Medicines and Healthcare products Regulatory Agency

20 October 2017 Closed Board

CHIEF EXECUTIVE'S REPORT FOR THE MONTH OF SEPTEMBER 2017

1. HEADLINES for September 2017

Brexit – We continued to use the joint letter from the Secretaries of State for Health and Business to the Financial Times, published on 4 July, as the basis for our external communications underlining this desire for an ongoing UK role in European Medicines Agency procedures. This was supplemented in September by Lord O'Shaughnessy's speech to the Association of British Healthcare Industries (ABHI) conference on medical devices, underlining that aspects of the new EU regulations would be in force as we leave the EU and therefore remain on UK statute books, supporting our desire to ensure that manufacturers can continue to supply both the EU and UK markets, ensuring no delay in patient access. This messaging has been well received by stakeholder groups – both industry and patient interests.

We have remained involved in the Brexit negotiations around Goods on the Market on the day of Brexit, attending the September round of Brexit negotiations in Brussels as part of a cross-Government team. We again highlighted the need to ensure continuity of supply across Europe as we exit the EU, and stressed – with specific examples - that many of industry's concerns would be eased by an early discussion about the future relationship.

Work has intensified around contingency planning, in particular with a view to the impact on both industry, and the MHRA, of a no deal scenario. The internal MHRA Task Force is examining the operational practicalities under different negotiation outcomes to ensure we have a sound analytical base around different options – and is starting to flesh out how operational processes would work, or differ than at present, if we are completely outside the EU framework.

Operation Pangea is the name given to a coordinated week of action targeting the illicit sale of medical products via the internet. It was instigated in 2008 by the MHRA who were then joined by a small number of likeminded countries. Now coordinated by Interpol, it has grown to be their largest global operation.
Operation Pangea X has just concluded and the engagement of countries has exceeded all previous operations with:

- 123 countries involved comprising of 197 police, customs and regulatory agencies.
- 1058 investigations taking place and 400 suspects placed under investigation.
- 715,000 packages were inspected and 470,000 seized by customs and regulatory authorities.
- Globally 25 million illicit and counterfeit medicines were seized amounting to a value of more than £38,000,000.

In addition to medicines, Operation Pangea X also focused on the sale of illicit medical devices, such as dental devices, implants, condoms, syringes, medical testing strips and surgical equipment.
The result of UK activity resulted in:

- Inspection of almost 1,500 packages and seizure of 1,333,597 units of medicines valued at £4 million.
- Of this total only 48 units (>0.004%) are suspected of being counterfeit, the majority seized being unlicensed medicines.
- Medicines from a range of therapeutic categories were seized and included those used for treating erectile dysfunction, narcolepsy and breast cancer.
- Twenty-three investigations were progressed and five search warrants executed.

Although there were 28 countries of origin, the primary sources were India, China, Hong Kong and Singapore.
In relation to the removal of websites acting unlawfully, a total of 3,584 were taken offline. Of the 3584 websites closed globally, the MHRA was responsible for investigating and closing 3413.

MHRA and Care Quality Commission – In September a Memorandum of Understanding was signed as a way of improving collaboration to protect public health. Our working relationship will help maintain an effective regulatory system for health and adult social care in England, while promoting patient safety and high-quality care. The Agency has worked closely with CQC on alert systems, medicines issues and online healthcare services.
The new MoU sets out the framework to support our joint working relationship. We agree on how to share information, to carry out regulatory functions and to benefit the public. The following principles underpin the MoU:

- addressing overlaps and gaps in the regulatory framework and responsibilities
- cooperating openly and transparently
- respecting each other's independent status
- using resources and intelligence effectively and efficiently.

Internal Communications Awards success – we were delighted to win two prestigious national awards from the Institute of Internal Communications – for best storytelling, and public sector internal communications team of the year.

