disrupted for either the UK or the EU.

DH relocates to 39 Victoria Street - DH staff are moving from Richmond House (RH), Wellington House and Skipton House (SKH) to 39 Victoria Street (39 VS) between October and December.

2. PRODUCT RELATED ISSUES

Medicines issues

Reclassification - In November, a national marketing authorisation for Viagra Connect (sildenafil 50mg) was approved as a non-prescription Pharmacy (P) Medicine in the UK. This followed a public consultation and advice from the Commission on Human Medicines (CHM). A press release and web update was published regarding which received extensive media coverage.

Report of the Expert Working Group (EWG) on Hormone Pregnancy Tests (HPT) – The CHM) considered the report of the EWG on HPTs at their November meeting and endorsed the conclusions of the report that the available evidence did not support a causal association between HPTs and congenital abnormalities, miscarriage or still birth. On 15 November, there was a Written Ministerial Statement, a meeting with members of the Association for Children Damaged by Hormone Pregnancy Tests and a press conference

to coincide with the publication of the report. There was significant parliamentary interest following its publication including an urgent question in the House of Commons and the House of Lords on the 15 November and a number of written parliamentary questions. Members of the EWG met with the All Party Parliamentary Group on 22 November and a debate is scheduled for the 15 December. Work is ongoing to plan publication of the supporting paperwork for the report and implementation of the recommendations.

Gentamicin update - Last month we reported that the Defective Medicines Reporting Centre (DMRC) worked closely with the DH, Licensing Division and Vigilance and Risk Management of Medicines (VRMM) regarding the impact on safety and supply from higher than expected levels of histamine in some batches of gentamicin. Throughout November the team continued to deal with the issue, working with VRMM to respond to enquiries about the type and extent of monitoring required and the type of histamine-related adverse reactions which had been reported with the product. The supply levels became critical earlier in November due to ongoing shortages and DMRC worked closely with LD and DH to facilitate the release of batches of the product just in time to prevent running out of stock. The manufacturers are now returning to full capacity and it is expected that the supply levels will be back to normal by the end of the year.

Devices issues

Anaplastic large cell lymphoma (ALCL) - MHRA launched a webpage on ALCL on 26 July 2017 to provide clear, timely and authoritative information on Breast implant associated anaplastic large cell lymphoma (BIA-ALCL) to patients and clinicians. In light of new evidence, MHRA updated the ALCL webpage to include the number of reports of ALCL reported to MHRA, on 23 November 2017. Stakeholders including professional bodies, Cancer Research UK, Macmillan and Breast Cancer UK were informed. MHRA also provided a statement to the Daily Mail including a link to the website to update them of this new information. MHRA has also informed the other Competent Authorities of this update. Since the release of this new information on the website there has been no subsequent media interest.

Medical Device Alerts – There was one alert in November 2017

Number	Title
MDA/2017/034	ThermoScientificTM OxoidTM CAZ10 CEFTAZIDIME, CT1629B Antimicrobial Susceptibility Test Disc – Concentration of antibiotic decreases if not frozen potentially leading to false resistance results.

3. REGULATION POLICY AND OTHER SCIENTIFIC TOPICS

European / International TOPICS

Heads of Medicines Agencies – The final week of November also saw the second HMA meeting of the Estonian Presidency, attended by Ian Hudson and Jonathan Mogford, followed by a joint conference with TOPRA (membership organisation for healthcare regulatory professionals). HMA itself discussed a range of issues including Brexit preparations, the clinical trials regulation, cannabinoids, referrals and IT development.

Strategic Working Group Between Medicines and Devices Networks – A strategic working group has been set up to develop further cooperation between the Heads of Medicines Agencies (HMA) and Competent Authorities for Medical Devices (CAMD) networks at a strategic level. This has been considered on a number of occasions however

it is more relevant and timely then ever; there are multiple factor such as increasing changing regulatory environments and convergence between medicines and medical devices. A teleconference was held between members and following this a consultation was circulated to national trade associations for medicines and medical devices for feedback on specific issues where cooperation between medicines and medical devices sectors would appear mutually beneficial and will improve regulatory effectiveness and efficiency; and next steps to take. A face-to-face meeting took place in Tallinn after the HMA meeting, which was successful in identifying a way forward. Specific areas identified to focus on included MDR/IVD; software and cyber security; evidentiary standards; training; and criticality and growth of awareness in this area.

