Medicines & Healthcare products Regulatory Agency

The MHRA's active role as part of the UK and global innovation ecosystem

Joint BIA and MHRA Conference 2018

Dr Ian Hudson, Chief Executive

CPRD NIBSC MHRA

Medicines & Healthcare products Regulatory Agency

CPRD

Clinical Practice Research Datalink

- NHS observational data and interventional research service
- Jointly funded by NIHR and MHRA
- Anonymised data
- Observational research studies: links between things like diet, or family history, and particular illnesses
- Clinical trials: UK/pan-EU

NIBSC

National Institute for Biological Standards and Control

- Standardisation and control of biological medicines
- Over 90% of international biological standards
- UK's Official Medicines Control Laboratory for biological medicines
- Research
- Close relationship with WHO
- WHO collaborating center for polio, influenza and HIV

MHRA

Medicines and Healthcare Products Regulatory Agency

- Regulation of medicines: quality, safety, efficacy
- Medical devices: overseeing the UK Notified Bodies
- Operating post-marketing surveillance
- Blood and blood products
- Quality surveillance system
- Regulating clinical trials
- British Pharmacopoeia
- Over 500,000 device types and over 15,000 medicines

MHRA support for bringing innovation safely to market

We support innovative product development by:

- **Horizon scanning** – *a cross-agency team of experts meets regularly to identify new science and scientific methods that may impact on regulation of products. Information from the Innovation Office informs our Horizon Scanning work*
- **Offering advice** – *help lines, innovation office, scientific advice, joint advice with NICE, Regulatory Advice Service for Regenerative Medicines*
- **Guidance**
- **Scientific meetings** to keep informed of advancements
- Influencing at European and international level – appropriate risk based regulations

MHRA support for bringing innovation safely to market

MHRA Innovation office:

- Facilitates understanding of regulatory requirements to bring innovative products to market
- Encourages early dialogue between companies/researchers
- Provides regulatory and scientific support to such groups in their interaction with the regulatory environment
- Co-ordinates scientific advice on regenerative medicines/ATMPs on behalf of all UK regulators (the ‘One Stop Shop’)

Further information: Innovation case studies and

https://www.gov.uk/government/groups/mhra-innovation-office

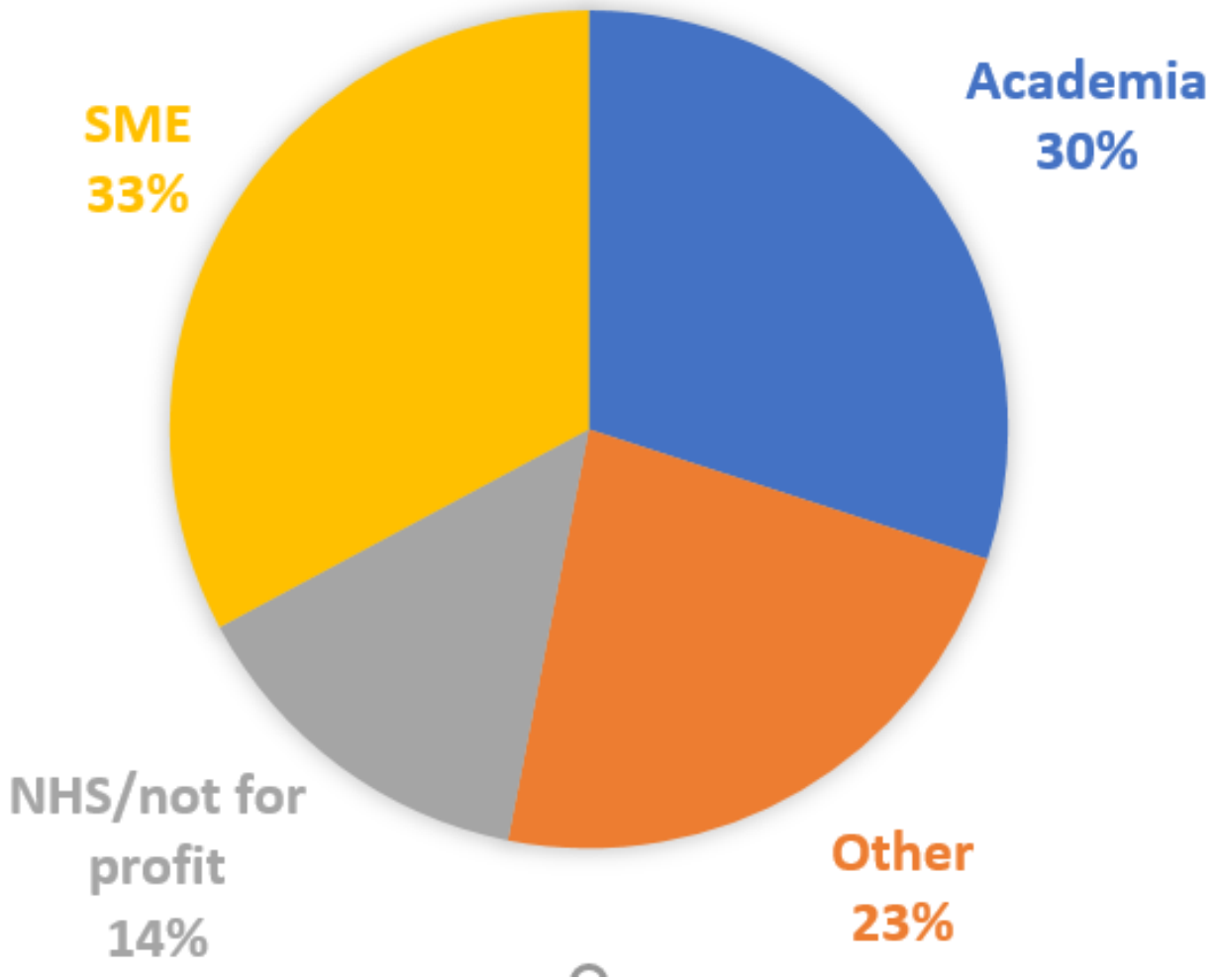
'Bringing innovation safely to market' (A key theme in the MHRA's Corporate Plan 2013-2018