2. PRODUCT RELATED ISSUES

Medicines issues

Valproate and risk of neurodevelopmental disorders – The Pharmacovigilance Risk Assessment Committee (PRAC) held its first public hearing to inform the ongoing review of the effectiveness of risk minimisation measures taken in 2014 in relation to valproate and risk of neurodevelopmental disorders. Patients, charities and healthcare professionals gave evidence at the public hearing. There was significant media coverage and Vigilance and Risk Management of Medicines (VRMM) worked with Comms to provide lines to take.
Daefective Medicines - Strathclyde Pharmaceuticals Limited recalled one batch of Xarelto (rivaroxaban) 20mg tablets because repackaging for parallel distribution introduced rogue 15mg blisters in two 20mg cartons. Xarelto is indicated for prevention and treatment of thromboembolic disease related to various conditions. Medical Assessor advice was that a patient could be seriously impacted if they mistakenly took 15mg once daily in place of 20mg (worst case for up to 28 days). Although the rogue blister was readily apparent, the Defective Medicines Report Centre's primary concern was for patient safety, so the decision was taken to recall the product as they could not rely on patients noticing.

Inspection Action Group – has been particularly busy with 39 active cases (18 GMP, 21 GDP) recorded at the end of September.

Devices issues

Essure - In September, manufacturer Bayer notified MHRA of their decision to withdraw from the CE re-certification and sale of Essure products in Europe due to commercial reasons. Comms Division worked with BBC Two's 'Victoria Derbyshire Show' to advise them of our position on the issue. On 20 September when Bayer announced a halt on the sale of Essure in all markets (except USA), BBC had another segment on their show covering the issue. The day after, we put a statement on our website to highlight our response. We engaged with nine key stakeholders including the Royal College of

Obstetricians and Gynaecologists and the National Aids Trust. Devices continue to obtain and review available information, including responses to the EU task force, to identify full ramifications of Bayer's decision.

Transvaginal mesh implants - Devices and Communications continue to work towards achieving the recommendations within the Mesh Oversight Group Report; published in July that are within its remit; in particular to raise awareness of reporting complications via Yellow Card Scheme. There has been increasing media, campaign group and parliamentary activities relating to meshes. This includes a meeting with Lord O'Shaughnessy (Parliamentary Under Secretary of State at the Department of Health) to set out the background of this issue and our actions to date and PQ for Oral Health session in parliament. Devices continues to advise the media, campaign groups and despite the concerns, from a regulatory perspective these devices were acceptably safe and has no plans to alter its stance on the regulatory status of these devices, nor had any regulator in the EU, or worldwide at this time. We also continue to work with clinical community and review available evidence such as paper published by Profession Bruce Campbell on a study of the complications relating to mesh for stress urinary incontinence.

Medical Device Alerts - There were three alerts in October 2017.

Number	Title
MDA/2017/029	Lung ventilators: Astral 100, 100SC and 150 – potential power loss due to faulty battery.
MDA/2017/030	All Accu-Chek® Insight insulin pumps – risk of alarm failure.
MDA/2017/031	IntelliVue patient monitors used with 12-lead ECG – risk of ECG trace distortion Specific models and software versions affected.

3. REGULATION POLICY AND OTHER SCIENTIFIC TOPICS

European/International issues

International Coalition of Medicines Regulatory Authorities (ICMRA) - The Agency hosted an all-member teleconference of ICMRA in September, building up to October's Summit in Kyoto.
We held a number of in-depth bilaterals with Singapore, Japan, Australia and Canada to discuss collaborative work

PREPARE (Platform for European Preparedness Against (Re-)emerging Epidemics) – The Clinical Trials Unit (CTU) met with a representative from PREPARE to discuss how the new CT Regulation may impact pandemic preparedness. PREPARE is an EU funded network for harmonised large-scale clinical research studies on infectious diseases, prepared to rapidly respond to any severe ID outbreak, providing real-time evidence for clinical management of patients and for informing public health responses.

