Global regulator and industry activities on drug/device combination products - focus on Europe

Janine Jamieson, Editorial Staff - Europe, IPQ Publications
CASSS EU Forum, May 2016, Paris

- Current positive initiatives in EU
- Proportionate, appropriate, risk based regulation
- Communication between all stakeholders is key
Emergence and convergence of new medical technologies

Credit: Tim Chesworth, Head Medical Devices and Combination Products AZ, CASSS EU 2016
Drug-device combination products

Increasing complexity of device components

Patient:
- Longer dosing intervals
- Patients treated at home

Medicinal product:
- Larger volumes
- Higher viscosities

Credit: Mark Chipperfield, CorvusDevice Ltd, MedTech & Pharma Platform 2014
FDA Office of Combination Products

“FDA expects to receive large numbers of combination products ... as technological advances continue to merge product types and blur the historical lines of separation between FDA’s medical product centers, CBER, CDER and CDRH.”

Raising...

regulatory, policy, and review management challenges

Definitions, guidance, industry resources, workshop recordings: [Link](#)
FDA Proposes Changes to Classification Rules for Combo Products

“We understand that regulatory uncertainty can stifle innovation as companies may avoid developing products. To promote the continued innovation of combination products, we want to make sure the process for classifying and assigning these products is clear and efficient,”

Thinh Nguyen, Director of FDA’s Office of Combination Products.
International Coalition of Medicines Regulatory Authorities (ICMRA)

The Future of Medicines and Challenges for International Regulators

- Ian Hudson, MHRA
- Supriya Sharma, Health Canada
- Tatsuya Kondo, PMDA
- Rita Purcell, HPRA
- John Skerritt, TGA
- Agnès Saint-Raymond, EMA

DIA Europe 18 April 2018
Harmonization Efforts – DIA Combination Products 2017

Credit: Demetra Macheras, AbbVie
Nicole Taylor Smith, Johnson & Johnson Medical Devices

ICH Q12 Combination products
EU: No combination product definition

Integral DDC products are regulated by **EITHER** the Medical Device Directive (MDD) or the Medicinal Products Directive

Primary Intended Purpose: Pharmacological, Metabolic, Immunological

**MEDICINAL PRODUCT** 2001/83 EC

Primary intended purpose achieved by other means: e.g. physical or simple chemical

**MEDICAL DEVICE** 93/42 /EEC
Regulation of medical devices

**Medical Devices industry**
- 25 000 companies, 95% are Small and Medium-sized Enterprises (SMEs).

**CE mark: Single market provision**

**Co-regulation Device CAs and Notified Bodies (NB)**

**Manufacturer can choose any accredited NB to work with**

**Different routes to conformity including Quality Management System audit**

**Controls proportional to risk Class I, IIa, IIb and III**

*Internal Market, Industry, Entrepreneurship and SMEs**
**Public Health and Food Safety**
Medical device co-regulation in EU

**Role of Competent Authority**
- Initial Designation of notified bodies and ongoing surveillance
- Pre Market Clinical Investigation - safety
- Post Market vigilance
- Enforcement

**Role of Notified Body**
- Independent test and/or certification bodies
- Conformity assessment procedures for specific range(s) of products
- Clinical evaluation assessment
- Level of involvement dependent on risk classification of medical device
  - from 80 following stringent audit)
  - in responsibilities - resource issue
What is a Notified Body?

- Private, independent testing or certification organisation
- Provide conformity assessment services for many different EC Directive products
- Designated by their National Competent Authority
- Member States are not obliged to appoint any NB but can appoint several
- Mostly commercial business, some not for profit organisations / charitable foundations
- Medical device Notified Bodies have been assessed against the requirements of 93/42/EC and 920/2013/EEC
- Following medical device scandals - Notified Bodies have had to restore confidence in the process.

Credit: Theresa Jeary, LRQA TOPRA Symposium 2017
What is the role of the Notified Body?

The role of a Notified Body is to conduct a conformity assessment under the relevant EU Directives. The Notified Body conducts the conformity assessment against the relevant sections of the applicable Directive (MDD, AIMDD or IVDD). The conformity assessment usually involves an audit of the manufacturer’s quality system and depending upon the particular classification of the device, a review of the relevant technical documentation provided by the manufacturer in support of the safety and performance claims for the device. The technical documentation is assessed against the essential requirements set out within the EU Directives and considers the relevant guidance set out by the EU.

Once the Notified Body has determined a manufacturer has conformed to the relevant assessment criteria, it issues a CE certificate to show that the products assessed meet the requirements.

The manufacturer signs a Declaration of Conformity and applies the CE mark (with or without the Notified Body number).