- MHRA Innovation Office launched 5 years ago

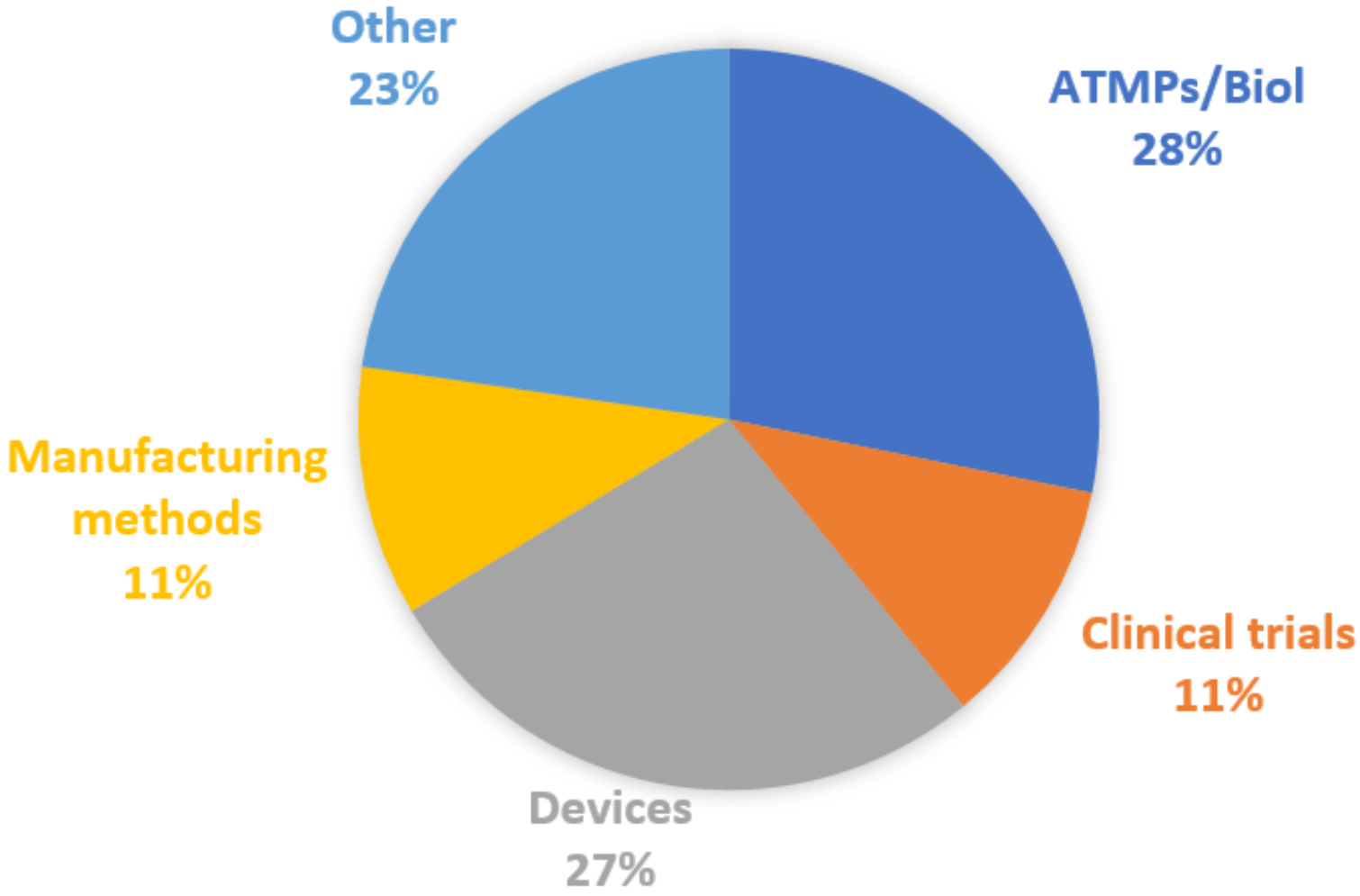
- In that time we have:

- responded to 570 enquiries
- held over 120 regulatory meetings
- responded to 60 'one stop shop'/ RASRM enquiries

Who is currently using the Innovation Office?



What topics are covered?



EU innovation activities

- Scientific advice
- EU innovation network
- Borderline operational group
- Strategic borderline (medicines and devices) group
- Novel licensing routes
- Balanced regulation and guidance

MHRA support for bringing innovation safely to market: Early access

- **UK Early Access to Medicines Scheme**: launched April 2014 to improve access, on an unlicensed or off-label basis, to important innovative medicines
  - *life threatening or seriously debilitating conditions without adequate treatment options*
- **Stage 1**: new Promising Innovative Medicine (PIM) designation to provide an early indication that a product may be a possible candidate for EAMS
- **Stage 2:** MHRA issues a new benefit:risk scientific opinion
  - *52 PIM designations and 19 benefit:risk scientific opinions granted*

MHRA support for bringing innovation safely to market

- Recognition that earlier access to innovative products must be balanced against need, information, risk and uncertainty
- Early access must be accompanied by strengthened vigilance systems, incl. real world data monitoring
- Must ensure that early access does not jeopardise ability to collect robust data long term
- Need to join up with other bodies to facilitate speedier patient access

International Coalition of Medicines Regulatory Authorities (ICMRA)

- ICMRA is a voluntary, executive-level, strategic coordinating, advocacy, and leadership entity of medicines regulatory authorities (MRAs) that work together to
  - ✓ address current and emerging human medicine regulatory and safety challenges globally, strategically and in an on-going, transparent, authoritative and institutional manner;
  - ✓ provide direction for areas and activities common to many regulatory authorities' missions;
  - ✓ identify areas for potential synergies;
  - ✓ wherever possible, leverage existing initiatives/enablers and resources

International Coalition of Medicines Regulatory Authorities (ICMRA)

Strategic Priorities:

ICMRA innovation workstream

3 parts:

- Horizon Scanning: Methodologies and Best Practice

- Horizon Scanning: Critical product and technology innovation, which will benefit from or require regulatory science based approaches for future regulation. Collaboration in the development of expertise necessary to support innovation as identified through horizon scanning.

- Novel approaches to licensing, the identification of barriers and determining progressive approaches that might be used to address these to deliver patient access.

Conclusions

Rapidly changing environment

Recognition of importance of supporting innovation.

National activities

EU collaboration

Global recognition and activities (through ICMRA)