International Conference on Pharmacoepidemiology (ICPE) and The *Clinical Practice Research Datalink* (*CPRD*) User Group meeting 2017 - The major annual conference for the International Society for Pharmacoepidemiology was held in Montreal in August this year. ICPE is the focal point for pharmacoepidemiologist worldwide and attracts many of CPRD's UK and international clients. A total of 70 abstracts using CPRD data were presented, with first authors from eight different countries, including six from CPRD and one from Vigilance and Risk Management of Medicines (VRMM). ICPE is a key customer engagement opportunity. CPRD takes advantage of this through the CPRD stand at the conference, arranging one-to-one meetings with customers throughout the

meeting and hosting the CPRD User Group meeting to coincide with conference. In addition to networking with customers, the User Group meeting provided a forum to update customers on the new cancer and mental health data linkages available and the forthcoming release of EMIS data.

UK TOPICS

Clinical Trials Regulation (CTR) implementation – Cross-agency meetings (Licencing Division, IE&S, Policy, IMD) were held in September to discuss the potential operational, legal and IT scenarios that occur as a result of the delay to the application of the Clinical Trial Regulation (CTR) which may be after the UK is expected to leave the EU. The UK IT project has been prioritised as part of the Operational Transformation (OT) project and Regulatory Board has recommended that the core IT aspects for MHRA case management (and interaction with ethics) begin again. Closer collaboration with Health Research Authority (HRA) and ethics committees is expected in any Brexit outcome and the MHRA/HRA co-assessment pilot is progressing to help inform future ways of working.
On a broader perspective, a meeting was held with HRA, MHRA and National Institute for Health Research (NIHR) representatives to discuss discovery work to explore the requirements for a joined-up national research infrastructure.
A European Commission meeting was held on 18-19 September. EMA provided an update on the delivery of the portal and database. They reported that release 0.6 requirements have been implemented as planned. These represent approximately 75% of Must requirements of the complete system.

Patient Safety and Vigilance Strategy (PSVS) – A PSVS update paper was presented at the September Corporate Executive Team and Board meetings. A report on signal detection from Commonwealth Informatics was discussed at the Steering Group meeting on 5 September and next steps are being considered. Good progress is being made with regards to using Clinical Practice Research Datalink in relation to devices safety. Preparations for the health summit with other key healthcare partners are progressing well and this will be held on 18 January 2018. Links are being made with the Digital and Operational Transformation work in terms of progressing and prioritising some of the PSVS activities.

Partnerships – We continue to build and embed partnership working with relevant bodies across Government, the health sector and industry. A new Memorandum of Understanding with Care Quality Commission was signed on 29 September. A partnership agreement with the Food Standards Agency is close to completion, and we are progressing discussions with Public Health England, Healthcare Safety Investigation Branch and Health Improvement Wales with a view to developing partnership agreements with them.
Plans are being finalised for the next round of quarterly partnership meetings in October, including with the National Institute for Health and Care Excellence (NICE), the Medicines Industry Liaison Group (MLG) and the Devolved Administrations, building on the constructive meetings held in July.

Certificating Body for International Standards – It was recognised as part of the 'Merger Workstreams' prior to The National Institute for Biological Standards and Control (NIBSC) joining the Agency that it would be sensible to have just one Certificating Body for the International Standard ISO 9001 rather than MHRA being accredited by the British Standards Institute (BSI) and NIBSC by Underwriters' Laboratories (UL).
Over the last year Quality Assurance (QA) has been working with Operations, Standards Processing Division (SPD) and the Centre for Aids Reagents (CFAR) and the Agency Quality Leads, to move to transition NIBSC to BSI, who are the Certificating Body for BPR. BSI have now audited NIBSC to confirm that it met ISO 9001. The audit identified no non-

compliances or opportunities for improvement and will now be added to the BPR Scope of Certification.

Human factors guidance - MHRA, in collaboration with key stakeholders, has published guidance on the human factors aspects of design for medical devices, including those in drug-device combination products. This guidance is intended for manufacturers, developers and notified bodies to highlight the important influence human factors have on patient safety. The advice is also relevant to device components of drug-device combination products that are regulated as medicines. Also, it will complement the work being carried out by the NHS to apply human factors approaches in the design of healthcare workplaces and practices.
https://www.gov.uk/government/publications/guidance-on-applying-human-factors-to-medical-devices

Variations Masterclass, 25 September 2017, BPR - This event is running through two identical sessions, the first took place on Monday 25 September 2017. We exceeded our target of 48 delegates with 50 actually registered to attend (and an additional 48 booked for the November session). To date the event revenue is £33,950 but there are an additional 15 delegates on a waitlist so we are looking at the possibility of running a third session early in 2018. Early feedback from the session is very positive with 96% of responses received to date saying the event met expectations.

