AIPPI 2017 Sydney World Congress
OCTOBER 13 - 17, 2017

AIPPI 120 Years

Pharma Session 3: Medical devices and patents – a shot in the arm for pharma?

Monday, October 16 2017

14:00-15:30

- Hector Chagoya, Becerril, Coca & Becerril (BC&B) (Moderator)

- Derek Minihane, Cochlear
- Michelle Pratt, Boult Wade Tennant
- John Toddaro, Merck (MSD)
- Dominic Adair, Bristows

BC&B
BECERRIL, COCA & BECERRIL, S.C.

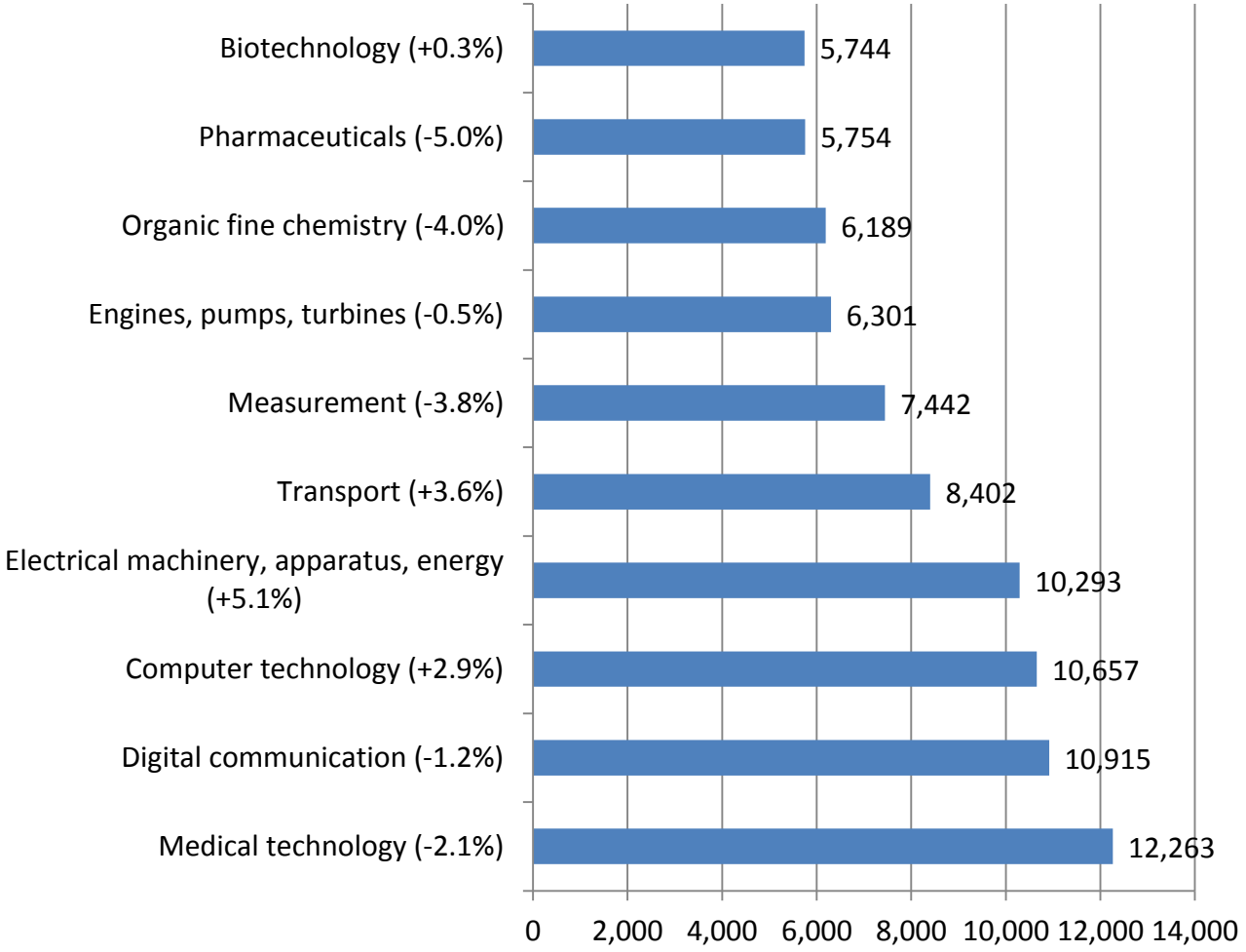
Cochlear®

boult
BOULT WADE TENNANT

MERCK
INVENTING FOR LIFE

BRISTOWS

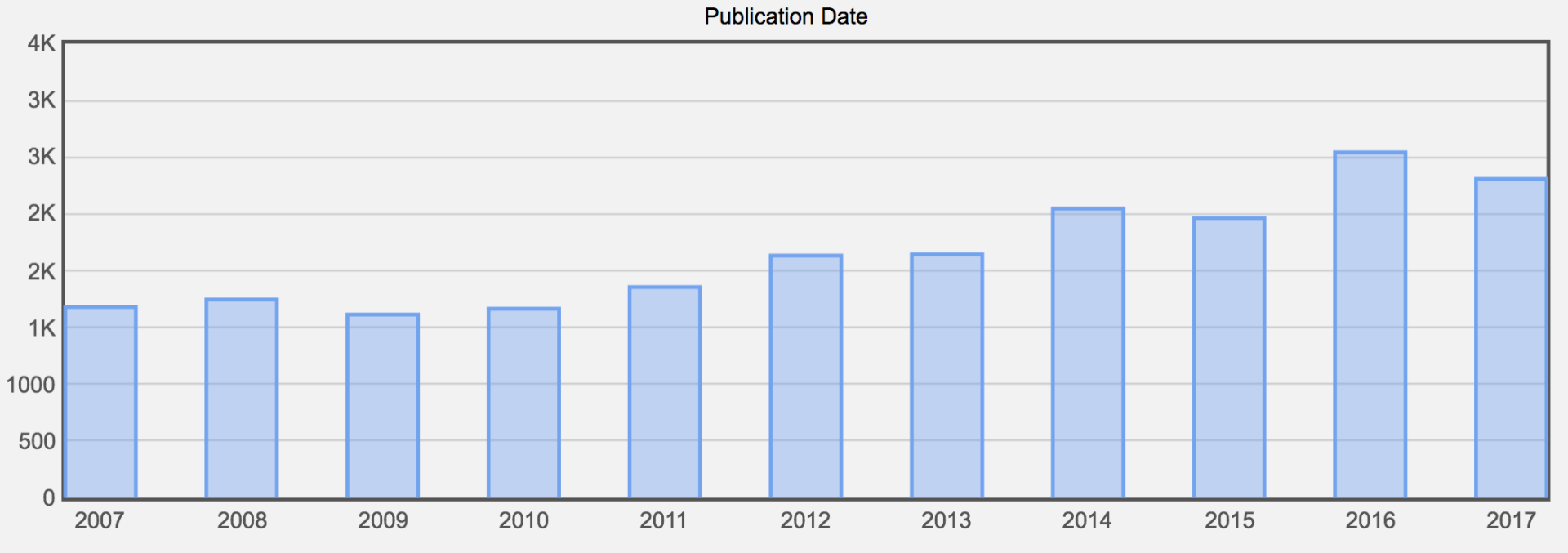
- Largest number of European patent applications in 2016 in top 10 technical fields of technology