Operational Working Group between Medicines and Devices Networks - The Operational Group held its second t/c on 23rd November. Amendments to the Mandate were agreed for consideration by HMA and CAMD. One of the two co-chairs was elected (Liz Baker MHRA) and nominations were encouraged from Device Competent Authorities for the other co-chair. Preliminary discussions were held on:

- Definitions of terms that are important for the borderline between medicines and devices,
- New Medical Device Regulation Classification Rule 21 on Substance Based Devices.
- Devices recommending off label use of medicines and
- Point of Care Devices

Heads of Medicines Agencies Working Group of Communications Professionals (WGCP) – Director of Communications Rachel Bosworth chaired the HMA Working Group of Communications Professionals meeting in Dublin at the end of November. Presentations and discussions ranged from regulation of the medical use of cannabis in Germany to co-ordination of social media campaigns on adverse drug reaction reporting and next year's immunization week. The UK's three-year term as chair of this group comes to an end in December and we did not offer ourselves for re-election given Brexit. The new chair of the group will be Italy and a handover will take place in December. WGCP colleagues expressed appreciation for the UK's work in chairing the group over the last six years and we emphasised that the UK would continue to be active contributors to the group until Brexit took place.

EU-US Good Manufacturing Practice (GMP) Mutual Reliance Agreement - on 1 November, Inspectorate leaders drafted a blog to mark the start of the EU-US GMP Mutual Reliance Agreement. MHRA has been very closely involved in the work leading to this agreement and was one of the initial group of eight EU agencies considered as equivalent by the FDA.

EU Project on blood tissues and cells - Inspections Enforcement and Standards **(**IE&S) will participate in a European Commission project termed a Joint Action which is designed to support innovation in the fields of blood for transfusion, tissue and cells for transplant and fertility treatment. The title of this Joint Action is 'facilitating the Authorisation of Preparation Processes for blood, tissues and cells' (GAPP). The objective is to develop a common and proportionate approach to the assessment and, where needed, authorisation of preparation processes in blood establishments and tissues establishments. Dr Hudson signed the declaration of honour to participate this month.
MHRA's role in GAPP is restricted to blood components and we will be working closely with the Joint Professional Advisory Committee (JPAC) and NHSBT who are formal collaborating partners in this Joint Action. The Human Tissues Authority will also participate on human tissues and cells.

The authorisation of the production and supply of blood or tissue components does not currently exist in either the blood or tissues and cells legislation. However, within the UK, 'approval' of new components occurs through JPAC's development of guidelines for the UK Blood Transfusion Services and is collectively known as the Red Book. MHRA proposes to utilise JPAC's experience which is informally used by many EU and international blood transfusion services.
GAPP is a 3 years project and is running alongside a Commission review of the legislation on blood and tissues and cells, a piece of work that MHRA is also involved. The review is due to report at the end of 2018 and an expected outcome is that both Directives will be revised, most likely to contain stronger legislative basis for authorisation of novel components. This revision of the Directives will probably commence in 2019.

UK TOPICS

Corporate Strategy/Corporate Plan development – At September's meeting, the Board discussed a core set of slides setting out the approach to corporate planning and in particular key challenges to address. Subsequently there has been engagement with staff and with key strategic partners to bring them along with thinking and secure buy-in to the final corporate plan at the turn of the year. This engagement included:

- industry partners through the cross-Trades Associations meeting and Medical Devices Industry Liaison Group;
- DH sponsors and with Lord O'Shaughnessy at the Annual Accountability meeting on 27 September;
- the Devolved Administrations;
- NICE.

Three key blocks of work form the basis from which to develop the corporate strategy and thence the Corporate Plan for 2018-2023:

i. Further ongoing work on the Brexit "deal" and "no deal" scenarios and the financial implications, including fees, building on work to date on which the Board is closely engaged;
ii. new work to take the key challenges and build a practical narrative of what we propose to do in each of these areas and to bring this to the December Board meeting; and
iii. taking through the Operational Transformation programme an agreed set of core products and services to address how to improve productivity.

2018-19 Business Planning - The business plan for 2018/19 will set out the key steps which the Agency expects to take in the next business year towards delivery of the new Corporate Plan priorities.
The plan will also need to pay due regard to priorities of the Department of Health including objectives in the Department's Single Delivery Plan once published. Policy Division has had initial discussions with DH sponsors to explore timescales and expectations for the Business Plan next year. The Department is expected to write out to all DH Arm's Length Bodies chairs imminently setting out expectations for business planning. We expect this to include a deadline for submitting a draft to DH sponsors in early February.