Conformity assessment against Directives
- Usually involves audit of Quality System
- Depending on classification, review of technical documentation
- Safety and Performance claims
- Essential requirements

Credit: BSI Website
How to find a notified body

New Approach NANDO website
Notified Bodies accredited for each type of device:

<table>
<thead>
<tr>
<th>Legislation</th>
<th>Products</th>
<th>Procedures</th>
<th>Articles/Annexes</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>93/42/EEC Medical devices</td>
<td>*MD 0100 - General non-active, non-implantable medical devices</td>
<td>EC declaration of conformity (full quality assurance system)</td>
<td>Annex II</td>
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<td>EC declaration of conformity (production quality assurance)</td>
<td>Annex V</td>
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<td>- *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care</td>
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<td>EC declaration of conformity (full quality assurance system)</td>
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<td>EC declaration of conformity (production quality assurance)</td>
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<td>- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis</td>
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<td>EC declaration of conformity (full quality assurance system)</td>
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<td>EC declaration of conformity (production quality assurance)</td>
<td>Annex V</td>
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<td>- *MD 0103 - Non-active orthopaedic and rehabilitation devices</td>
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<td></td>
<td>EC declaration of conformity (full quality assurance system)</td>
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<td>EC declaration of conformity (production quality assurance)</td>
<td>Annex V</td>
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<td>- *MD 0104 - Non-active medical devices with measuring function</td>
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<td>EC declaration of conformity (full quality assurance system)</td>
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</tbody>
</table>
New Medical Device and IVDR regulations

Link: https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en
The two legislative acts should ensure appropriate interaction in terms of consultations during pre-market assessment, and of exchange of information in the context of vigilance activities involving such combination products.

For medicinal products that integrate a medical device part, compliance with the general safety and performance requirements laid down in this Regulation for the device part should be adequately assessed in the context of the marketing authorisation for such medicinal products.

Directive 2001/83/EC should therefore be amended.
New Article 117 amending MPD for integral medical devices

Article 117

Amendment to Directive 2001/83/EC

In Annex I to Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

‘(12) Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council (1), a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer’s EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.

- an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I [of the MDR]
- issued by a notified body designated ... for the type of device in question.”

How will this work in practice ??
Whereas ... medical devices with integral medicinal component

Medical devices incorporating ancillary medicinal substances

Medical Device Directive 93/42/EC:

The quality, safety and usefulness of the substance must be verified by analogy with Annex I to Directive 2001/83/EC.

- Class III high risk devices under rule 13 of MDD
- Notified Bodies consult Medicines CA or EMA for opinion on medicinal substance
Current combination product guidance

EUROPEAN COMMISSION
DG ENTERPRISE and INDUSTRY
Directorate F, Unit F3 “Cosmetics and medical devices”

MEDICAL DEVICES: Guidance document

Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative

GUIDELINES RELATING TO THE APPLICATION OF THE COUNCIL DIRECTIVE 90/385/EEC ON ACTIVELY IMPLANTABLE MEDICAL DEVICES THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES

MEDDEV 2.1/3 rev 3

Foreword

The present Guideline is part of a set of Guidelines relating to questions of application of EC Directives on medical devices. This guideline is not legally binding, since only the European Court of Justice can give an authoritative interpretation of Community law. It has been elaborated by an expert group including experts from Member States’ Competent Authorities, the Commission’s services, as well as industry trade associations. It is therefore intended that the document will provide useful guidance which should assist common positions to be taken throughout the European Union. Due to the participation of the aforementioned interested parties and of experts from Competent Authorities, it is anticipated that these guidelines will be followed within the Member States and, therefore, ensure uniform application of relevant Directive provisions.

The present guideline provides non-exhaustive lists of examples of medical devices, accessories to medical devices and medicinal products. Further examples may be found in the manual on borderline and classification in the Community Regulatory framework for medical devices, published on the European Commission website. The present Guideline will provide useful guidance which should be common in borderline cases between medical devices and herbal medicinal products. This issue may be further developed in this guidance in the near future.

Note: This document is a revision of an earlier document published in July 2001 as MEDDEV 2.1/3 rev 2. Some of the examples given in the MEDDEV 2.1/3 rev 2 have not been included in the present Guideline. These examples will be further elaborated in the above mentioned manual on borderline and classification in the Community Regulatory framework for medical devices. This guidance incorporates the changes introduced by the Directive 2001/83/EC. These changes have to be applied as of 21 March 2010.