https://www.epo.org/about-us/annual-reports-statistics/statistics.html#granted

By Michelle Pratt

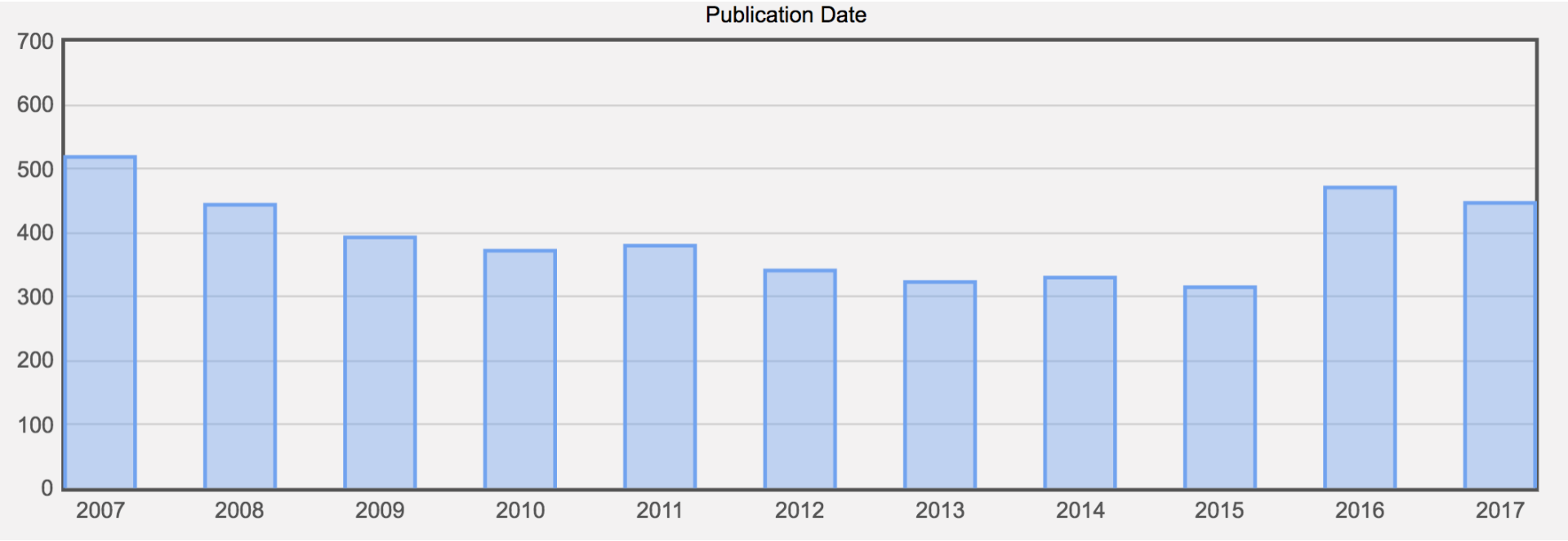
PCT Applications published for A61 IPC AND G (Physics)



Consulted in Patentscope® October 2017

By Hector Chagoya

PCT Applications published for A61 AND G (Physics) AND C (Chemistry) IPC's



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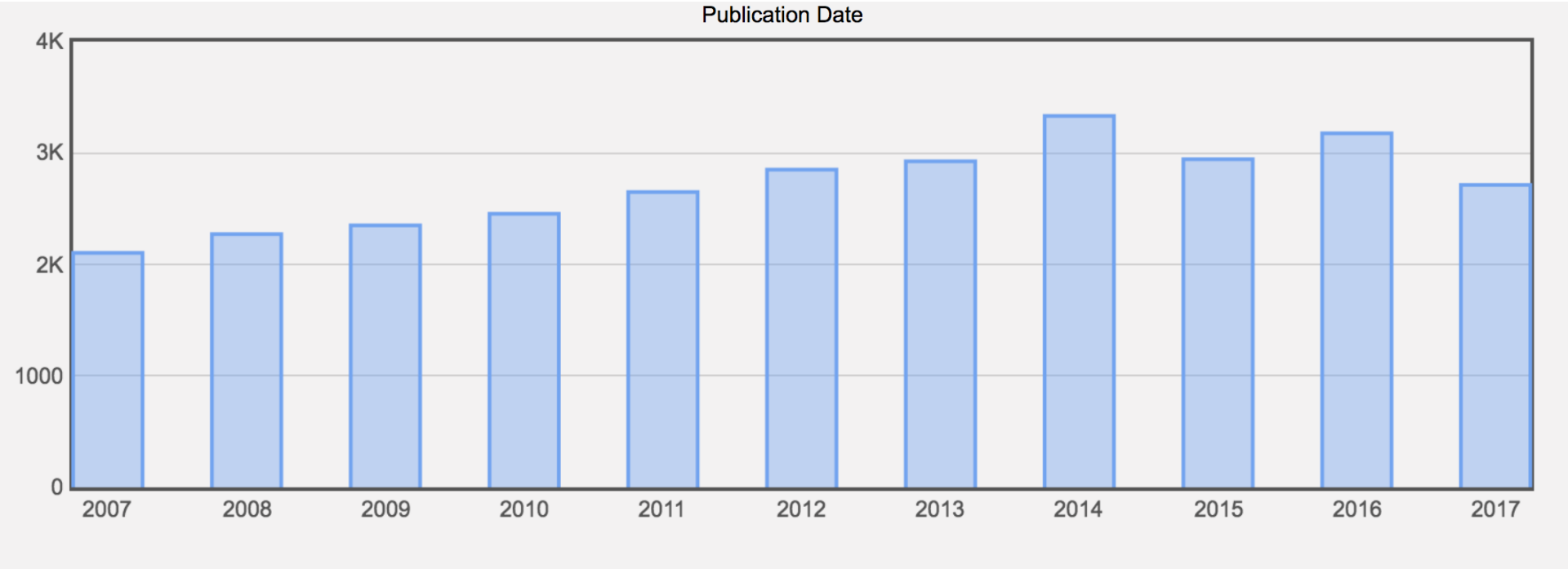
By Hector Chagoya