Patient Safety and Vigilance Strategy (PSVS) – Work has been continuing across all the Project Teams. Good progress is continuing to be made with regards to using Clinical Practice Research Datalink in relation to devices safety and final revisions are being made to a study protocol before it is submitted to the Independent Scientific Advisory Committee for consideration. Preparations with other key healthcare partners for the health summit on 18th January have continued to progress well; there has been much interest from senior stakeholders. An update on progress will be going to CET in December.

Herbal Medicinal Products – Following Regulatory Group agreement in October to our proportionate approach, we have been working to implement MHRA commitments in the Government's response to recommendations 1 and 2 of Professor Walker's report on the Regulation of Herbal Medicines and Practitioners. With regard to recommendation 1, a review of potentially potent or toxic ingredients, we have developed a draft tender specification to commission an external contractor to produce a range of options on how to undertake such a review. This has involved close liaison with colleagues in Licensing, Inspection Enforcement & Standards, and Procurement, with a view to the tender being published early in the New Year. We also continue to engage with DH to develop a targeted and proportionate communications plan on current regulatory controls in the herbal sector as part of implementing Walker Report recommendation 2.

Accelerated Access Review – A Government response to the Accelerated Access Review was published on 3 November 2017. Sir Andrew Witty former CEO of GlaxoSmithKline will head the new Accelerated Access Collaborative of which we will be a part. The focus remains on NHS uptake and adoption but the licensing process, early access and horizon scanning are also elements of this work. The new pathway will be launched in April 2018 with work beginning now to implement some recommendations and develop others. We continue to be involved in meetings with OLS about draft criteria for the transformative designation, now likely to be called breakthrough designation, and also a proposed new scheme for medicines and medical devices small businesses to receive some funding to assist with real world data collection.

Launch of the Life Sciences Strategy - The Industrial strategy sector deal was announced on 6 December 2017. This is a commitment and partnership from Government, business, NHS and universities to develop and commercialise new treatments, creating jobs and benefits for patients. As we expected there were no direct references to MHRA or actions for us at this stage.

There are 5 foundations to the deal: Ideas, Business environment, Infrastructure, People and Places. These are to address 4 grand challenges of AI and data, future of mobility, clean growth and ageing society. The deal supports implementation of the AAR and work to support medicines manufacture, clinical trials and to attract inward investment. People and places themes are about skills and local actions. Areas of interest to MHRA in the Ideas, Business environment and infrastructure themes are:

Ideas

- **The Health Advanced Research Programme** will aim to put the UK at the forefront of work to address the global healthcare challenges of the next 20 years. It will seize the opportunities in new technologies that will shape our world such as genomics and artificial intelligence (AI), and which will create new industries in the process. Working with industry, charities, the NHS and universities. Initial collaborations include the '**Data to early diagnostics and precision medicine' programme** with up to £210m from the Industrial Strategy Challenge Fund (including *Genomics Whole genome sequencing of UK Biobank and extension of the cancer genome pathway*); and **Digital diagnostics and artificial intelligence: Use of AI in pathology and radiology diagnostics, demonstrating these technologies at scale within the NHS** to enhance the power of health data and technology to diagnose life-changing diseases at the earliest possible stage. More information will be announced in further sector deal announcements

Business environment

- **Investment -** MSD investment in discovery science as well as commitments from GSK, AZ and Vertex.

- **Manufacturing - Support the growth of medicines manufacturing .** A £146m investment programme from the Industrial Strategy Challenge Fund will support measures to grow medicines manufacturing.,.

Collaborations between companies and academia, developing innovative clinical trials, Infrastructure