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 four PQs in September (all four were answered on time) on subjects including:

- Risks associated with the *human papillomavirus* (*HPV*) vaccine that have been reported and recorded.
- The Agency's budget for each of the last 10 years.
- The number of product seizures made by the Agency in each of the last 10 years.

Private Offices Cases (POs): the target for 2017/18 is to meet DH deadlines in at least 90% of cases. Performance for the month was 100%. The Agency led on two PO cases in September and contributed to three DH led cases. The two cases on which MHRA led were about warnings on cytotoxic medicines and Brexit and an enquiry about placing a natural inhaler on the market.

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).

Rolling FOI KPI total

Aug-17
as at 31/08/2017

	FOI Requests Received 2017/2018			
	Q1	**Jul**	**Aug**	**Total**
Received	135	55	59	**249**
Replies sent on time	134	55	58	**247**
Replies not yet due	0	0	1	**1**
Breaches	1	0	0	**1**
Compliance %	99.3%	100.0%	100.0%	**99.6%**

5. COMMUNICATION

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

Managers' Conference – De Vere Grand Connaught Rooms – The managers conference took place on 22 September, and featured a session on 'neuroscience for organisational change' presented by external speaker Hilary Scarlett. There were also updates from the Chief Executive, presentations and a panel discussion on Brexit, operational transformation and the development of the new corporate plan, and pop-up sessions. Of the 377 managers in the Agency (including CET), we had a total of 250 attendees. As part of the event we used Sli.do to capture feedback and comments, and the "active users" more than doubled compared to the February conference. We are currently evaluating feedback from those who attended and this will go to the Corporate Executive Team in November.

All Staff meeting - Approximately 50% of staff attended our four All Staff meetings held at BPR and one All Staff Meeting held at The National Institute for Biological Standards and Control (NIBSC), where staff were updated on current issues which led to a number of questions via Sli.do and from the floor.

Shaping our Future staff engagement campaign – a brand for the campaign has been developed for the internal Shaping our Future staff engagement campaign, which brings together communications on the Agency's major change programmes, as agreed by Corporate Executive Team. This was launched at the Managers' Conference and also publicised at the All-Staff Meetings and a series of staff engagement 'consultation' events are being planned to take place in October. The events provide an opportunity to engage staff in the:

- early stages of planning for the new Corporate Plan;
- emerging themes from the Operational Transformation programme;
- engagement around key Brexit developments; and
- updates around the BPR office move plans.

Substandard and Falsified (SF) Global Communications - Agency colleagues attended the WHO Steering Group meeting on SF medical products during w/c 25 September. We presented the results from our Global Communications Survey, together with proposals for developing the guidance and advice that member states have indicated they would like through their specific responses within the survey.
We presented a menu of options for the guidance and a timetable and roadmap for its delivery. Approval was gained from SG members and we will now consult with members of the Communications Working Group on detailed proposals.
We continue to provide advice and guidance to regional WHO colleagues in Myanmar to enable the development of localised communications initiatives to target misdistribution of oral artemisinin monotherapies (AMT) through intermediary healthcare professionals.

Fake Medicines (FMD) Campaign - The new campaign webpage went live on 12 September – replacing the phase one slimming pills specific webpage. We updated text, images and call to action buttons on the webpage and connected webpages.
To promote the userability and longevity of the webpage, the campaign webpage is designed around 3 calls to action rather than one specific medical product. These calls to action are:

- Check – check to see if a website is registered to sell medicines;
- Report – Report any suspected #FakeMeds, suspicious websites or retailers

- Side Effects - report any suspected side effects

By promoting these calls to action we are trying to motivate the audience to change their behaviour, as per the #FakeMeds campaign KPIs.