PCT Applications published for A61M IPC (DEVICES FOR INTRODUCING MEDIA INTO, OR ONTO, THE BODY (introducing media into or onto the bodies of animals A61D 7/00; means for inserting tampons A61F 13/26; devices for administering food or medicines orally A61J; containers for collecting, storing or administering blood or medical fluids A61J 1/05); DEVICES FOR TRANSDUCING BODY MEDIA OR FOR TAKING MEDIA FROM THE BODY



Consulted in Patentscope® October 2017

By Hector Chagoya

Technology trends

Medical devices:

- Lasers used in eye-surgery
- Endoprosthesis
- Wound dressing
- Stent
- Catheter
- Syringe
- Implantable devices

Medical devices (coupled with pharmaceuticals):

- Catheter coated with an antibiotic agent
- Progesterone-releasing intrauterine device
- Drug-eluting coronary stent
- Inhalers containing a medicinal product
- Wound dressing containing an antimicrobial agent
- Transdermal drug-delivery patches

By Michelle Pratt

Medical devices further

- Patient monitoring devices
- Mobile phone apps such as wellbeing apps connected to medical devices
- Wearable technology for medical devices

By Michelle Pratt

Intellectual Property

Inconsistency in the way European law treats medical devices and pharmaceuticals

	Non-medical device	Medical Substance/ composition	Medical device
Product per se	✓	✓	✓
Medical use	n/a	✓	?

By Michelle Pratt

Inconsistency arises in the wording of the EPC

In Europe, methods of treatment by therapy, surgery or diagnosis that is practiced on the human or animal body are not patentable

Article 53(c) EPC dictates that this provision shall not apply to products (which includes medical devices) *FOR USE* in such a method

Articles 54(4) and (5) EPC provides a novelty-generating provision whereby known substances and compositions are allowable when intended *FOR USE* in a novel and inventive method

Contrary to substances and compositions, medical devices can as a rule not directly derive novelty from a new medical indication

By Michelle Pratt

Criteria for a medical device to derive novelty from a new medical indication

1. The device must have an active ingredient that carries out its function *(T2003/08)*
2. The active ingredient must perform the primary function, not the position or shape of the device *(T1099/09)*
3. The device has to be consumed during treatment *(T227/91)*
4. The device has to be a finished product ready for use without surgical insertion *(T775/97)*
5. The device must be in contact with the patient's body during the treatment *(T138/02)*

By Michelle Pratt

Drafting second medical use claims comprising devices

- "Use of a specific ligand for human immunoglobulin in the manufacture of a column having said ligand coupled thereto for the treatment of a patient suffering from dilated cardiomyopathy"

T2003/08

By Michelle Pratt

Regulatory Framework

The new EU Medical Device Regulations

25 May 2017: TWO NEW REGULATIONS IN FORCE

OLD		NEW
Medical Devices Directive (93/42/EEC)	⇨	Regulation (EU) 2017/745 on medical devices (the "**MDR**") – applicable May 2020
Active Implantable Medical Devices Directive (90/385/EEC)		
In Vitro Diagnostic Devices Directive (98/79/EC)	⇨	Regulation (EU) 2017/746 on in vitro diagnostic medical devices (the **"IVDR**") – applicable May 2022