- **Implement the Accelerated Access Review,** as outlined in November, to improve access to new technologies in the NHS by streamlining pathways and supporting small and medium-sized businesses:
    - Establish an Accelerated Access Collaborative to develop a streamlined pathway to bring breakthrough products to market and then to patients;
    - £86m of government funding focused on supporting innovators and the NHS locally;
    - A digital health catalyst which supports small and medium-sized businesses partnering with the NHS to develop technologies; and
    - Improve NHS England's commercial capacity and capability.
- The government and industry are working closely together to improve the UK's clinical trials environment – a key source of inward investment in the sector – with action underway to streamline NHS approvals processes and industry taking forward cutting-edge novel trial designs. (All actions are for HRA and NIHR).
- **Develop a number of regional, interoperable Digital Innovation Hubs** which support the use of data for research purposes within the legal framework, and meet the strict parameters for sharing data and the security standards set out by the National Data Guardian. They will create controlled environments for real-world clinical studies, the application of novel clinical trial methodology, and the comprehensive evaluation of new innovations so that patients can benefit from scientific breakthroughs much faster. NHS England, NHS Digital and Health Data Research UK in partnership with others will lead the delivery of this programme, drawing on input from multiple stakeholders including the academic sector, the life sciences industry, the charity sector and patients. (As we have advised before, Janet Valentine involved on links to CPRD and we think current plans are ambitious based on current NHS IT systems and data types that will be available).

Engineering and Physical Sciences Research Council (EPSRC) - NIBSC is part of a hub that has recently been funded by the EPSRC to advance the manufacture and deployment of cost-effective vaccines using exemplar vaccine targets such as rabies and chikungunya. The hub brings together industry and academia and is led by Professor Robin Shattock of Imperial College. A Principal Scientist in Virology, is the lead scientist at NIBSC, and the role of NIBSC will be to develop relevant reference materials and supporting regulatory science advice.

A scientist has been invited to represent NIBSC for the Coalition for Epidemic Preparedness Innovations (CEPI) Joint Coordination Group which oversees CEPI's vaccine development work for potential emerging pathogens. NIBSC is involved in producing reference materials for this with the three initial target pathogens of Middle East Respiratory Syndrome Corona Virus (MERS-CoV), Nipah Virus (NiV) and Lassa fever.

A lead scientist at NIBSC is also the representative of the Standards and Assays Working Group coordinated by CEPI and attended its first meeting with another Principal Scientist in Virology. They gave a presentation on NIBSC progress towards producing reference materials for MERS serology. The working group is part of CEPI's programme to develop vaccines for emerging pathogens in preparedness for potential outbreaks.

New Dashboard to Monitor Applications for Use of The Clinical Practice Research Datalink (CPRD) Data – Access to CPRD data is governed by internal quality and eligibility checks followed by peer-review by the Independent Scientific Advisory Committee (ISAC). Over the past 9 months CPRD has implemented a customised SalesForce customer

relationship management system which has transformed the way research applications are managed and monitored.
Weekly dashboards monitoring a range of metrics are automatically generated by the system and circulated to the ISAC secretariat, senior CPRD staff and the ISAC Chair. This data will be used as part of the forthcoming internal review aimed at further improving customer service and streamlining the ISAC application process.

Central Alerting System (CAS) - the opening meeting of the CAS Governance group (set up to oversee delivery of the new system) was held on 28 November 2017. Progress is being made with DH in terms of accessing information needed from the server environment, and we are finalising a testing plan ready for early December.
We have visited one independent hospital to review their alert process, understand their current use of CAS and to begin understanding the impact of requiring responses from this sector. We have a number of other visits lined up in December 2017. We are also speaking to Hospice UK on 1 December, and will be looking to visit hospices for the same reasons.

Patient and Public Engagement (PPE) strategy: We hosted a meeting of the Arms-Length Body Patient and Public Involvement Strategic Forum (20 November 2017) that was attended by representatives from Health Research Authority (NIHR), Healthwatch England, National Institute of Health Research, NHS England, NHS Improvement, The National Institute for Health and Care Excellence (NICE) and Public Health England. Together with updates on current work from each participating organisation, the meeting discussed a current NIHR work programme to develop national standards for patient and public involvement in research

Good Manufacturing and Distribution Practice (GMDP) Symposium (21-24 November 2017), London - Over 1200 delegates attended across this four-day event, generating an income of over £500,000.

Good Distribution Practice (GDP) Symposium (28 November 2017), Glasgow - Nearly 100 delegates attended this repeat event in Scotland, generating an income of circa £50,000.

Variations Conference (24 November 2017), London - Approximately 50 delegates attended this income generating repeat event following the oversubscribed workshop in September.

Applying for a Marketing Authorisation in the UK Workshop (29-30 November 2017), London - Nearly 120 delegates attended this two-day event which was developed following the success of previous 'Abridged Applications' events. This event generated a further c.£70,000.