2 OJ L 247, 21.09.2007
Drug-Device combinations: Not integrated
E.g. Refillable Insulin Pen

- Kit comprising an insulin pen and insulin cartridges
- Re-fillable, multiple use
- Pen is subjected to the MDD
- Insulin cartridge is a medicinal product

Oral suspension → medicine
Spoon for administration → device
Consider effects of drug on device

- **Warnings:**
  - *Non-indicated formulations* may contain neurotoxic preservatives, antimicrobials, or antioxidants, or may be incompatible with and damage the system. Failure to comply with all product instructions, including use of drugs or fluids not indicated for use with system, or of questionable sterility or quality, or use of non-Medtronic components or inappropriate kits, can result in improper use, technical errors, increased risks to patient, tissue damage, damage to the system requiring revision or replacement, and/or change in therapy, and may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug under- or overdose.

[Link](#)
On-body infusor delivery systems for large volume, high viscosity drugs/biologics

Non-integral: CE marked *

Integral: medicines CA

- Ecell:
  - power source
  - driving mechanism
- Printed circuit board

Amgen website: Link  West website: Link  SteadyMed Website: Link

* EPAR and EBE paper discuss major objection received for MAA
Some relevant considerations for electro-mechanical devices

- ISO 14971 Application of risk management to medical devices
- ISO 11608-1 Needle-based injection systems for medical use: Requirements and test methods
- IEC 60068-2 Environmental Testing of Electronic Equipment
- IEC 60601-1 Safety for a range of electrical medical devices (EMD)
- IEC 62366-1 Application of usability engineering to medical devices
- Consider: criticality of battery reliability and life, disposal of electrical equipment
  - Etc....

Reflections:

- medical device quality management system and review by Notified Bodies more appropriate than CTD.
- Allowing for controls and flexibilities necessary for frequent updates to risk analysis and compliance with current regulatory expectations, including cybersecurity.
- But for pre-filled syringes / pens .......???
Annex I safety and performance requirements

- Annex I of MDD Essential Requirements applicable but variability in extent of review by medicines agencies
- MDR introduces significant increase in number of requirements

- Emphasis on state of the art requirements
- Greater focus on risk management systems
- More focus on substances and materials of construction
- Specific attention to safety with respect to chemical safety (REACH)
- Minimization of risk of the ‘system’ rather than individual elements.
- New clauses on software and electronic systems
Human factors - usability

IEC 62366-1:2015
Medical devices -- Part 1: Application of usability engineering to medical devices

Medical devices -- Part 2: Guidance on the application of usability engineering to medical devices

Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development

Draft Guidance for Industry and FDA Staff

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health,
Center for Drug Evaluation Research,
Center for Biologies Evaluation and Research,
Office of Combination Products in the Office of the Commissioner

February 2016

Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA: Draft Guidance for Industry

DRAFT GUIDANCE
This guidance document is being distributed for comment purposes only.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health,
Center for Drug Evaluation Research,
Center for Biologies Evaluation and Research,
Office of Combination Products in the Office of the Commissioner

September 2017

Human Factors and Usability Engineering -- Guidance for Medical Devices Including Drug-device Combination Products

Version 1.0
September 2017
EMA increasing mention of medical devices

Concept papers:
- Developing a guideline on Quality requirements of medicinal products containing a device component for delivery or use of the medicinal product, (Feb 2017)
- Revising of the guideline on the pharmaceutical quality of inhalation and nasal products, (Mar 2017)

Q & A guidance:
- Marketing Authorization Pre-authorization guidance Quality Section 3.3.11 Medical Devices, (Aug 2017)
- Scientific guidelines Q&A on Quality Part 2 Specific types of product - Needle safety systems, (Sep 2017)
EMA QWP/BWP Concept paper on DDCs

Comments received:

- Proposal to develop guidance welcome - needed across EU
- Alignment with new MDR (Art 117)
- Engagement with device stakeholders positive; appreciate WS/training; address advice for development
- Consistent wording/terminology (ISO), more clarity on scope (Applicability for clinical trials?); global alignment

Armin Ritzhaupt, EMA TOPRA Symposium Oct 2017
CAMD roadmap and priorities for implementation of the MDR/IVDR, Nov 2017

CAMD Implementation Taskforce
Medical Devices Regulation/In-vitro Diagnostics Regulation (MDR/IVDR) Roadmap