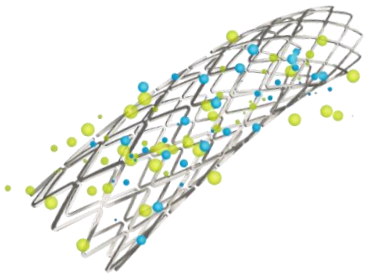
By Dom Adair

Classification

Medical Devices		In Vitro Diagnostic Devices	
Class I (non-sterile, non-measuring)	Stethoscope 	Class A	Specimen jars 
Class I (sterile, measuring)	Sterile needles 		
Class IIa	Surgical clamps 	Class B	Home pregnancy tests 
Class IIb	Lung ventilators 	Class C	Blood glucose tests 
Class III	Pacemakers 	Class D	HIV tests 

By Dom Adair

Drug-Device Combinations



MEDICAL DEVICE

- Device incorporates as an **intergral part** a medicinal product with an **action ancillary** to that of the device

Examples:

- Drug eluting stent
- Wound dressing with antimicrobial agent
- Catheter coated with heparin or antibiotic

MEDICINAL PRODUCT

- Action of medicinal product is **principal and not ancillary** to that of the device

Examples:

- Pre-filled syringe
- Transdermal patch

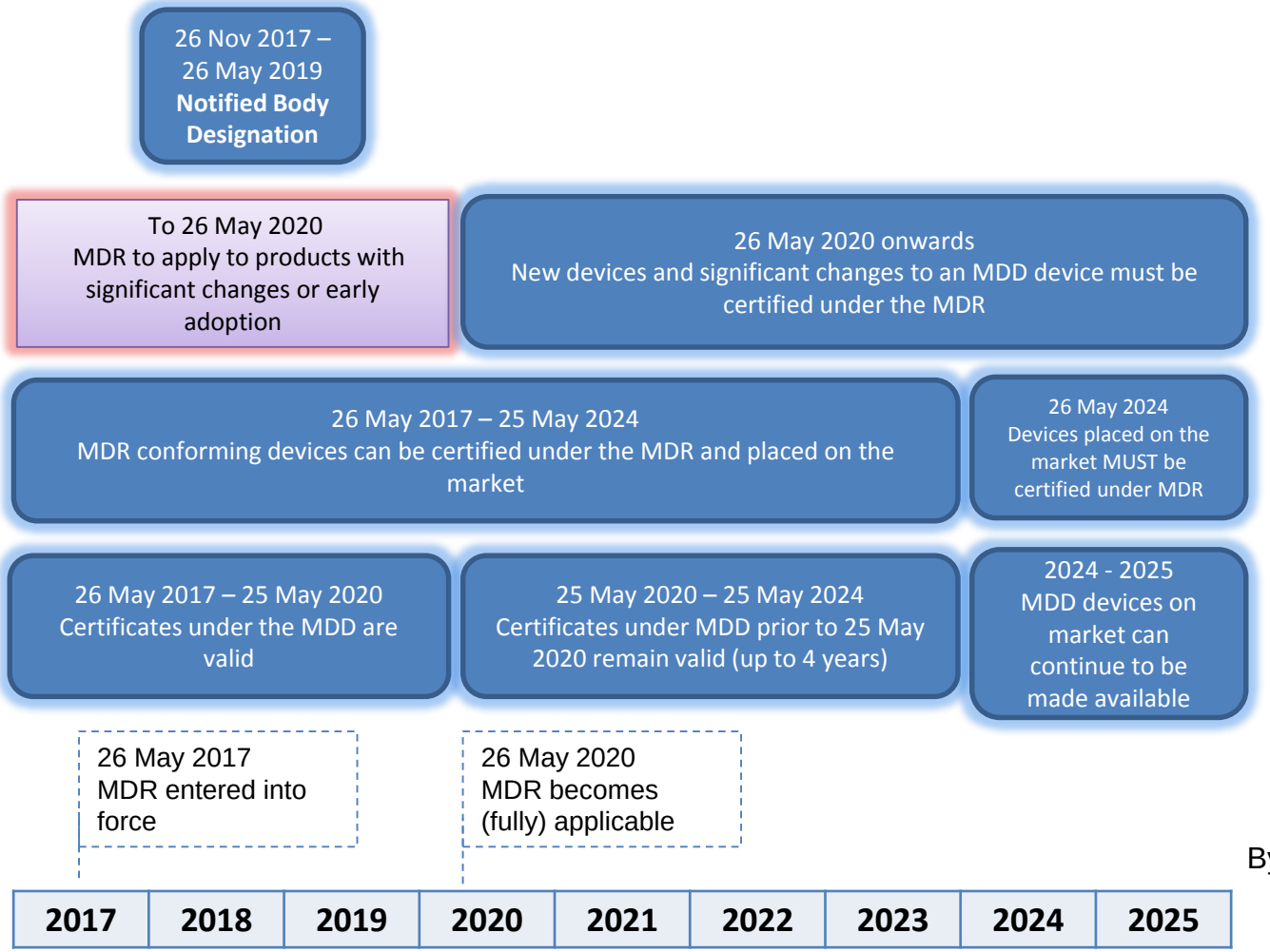
By Dom Adair

What's Changed?

- **Broader scope** (previously unregulated products now covered)
- **Stricter classification** requirements and some major reclassifications (e.g. large increase in IVD conformity assessments)
- **Emphasis on safety and data** (evaluation; post-marketing surveillance; new traceability requirements; clinical trials for class III)
- **Stricter scrutiny** by and of Notified Bodies (e.g. unannounced audits)
- **Transparency and traceability** (e.g. Unique Device Identification; Centralised European Database: EUDAMED)
- **Creation of Medical Device Coordination Group (MDCG)** (expert panel of member state representatives promotes harmonisation)
- **Increased liability** (joint and several liability for authorised representatives; insurance cover mandatory; penalties regime)

By Dom Adair

Timeline and Transitional Provisions: MDR



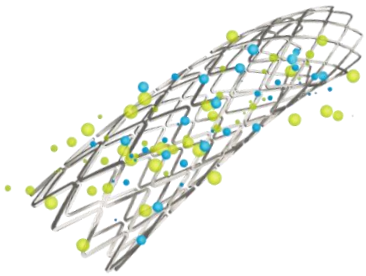
By Dom Adair

Preparation: what needs to be done?

- **Evaluate portfolio**
  - Is there a change in classification?
  - Is enhanced clinical data needed?
  - Are changes needed to design or intended purpose?
- **Engage with Notified Bodies**
- **Build compliance with new Regulations into design and development**
- **Increase capacity of internal management support**

Clinical Data & Data Exclusivity

Drug-Device Combinations