Animal Welfare and Ethical Review Body – The Chair of NIBSC Animal Welfare and Ethical Review Body (AWERB), gave a presentation on NIBSC's activities to reduce and replace animal usage for batch release at the first AWERB hub meeting on 1 December at the Zoological Society at London Zoo. The hub brings together the AWERB chairs in the Home Counties region to exchange information and promote good practice for animal welfare and ethics. The AWERB hub network arose out of an initiative of the Home Office's Animals in Science Committee.

NIBSC is a partner in **the European Bank for induced Stem Cells (EBiSC)** project, established to provide high quality induced pluripotent stem cell (iPSC) lines with a range of diseases, allowing researchers access to iPSC lines which otherwise would be very time consuming to acquire and derive. A workshop, co-coordinated by NIBSC and EBiSC, took place in Berlin on 2 - 3 November, to disseminate the experiences of key opinion leaders

in the iPSC field and saw over 90 registrants from across the globe attend representing a mixture of academia, industry, Government, not-for-profit and Small and Medium-Sized Enterprise (SME) organisations.

Agency campaign honoured with a PRCA award - An Agency-led social media campaign run last November to encourage increased reporting of adverse drug reactions (ADRs) across Europe was announced winner of the 'Health and Wellbeing' campaign category at the Public Relations and Communications Association's (PRCA) annual award ceremony in London on 7 November. With 20,000 members, the PRCA is Europe's largest and most influential PR and communications membership body.
Two colleagues from Communications Division were at the ceremony to collect the award on behalf of the cross-divisional project team. It was presented in front of an audience of some 700 industry professionals.
This is not the first recognition for the campaign, which was born from the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action project being led by the Vigilance and Risk Management of Medicines (VRMM) division.
The project involved our leading the development and implementation of the social media campaign, which ran in 21 EU countries through collaborations with communications and pharmacovigilance teams in other national regulators.
The campaign led to a 13% increase in suspected ADR reporting (1,056 reports) between 15 regulators in the campaign week.
Social media analytics tell us that during the campaign 2,562,071 people were reached; our animation was viewed 337,781 times; with 22,584 likes, clicks, retweets and shares on social media.

Other campaign accolades include:

- A recent Bronze award from the Government Communication Service at the 2017 Public Service Communications Excellence Awards
- Short-listed finalist for the Chartered Institute of Public Relations (CIPR) Healthcare campaign award
- International Society of Pharmacovigilance (ISoP) poster prize – second place out of nearly 300 entries.

More awards - In another coup for the Agency, we also recently received two awards at the annual Institute of Internal Communications 2017 awards ceremony.
Our My Story campaign was announced as winner of the 'Storytelling' category against stiff competition from household names like Ikea and Nationwide Building Society. The judges commented: "A very impressive entry. This storytelling campaign was very well thought through and used industry best practice as a guide. It also had very clear objectives that set out what success would look like for them – and they achieved it".
To crown a successful evening, we were also selected as Public Sector Internal Communications team of the Year.
Commenting on the line-up of recent awards, Communications Director Rachel Bosworth said: 'Colleagues across the agency have contributed to these campaigns and it's great to see everyone's efforts being recognised. In what is a highly competitive communications landscape it is really encouraging to see industry experts recognising our internal and external communications work.'

4. MINISTERIAL AND PARLIAMENTARY PRIORITIES

Parliamentary Questions (PQs): the aspiration for 2017/18 is to meet DH deadlines in 100% of cases, this is in line with other DH staff. The Agency answered twenty-four written PQs in November (two re-drafts were requested by DH - one PQ was recorded late by DH as they requested a minor redraft to a PQ that had been sent up before the deadline and

the re-drafted reply was returned shortly after the deadline). The PQs were on subjects including:

- The Human papillomavirus (HPV) vaccine.
- The Expert Group's Report on Home Pregnancy Tests (HPTs) that was published in November.
- Brexit and associated implications for regulation of medicines.
- Sodium Valproate.
- Lariam.
- Animal testing.

The majority of PQs were about the Expert Group's Report on HPTs, the HPV vaccine and Brexit related issues. The Agency also contributed to seven PQ replies. In addition, the Agency provided briefing for both an Oral PQ and an Urgent Question on the Expert Group's Report on HPTs.

Private Offices Cases (POs): the target for 2017/18 is to meet DH deadlines in at least 90% of cases. All cases were returned on time. The Agency led on thirteen PO cases in November (one reply was returned for re-draft) and contributed to three cases. The cases on which MHRA led were about Sodium Valproate, mesh and Brexit.