2. Scope & Classification

<table>
<thead>
<tr>
<th>Activity</th>
<th>Recommended responsible parties/owners</th>
<th>Priority level</th>
</tr>
</thead>
</table>
| 2.1 Classification guidance for IVDs around classification rules and scope, giving practical examples | • IVD WG  
• C&B WG  
• Software WG | High |
| 2.2 Information and guidance on classification for MDs (changes on classification rules) | • C&B WG  
• Software WG  
• NET WG  
• IVD WG | Medium |
| • Information to highlight changes to classification rules  
• Guidance on new classification rules/changes to existing rules e.g. MEDDEV 2.4/1 update/addendum  
• Software classification guidance (to liaise with workstream 2.1 IVD Classification) | | |
| 2.3 Common specifications for annex XVI products for MDs | • COM  
• MDCG  
• NBQG | High |
| 2.4 Implementing act on reprocessing SUDs for MDs | • COM  
• MDCG | Medium |
| 2.5 Guidance for combination products and companion diagnostics (CDx) around appropriate level of interaction with relevant authorities (ref: 3.4) | • C&B WG  
• IVD WG  
• (EMA-CAMD borderline WG, EMA, medicines CAs, tissues & cells CAs, EDQM)  
• NBQG | Low |
Specific areas of development

Borderline products

So-called borderline products are those for which it’s not clear whether they fall under the medical devices legislation or another piece of legislation.

These cases are of great concern to EU countries, the European Commission and other stakeholders since they can lead to different interpretations within the EU, and as a consequence, may put public health at risk and distort the Single Market.

To ensure a uniform approach, the Commission tries to facilitate a dialogue between regulators and industry, where diverse interpretations exist.

Key documents on Borderline and Classification

- Medical Devices Expert Group on Borderline and Classification
- Other useful guidance
HMA & CAMD Borderline and Combination Products Working Group

Advise HMA & CAMD on issues relating to the MP/MD borderline and regulation of so-called “combination products”

- To reach common understandings between Member States in relation to interpretation of legislation relevant to the borderline. To provide a forum to discuss the classification of products to aid in decision-making
- To agree common understandings and best practices around assessment and regulation of so-called “combination products”
- To identify gaps in legislation relevant to these products and propose guidance to ensure consistent regulatory decision making and protection of public health,
- (achieved by working through established European networks where possible)

(HMA: Heads of Medicines Agencies)

(Excerpts from mandate agreed October 2016)

(CAMD: Competent Authorities for Medical Devices)
In July 2000, Member States and the European Commission agreed to set up the Notified Body Operations Group (NBOG). This was in response to widespread concern that the performance of Notified Bodies in the medical device sector, and that of the Designating Authorities responsible for them, was variable and inconsistent.

Accordingly NBOG’s terms of reference were agreed to be:

To improve the overall performance of Notified Bodies in the medical devices sector by primarily identifying and promulgating examples of best practice to be adopted by both Notified Bodies and those organisations responsible for their designation and control.

Chair
Dr. Rainer Edelhäuser
ZLG - Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
Heinrich-Böll-Ring 10
D-53119 Bonn
Germany

Vice-Chair
Maria Carlton
Health Products Regulatory Authority (HPRA)
Kevin O’ Malley House
Earlsfort Centre, Earlsfort Terrace
IE-Dublin 2
Ireland
One notified body perspective...

**NB Assessment Report**

- The product approval is ultimately determined by the Medicines Agency who shall take into consideration all the evidence provided.
- Important that the NB assessment report provides sufficient details to the Medicines Agency of what the NB has assessed and details the conclusion regarding suitability of conformance to Annex I to enable an informed assessment.

**Important for NBs to engage with Medicines Agencies to understand their perspective to facilitate the process.**

Credit: Theresa Jeary LRQA, TOPRA Symposium 2017, London Joint Pharma/Devices session
An Overview of EBE Advocacy Work on Drug/Biologics-Device Combination Products

Serge Mathonet Sanofi R&D Global Regulatory CMC Biologics
EU CMC Strategy Forum, May 14, 2018, Noordwijk, Netherlands
• Options on where to locate device and DDC product information and case study on the extent of device and DDC product information required in eCTD Module 3.

• Reflection and position on involvement of Notified Body review (scope and timing) as will be required by MDR Art 117,

• Position on a risk-based approach to classification of device post-approval change reporting level, discussing guiding principles for categorization of device variations and providing examples of variation requirements experienced by Industry,

• Perspectives on dossier content and/or regulatory review issues on emerging technologies i.e; Large Volume Devices for high viscosity biological products, electromechanical devices and electronic add-ons to existing products (digital health)

Need for tripartite workshop (EMA/NB/Industry)

Need for  MDR Art 117 EMA/NB Pilot Program toward an integrated review process
Technical and procedural concerns and challenges being discussed amongst industry relating to Art. 117