- #FakeMeds have partnered with Slimming World to create a survey to identify their memberships' motivations and experiences of slimming pills. The survey has closed receiving 1698 responses. After reviewing the results, we are preparing communications content and working with national media sources (TV, Radio and online) as well as vloggers and bloggers to support the launch of our media story in October 2017.
- We included #FakeMeds advice on how to purchase medical productions online safely in our proactive communications warning students about self-medication and self-diagnosis and press releases highlighting the sentencing of 2 individuals guilty of supplying unauthorised and unlicensed medication.
- We are working to promote our role protecting people from fake dental equipment ahead of the British Dental Industry Association (BDIA) conference in October 2017. Our Group Manager for Devices, Graeme Tunbridge, is being interviewed by the BBC on the topic. We are also finalising content (including filming a video) to highlight #FakeMeds partnership with the BDIA conference.

Medical device regulation comms - MHRA provided researchers from BBC Two's 'Victoria Derbyshire Show' with an extensive brief for a programme they plan to run in October about the regulation of medical devices. Work continues between Comms and Devices and the BBC to ensure balanced coverage.

Huffington Post Article – NIBSC scientist Andrew Macadam was interviewed for a Huffington post article about his paper on plant-made polio vaccines and the paper was discussed as part of a podcast on polio for This Week in Virology.

WEB-Recognising Adverse Drug Reactions (RADR) – Work has started with the appointed company on maintenance of the WEB-RADR mobile app. The 7 September stakeholder event was a great success, and was attended by over 150 representatives across industry, patient organisations, regulators and healthcare professionals. A project extension has been approved by IMI, extending WEB-RADR until 31 December 2017.

6. ORGANISATIONAL TOPICS

Relocation to Canary Wharf – the MHRA is progressing well and is on track to relocate to 10 South Colonnade (10SC) between the months of May to June 2018.
As part of staff engagement, staff will be provided with a taste of their own '10SC Model Office' at 151 BPR. This will include several desks, chairs and a set of personal lockers for staff to book and trial, starting week-commencing 23 October and in situ until the relocation in 2018. As part of this 'Model Office' trial, staff will also be able to book two nearby meeting rooms – all by using the new Matrix keytree booking system; which will be installed for use at 10 South Colonnade. We are also planning to install a Gov Wifi wireless network which will in due course replace the current Guest MHRA network for visitors in preparation for the move to 10SC where the Gov Wifi wireless network will be the norm for visitors.

Operational Transformation (OT) is a significant organisation-wide transformation programme. The aim of OT's first phase of work is to produce a business case for proposals to redesign and realign what we do to maximise public health impact, both in the UK and Internationally. The business case will come to the CET and Board in November.
This first phase comprises six work streams, each of which have made significant progress since the programme mobilised in July 2017:

Setting our strategic direction – our two works streams, Ways of Working and Market and Customer Insight, have been merged into a single story for our Transformation. A Strategic Direction report outlining our evolving strategic imperatives has been developed, and went to CET on 6 October.
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. Stephen Lightfoot is being kept up to date by the OT programme as the Board member with responsibility for this.

CPRD and Devices - Joint working - CPRD has been working closely with the Devices and Vigilance and Risk Management of Medicines (VRMM) divisions over the past year as part of the Joint Patient Safety and Vigilance Strategy Project team that is exploring the use of CPRD data to support devices vigilance. As part of this project, work was undertaken to explore the utility of CPRD for monitoring outcomes in patients with breast implants, hip and knee replacements, and transvaginal tapes. CPRD has also contributed to a strategy document being prepared by the project team on the use of CPRD data to support vigilance functions within the Devices division. Finally, CPRD has also been supporting colleagues in Devices in their work on regulatory implications of machine learning algorithms used as part of software applications.

The Quality Assurance lead for use of Human Tissue. NIBSC,has been working for some time on streamlining the process of collecting data required for the Human Tissue Authority (HTA). The licence held by NIBSC for its research work using human tissue, requires a large amount of data to be gathered, that in 2015 took around 30 man hours of work. In 2017, following a great deal of work to reconsider how the data is held, it took only 2 hours to gather, and allowed fast consultation of the response and sending the report back to the HTA. This was a good example of how it pays to invest time and effort in streamlining our ways of working.