Submissions: Two submissions were sent in November about:

- The Exert Group's Report on Home Pregnancy Tests
- Sildenafil.

FOI Response Time Compliance: the target for 2017/18 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).

October-17

as at 31/10/2017	**FOI Requests Received 2017/2018**			
	Q1	**Q2**	**Oct**	**Total**
Received	135	156	48	**339**
Replies sent on time	134	156	48	**338**
Replies not yet due	0	0	0	**0**
Breaches	1	0	0	**1**
Compliance %	99.3%	100.0%	100.0%	**99.7%**

5. COMMUNICATION

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

LifeVac – We took a number of enquiries about MHRA's regulation of LifeVac, an anti-choking device. After liaising with colleagues in Devices, we sent a statement to Huffington Post, Daily Mail, Cambrian News and Sunday Times Ireland.

Daily Mail – The paper formally responded to our rebuttal letter of a devices article from a few weeks ago, which addressed the points we made. They have offered to amend specific points but ultimately made no admission of any gross inaccuracies.

Fake Medicines Campaign – We worked with Sky News on a feature discussing erectile dysfunction medication as part of the #FakeMeds campaign. Sky produced a video that included an interview with Danny Lee-Frost, from Enforcement, and interviewed Danny on Facebook Live. 68,000 people watched his 13-minute interview where he talked about our work and key messages. The pre-recorded video has been viewed over 255,000 times so

far and has been used on Sky's Facebook page which has over 7m followers. Two of their presenters - Kay Burley with 390,000 followers and Sarah Hajibagheri with 3,689 followers also shared our messages with their followers. We also engaged with stakeholders who supported the Sky News piece on social media, including Royal Pharmaceutical Society, Brook, and General Pharmaceutical Council.
We worked with the BBC Inside Out programme to film an interview with Dr Chris Jones, Inspections Enforcement and Standards (*IE&S*) division, about DMAA and our work raising awareness of the issue for a documentary on doping in amateur sport. This is anticipated to air in January.
We finalised the joint MHRA and Slimming World press release, media launch strategy, stakeholder strategy and Twitter cards for the launch of the #FakeMeds survey on 30 November. We filmed Lynda Scammell, IE&S division, highlighting our key campaign messages on the risks of taking dodgy diet pills. We edited the video to use for the launch of the #FakeMeds survey. The press release and associated communications package generated extensive media coverage.

SCOPE Adverse Drug Reaction (ADR) Reporting Campaign – Comms led the development and implementation of a Europe-wide campaign to encourage ADR reporting, working in conjunction with 19 Member States, various European bodies, Brazil and New Zealand. This follows the successful ADR campaign last year. We managed the campaign, worked with the WHO Uppsala Monitoring Centre on the animations, produced templates and a campaign guide. In the UK, we sent the campaign guide and assets to over 230 stakeholders on 20 November 2017 and around 50 supported the campaign, including Mind, the General Pharmaceutical Council, Royal Pharmaceutical Society, Rowlands Pharmacy, NHS England and the Care Quality Commission.
We promoted the campaign across Facebook, LinkedIn, Instagram and Twitter, with over 135,000 impressions on Twitter, 18,000 on Facebook, 8,100 on LinkedIn and 11,000 on Instagram. Further evaluation will be carried out in December.

6. ORGANISATIONAL TOPICS

The MHRA relocation move to 10 South Colonnade (10SC) in Canary Wharf – Progress on the MHRA relocation to 10(SC) continues well. There are many meetings taking place to achieve this project delivery with great staff engagement and collaboration across the entire agency. The target move date remains June 2018.

Operational Transformation (OT) - Phase 1 of the OT Programme – This first phase comprised six work streams, each of which have made significant progress since the programme mobilised in July 2017, and culminated in the development of a Programme Business Case (PBC)

Commencing Phase 2
Whilst the PBC has been reviewed and refined, work has continued to prepare for the next phase of the programme which will focus on the next level of design, as well as getting delivery underway, both for 'quick win' areas and those projects that have long delivery timeframes:

- *Governance & Programme Management and Ways of Working:* Phase 2 planning has begun, considering the overall approach for phase 2, whether any refinements to governance is required and handling both the design and implementation elements of this High level TOM development – workshops are being run over the next few weeks to develop an indicative view of the high level TOM, thereby supporting areas of further detailed design and implementation

Operational Transformation is inextricably linked with the development of the new Corporate Plan and Brexit Task Force work and the respective teams are working closely

together to deliver an integrated approach. Additionally, the Programme Team are working closely with the move team to understand how OT might provide opportunities in Canary Wharf.