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By Dom Adair

Clinical Data and Data Exclusivity

- If the drug-device combination is a medicinal product, the usual European regime in Directive 2001/83/EC for regulatory data protection applies: i.e. 8+2+1 years of protection
  - 8 years' data exclusivity (no generic filing may rely on reference product data)
  - 2 years' market exclusivity (generic filings may rely on data but not be marketed if approved)
  - 1 extra year market exclusivity for new indications authorised during the first 8 years offering significant clinical benefit
- If the drug-device combination is a medical device, the regulatory data protection regime under Directive 2001/83/EC does not apply
- Is this fair if class III products require clinical trials? Probably yes: the considerations are different. There is no abridged procedure

By Dom Adair

Linkage (Patents & Regulatory)

Supplementary Protection Certificates (SPCs)

- Form of IP that extends protection of patented active ingredients present in pharmaceutical products
- Designed to compensate for delays in obtaining Marketing Authorisation (MA)
- Based on a patent that protects the active ingredient
- SPC application must be filed within 6 months of grant of patent or 6 months from obtaining 1st Marketing Authorisation, whichever is later
- Granted by National Patent Offices
- Additional term is:
  - [(MA Approval Date- Filing Date of the Patent application) - 5 years] but maximum of 5 years
  - (additional 6 month Paediatric extension)

By Michelle Pratt

SPCs for medical devices?

"The scope and sectors covered by the SPC regulation were decided over 20 years ago. However in these two decades many of the underlying aspects of the SPC regulation have changed, amongst others, changes in innovation patterns, big data, bio-medicines, personalised medicines, increasing importance of medical devices as well as changes in marketing authorisation procedures."

(European Commission call for tender: Study on the economic impact of Supplementary Protection Certificates, pharmaceutical incentives and rewards in Europe (2017))

By Michelle Pratt

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Thanks for your attention!