The Research Excellence Group (REG) has been set up at NIBSC with the mission to 'big up' the research activities going on at the Institute and to put in place processes to help develop and enhance the research culture at NIBSC.
The aims are to engage and encourage researchers at NIBSC, and support them in the development of research projects and with associated activities (grants, talks, publications), with a particular focus on supporting PhD students and building the PhD programme, and on promoting cross-divisional working.
One area has been the development of the biannual NIBSC PhD Student Mini Symposia, the first of which took place on 20 September, providing the PhD students with the opportunity to share their work and promote scientific discussion amongst staff.
(next one will be March 2018). There were seven oral presentations from the students and a poster session, covering the wide range of research topics investigated at NIBSC. A selected panel of NIBSC scientific staff were tasked with judging the oral and poster presentations, and prizes were presented for the best talks and posters on the day.

- A colleague (Technology, Development, and Infrastructure [TDI]; University College London) received the prize for the best oral presentation for her talk titled 'Using hydrogen/deuterium exchange mass spectrometry and computational screening to facilitate the stabilisation of biotherapeutics proteins.'
- Colleagues from (Biotherapeutics; King's College London), (TDI; Imperial College London) and (Gene Therapy – Advanced Therapies; University College London) also received prizes for their poster presentations.
- The REG also oversees and supports the Director's NIBSC-authored 'Paper of the Month' and the NIBSC Journal Club. Other activities are in development and suggestions are always welcome to any member of REG.

Good Clinical Practice (GCP) Symposium – This year's annual GCP Symposium took place on 6 - 7 September at the Royal Armouries Museum in Leeds. The main focus of the Symposium was to update stakeholders on regulations and guidance in clinical trials and had ~400 delegates in attendance; roughly 50:50 split between commercial and non-commercial stakeholders. Early feedback included comments on the professionalism of the MHRA speakers and its constructive pitch to be helpful to the stakeholders. Delegates included representatives from the FDA, Health Canada and the Care Quality Commission, attending from a regulators perspective. Topics covered included Trial and System Design, Oversight of Investigational Medicinal Product (IMP) management and Interactive Response Technology, Data Integrity controls, Monitoring and Oversight of Monitoring.

OPERATIONAL PERFORMANCE

New UK Marketing Authorisations (MAs) - New Active Substances - 3 new active substance applications were assessed in September. The mean assessment time since April 2017 is 50 working days or 73 calendar days.

New UK Marketing Authorisations (MAs) - Existing Active Substances - The number (volume) of new MA applications assessed in September was lower when compared with the average number of assessments completed in 2016/17. The numbers of new MA applications determined in September was lower compared with the average monthly figures for 2016/17.

Variations to UK MAs

Procedure	Type II Assessed This Month	Type II Assessed 2016/17 Average per month
National, UK-only	38	53
MR, UK=RMS	36	23
MR, UK=CMS	67	45
Total	135	121
Procedure	**Type II Determined This Month**	**Type II Determined 2016/17 Average per month**
National, UK-only	60	66
MR, UK=RMS	57	29
MR, UK=CMS	28	52
Total	145	147

Parallel imports (PLPIs) – In September, 67 PLPI initial submissions were received, 61 were assessed and 40 were determined (86, 15 and 35 respectively in August). Median time from submission to grant was 7.3 months (6.7 months in August). 512 PLPI variation applications were received, 601 were assessed and 589 were determined (745, 911 and 984 respectively in August).
Average time from submission to grant was 3.1 months (2.2 months in August). 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 (28/28) completed in September 2017 were published within the 60-day high-level target time from grant of the marketing authorisation. Three updates to PARs (Type II Medical) with non-safety variations of clinical importance completed in September 2017.

Clinical Trial Authorisations (CTAs) - There were a total of 78 CTA applications processed in September with 78 (100%) processed within the 30 day target. This included 12 Phase 1 applications processed in an average time of 12.50 days (target 14 days), with 12 (100%) within the 30 day target. Of all other CTAs, 66 were processed with an average time of 25.97 days and 66 (100%) within the 30 day target.
In the year to date there have been 77 Phase 1 applications processed in an average time of 12.6 days and 424 non-Phase 1 CTA applications processed in an average time of 24.6 days.