The payroll element of the Fusion system also successfully went live in November, making the activity involved in running the payroll a more automated process
The HR Division continue to embed the benefits of the Oracle Fusion system into the Agency's ways of working. Taleo Learn and the Goals and Performance modules of Fusion have been cascaded to all staff after a series of well attended workshops at BPR and NIBSC. A new corporate goal was cascaded to all staff through the system, the first time we have had the functionality to do so, along with the ability to monitor staff engagement with the system Agency wide. The corporate goal is an objective designed to ensure that all staff comply with all Agency policies and procedures, including mandatory training. Managers are responsible for ensuring that their teams achieve this goal too, with no member of staff or manager able to achieve an 'exceeded' rating in the end of year performance management review process where this is not achieved.
The payroll element of the Fusion system also successfully went live in November, making the activity involved in running the payroll a more automated process.

Mindful Employer charter - As part of our health and wellbeing programme the Agency has signed up to the 'Mindful Employer' charter. This is a commitment towards our putting the principles into practice and demonstrating our support to the mental wellbeing of our employees. Be a MINDFUL EMPLOYER is a UK-wide initiative run by Workways, part of Devon Partnership NHS Trust.

British Standards Institute (BSI) audit – On 28 November, the British Standards Institute (BSI) carried out a surveillance audit for the Agency's accreditation to BS OHSAS 18001:2007 (British Standard for Occupational Health and Safety Assessment Series).
The audit was successfully hosted by the Agency's Lead Health & Safety (H&S) Advisor, the BPR Safety Advisor and the Interim Overseas Travel Advisor, and all were noted in the report for their professional approach.
The assessment team reported that in line with the organisation's policy and objectives (5-year Strategy) the Management System has demonstrated that it is aimed to support the strategic direction, and generally deliver the intended results. The organisation continues to put its health and safety system at the forefront of the business and future plan, despite the high volume of change.
There were no major non-conformities raised although two minor non-conformities were given, one on retrieval of records where some training records for staff attendance at Hostile Environment Awareness Training could not be found, and secondly, where a corrective action from an internal audit was not closed on the Safety Organiser system.
In addition, one opportunity for improvement was given for the reviewing frequency of the H&S Policy Statement.
The auditor said the Agency was compliant overall and had demonstrated significant improvements to the management system over the past year, for example on management of overseas travel risks, and on the introduction of Safety Advocates at BPR.

Meetings of the Chief Executive – In November the CEO and the Chairman met with Mike Thompson, Chief Executive of the Association of the British Pharmaceutical Industry (ABPI).
On 9 November, the CEO went to visit the Health and Safety Executive's laboratories in Buxton; this was a very successful visit and many areas of potential collaboration were identified.
An introductory meeting was held with Professor Mary Reilly, President of the Association of British Neurologists (ABN) which highlighted a number of areas of collaboration between

the MHRA and the ABN. Another introductory meeting was held on 23 November with the Faculty of Physician Associates which was also very helpful.

Bilateral meetings with 5 UK medicines trade associations have been taking place; the main topics discussed at these meetings include making a success of Brexit, the trade associations priorities for 2018/19, the development of the MHRA Corporate Plan and Operational Transformation.
On 15 November, the CEO participated in an interview at Pharma Integrates 2017, on the Agency, Brexit and life sciences.
On 20 November, the CEO and Director of Policy met with the Department for International Development (DFID); a meeting was also held with the Academy of Medical Royal Colleges to discuss Brexit.
Over 28 -30 November the CEO attended the HMA meeting in Tallinn, Estonia; and gave a presentation on the ongoing work exploring areas of collaboration between the HMA and CAMD networks.

OPERATIONAL PERFORMANCE

New UK Marketing Authorisations (MAs) - New Active Substances - 4 new active substance applications were assessed in November. The mean assessment time since April 2017 remains at 50 working days or 73 calendar days.

New UK Marketing Authorisations (MAs) - Existing Active Substances - The number (volume) of new MA applications assessed in November was higher when compared with the average number of assessments completed in 2016/17. The number of new MA applications with UK as RMS has reduced significantly in November. The numbers of new MA applications determined in November was higher compared with the average monthly figures for 2016/17. (as below)

Procedure	MAA Assessed This Month	MAA Assessed 2016/17 Average per month
National, UK-only	43	34
Decentralised, UK=RMS	12	28
Decentralised and MR, UK=CMS	48	34
Total	113	96

Procedure	MAA Determined This Month	MAA Determined 2016/17 Average per month
National, UK-only	39	27
Decentralised, UK=RMS	39	24
Decentralised and MR, UK=CMS	31	53
Total	119	104

Parallel imports (PLPIs) – In November, 100 PLPI initial submissions were received, 101 were assessed and 92 were determined (84, 107 and 33 respectively in October).
Median time from submission to grant was 7.5 months (7.3 months in October).
477 PLPI variation applications were received, 657 were assessed and 745 were determined (1101, 1017 and 1045 respectively in October).
Average time from submission to grant was 2.8 months (2.2 months in October).
Training of the four new assessors is progressing well and service levels are anticipated to improve with the completion of the training programme and experience in the role.

Public Assessment Reports (PARs) - 100% of UK Public Assessment Reports and Lay

Summaries (2323) completed in November 2017 were published within the 60-day high-level target time from grant of the marketing authorisation. 2 updates to PARs with non-safety variations of clinical importance (Type II Medical) were completed in November 2017

Clinical Trial Authorisations (CTAs) - There were a total of 103 CTA applications processed this month (*1st November* to *30th November inclusive*) with 103 (100%) processed within the 30 day target. This included 17 Phase 1 applications processed in an average time of 12.82 days (target 14 days), with 17 (100%) within the 30 day target. Of all other CTAs, 86 were processed with an average time of 25.78 days and 86 (100%) within the 30 day target.
In the year to date there have been 106 Phase 1 applications processed in an average time of 12.5 days and 572 non-Phase 1 CTA applications processed in an average time of 24.8 days.
In total 678 applications have been processed in the financial year to date (+ 41 compared with the same period last year

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 4202 UK ADR reports were received in November 2017, of which 853 were received from patients, parents and carers. A further 16,260 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 marketing authorisation (MA) holders within the High-Level Target of 11 days. Of 179 general enquiries received, 85% were answered within 7 working days and 99% within 10 working days.

Devices adverse incidents - 1,836 Adverse Incident reports received in November (which compares with 1,625 for the same month last year), an increase of 13.0%. Cumulative total for 2017 is 17,745 which compares with 15,687 in 2016, an increase of 13.1%.

Devices clinical investigations - 100% of clinical investigations have been completed within 60 days and the average review time for the year to date is 55 days. 5 clinical investigations were completed in November and 45 have been completed this financial year.

Biologics batch release – Test release certificates for vaccines and blood products were issued for 183 product batches in November, an increase from the 113 batches released last month. Plasma pool releases also increased this month with 255 releases compared to 225 batches last month. The target for timeliness of product testing was achieved in November.

7. OTHER INTERNATIONAL TOPICS

The Head of Viral Vaccines, attended the 1st General Meeting of the WHO-National Control Laboratory Network for Biologicals in Noida, India, from 31 October to 2 November 2017.
He also co-hosted a meeting held at NIBSC with representatives from the Korean Ministry of Food and Drug Safety (MFDS) and SK Chemicals, 9-10 November which focused on Cell Culture derived Influenza vaccines and emerging infections.

Three NIBSC members attended the 3rd WHO Implementation Workshop on the Quality, Safety and Efficacy of Typhoid Conjugate Vaccines (TCV), 21-23 Nov, in Osong, South Korea. Two of the members gave presentations on 3 International Standards, which were developed for Vi polysaccharide and anti-Vi IgG. A talk was also given on ‘Sophisticated physico-chemical analysis for TCV’ and led a case study on ‘Data analysis and decision

making for quality control test for TCV'. Ian summarised achievements of the workshop and prepared a report for WHO as rapporteur. They also had two separate meetings with the Director General and senior scientific staff of the National Institute for Food Drug Safety Evaluation (Ministry for Food and Drug Safety) to discuss current projects and further opportunities for cooperation as part of the Memorandum of Understanding (MoU).

Support for individual countries in Member States Mechanism - Myanmar - We ran a communications workshop in Nay Pyi Taw between November 6 and 10 2017 with regulator (MFDA), in support of a World Health Organisation (WHO) workshop programme.

Dr Ian Hudson
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