Pharmacovigilance Adverse Drug Reactions (ADRs) – During September the Division continued to meet all Agency targets related to the capture of ADR reports and signal detection. A total of 3468 UK ADR reports were received in September 2017, of which 655 were received from patients, parents and carers. A further 24430 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 189 general enquiries received, 95% were answered within 7 working days and 99% within 10 working days.

Devices adverse incidents - 1,551 Adverse Incident reports received in September (which compares with 1,307 for the same month last year), an increase of 18.7%. Cumulative total for 2017 is 13,767 which compares with 12,574 in 2016, an increase of 9.5%.

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. 7 clinical investigations were completed in September and 33 have been completed this financial year.

Biologics batch release – Test release certificates for vaccines and blood products were issued for 115 product batches in September, a very small drop from 123 issued in August. Plasma pool releases were made on 81 batches compared to the 129 in the previous month. The target for timeliness of product testing was achieved in August.

7. OTHER INTERNATIONAL TOPICS

The 2nd Colombian Scientific Meeting – Colleagues from NIBSC Biotherapeutics and from Standardisation Science in the Technology, Development, and Infrastructure Division, co-chaired and spoke at the 2nd Colombian Scientific Meeting on Quality Assessment of Biosimilar and Similar Biotherapeutic Products in Bogota, Colombia, which was organised by the Generics and Biosimilars Initiative. They spoke on preparation and production of reference standards in support of biotechnology products and on Value assignment of International Standards – challenges for potency labelling of biotechnology/biosimilar products.

Chinese Delegation – A delegation from National Institute for Food and Drug Control (NIFDC) China, led by, deputy director, , visited NIBSC on 12 Sep 2017, to deepen the cooperating relationship with NIBSC and identify further collaboration opportunities. NIFDC colleagues introduced priorities and strategy in their institute, and NIBSC colleagues updated on current collaboration projects including those about Japanese Encephalitis Virus (JEV), and Human Papilloma Virus (HPV). Both sides agreed to build further collaboration platforms in areas such as monoclonal antibodies, in-vitro diagnostic (IVD) products, and pseudotype viruses. NIFDC provided an update on the distribution

procedures for Enterovirus 71 Neutralising Antibody International Standard (EV71 NtAb IS), which is part of the agreement signed between the two organisations in March this year.

Bureau International des Poids et Mesures (BIPM), Canada - on Sept 28-29 (Technology Development and Infrastructure), (Biotherapeutics), (Virology) visited Ottawa, Canada to attend the BIPM Fall meetings of their Consultative Committees, the Amount of Substance (CCQM) Protein Analysis Working Group (PAWG), Cell Analysis Working Group (CAWG) and Nucleic Acid Analysis Working Group (NAWG). These meetings bring together representatives from global National Metrology Institutes dealing with the measurements in bio-analysis who are working to establish their capacity to measure these different types of materials in SI units. Biological standards produced by NIBSC, and established by WHO, are typically assigned a consensus value and a more pragmatic value (the International Unit) in the measurement of biological activity of many of their physical standards is applied. We recognise that with improved scientific understanding and advances in analytical technology, it is possible that, for some standards, this “biological activity” may now be measured in SI units (e.g. number, kg, mL etc.) going forward, in a similar manner to the improvements in measurement of Insulin over the past 70 years. Engaging with national measurement institutes will enable NIBSC to encourage this process of advancing better measurement of biologicals, as we develop future International Standards.

The Regulatory Research Division (RRD) of Health Canada - On 27 September as part of the visit, the three scientists above also visited the RRD to inform scientists there of current scientific interests at NIBSC. Subsequent discussions identified areas of mutual interest dealing with Vaccines, Stem Cells, Cell and Protein Analysis which will hopefully lead to closer links between NIBSC and the RRD of Health Canada in the future.

Dr Ian Hudson
Chief Executive