- Specifically what is the purpose of the Notified Body Assessment/opinion?
- Recognise that evaluating complex devices claiming compliance with multiple ISO Standards is typically outside the competence of any CA
- But, also recognition that the same level of assessment may not be applicable to all device-types, commensurate with overall risk of product?
- Concern about the efficiency of the process in relation to overall MAA review/approval process and timing
- Not wanting to delay/significantly impact product approvals based on overly-long NB assessments
- Being able to leverage assessments across products where appropriate to do so
- Recommendations from this second paper possibly helpful to develop future process-related guidances i.e. within NB group (akin to process NBs developed for competence to review substance based devices for Rule 21 of MDR) and/or EMA (i.e. future CHMP Quality guidance for DDCs)
Key points from the EBE paper

- Location of device and DDC product information in Module 3 flexible
- Industry broadly aligned on the extent of device and DDCP information required.
- Example of Module 3 Dossier content strategy provided for a pre-filled pen
- Enhanced requirements in MDR Annex 1 reviewed
- Involvement of Notified Body review a critical issue for manufacturers
- M3 guidance to consider post approval impact - align with ICH Q12 principles
- Variation examples given based on shared experiences
- Emerging technologies remain an open question....

- Aims to encourage discussion between industry and EMA on issues
Paper 2 – Context and key areas of discussion

- **4 key areas of discussion**
  - Regulatory review process & recommendation on how combined Advance Therapy Medicinal Product (cATMP) review process could be adapted
  - Roles and responsibilities of key stakeholders
    - Recommended considerations for Notified Body, Manufacturers, Competent Authorities
  - Review of products within scope of Article 117
    - Recommended risk approach to products where NB assessment required
  - Technical and Quality requirements
    - Recommended scope of NB assessment vs. CA for MAA dossier

→ Publishing timeline: July 2018
**EMAP/CAT and Notified Body Collaboration**

Procedural advice on the evaluation of combined advanced therapy medicinal products and the consultation of Notified Bodies in accordance with Article 9 of Regulation (EC) No. 1394/2007

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**EMA/CAT and Medical Devices Notified Body (EMA/CAT-NB) Collaboration Group**

The European Medicines Agency/Committee for Advanced Therapies and Medical Devices Notified Body (EMA/CAT-NB) Collaboration Group facilitates the implementation of the aspects of Regulation (EC) No. 1394/2007 relating to advanced-therapy medicinal products (ATMPs) when they are combined with medical devices (MD). It is a temporary, ad-hoc, specialised advisory group of the Committee for Advanced Therapies (CAT).

**Mandate, rules of procedure and work programme**

More information on the EMA/CAT-NB Collaboration Group’s responsibilities and composition is available in these documents:

- [Mandate, objectives, rules of procedure](#)
- [Work plan](#)

**Composition**

The EMA/CAT-NB Collaboration Group represents the regulatory stakeholders for ATMPs and medical devices. The Group includes:

- up to four representatives from the CAT;
- two representatives from the Co-ordination of Notified Bodies for Medical Devices;
- two representatives from the Notified Body Operations Group;
- two representatives from the European Medicines Agency.

Representatives of the European Commission may participate as observers.
Opportunities for discussion....

**June:**

- EMA BWP Interested parties meeting 18-20, London
  - DDC topic
- DIA CMC Workshop, 20-21, Basel
  - EMA QWP speakers and TUV SUD notified body in two DDC sessions
  - TUV SUD dedicated project manager on Art 117
- Part 2: TOPRA Regulatory Rapporteur article on NB Opinion (Mark Chipperfield, Corvus Device and Tim Chesworth, AZ)
  - Part 1 published May 2018
FDA and Combination Products Coalition

- **FDA on final cGMP guidance dialogue:**

  - “Rather than industry providing only "abstract arguments," the process involved industry groups like AdvaMed and the Combination Products Coalition (CPC) providing "very frank, pretty substantive, pretty detailed analysis of what they needed and why, and why their solutions made sense.”

  - “**We really do want to hear from you. I can’t emphasize enough ... about the need for coordination and trusting engagement that is so incredibly helpful.**”

John (Barr) Weiner, Associate Director, Office of Combination Products at Food and Drug Law Institute (FDLI) Conference, Washington D.C. May 2017 - IPQ April/May 2017
EMA on innovative medicinal products

EMA on innovative products including drug/device combinations

- “We need to think outside of the box.”
- “Not any more medicines vs devices, they are a mix of everything and going from one to the other ... stop trying to fit them into CTD as we have in the past.”

Agnes Saint-Raymond Head of International Affairs, EMA at DIA Europe, April 2018 ICMRA session on The Future of Medicines and Challenges for International Regulators
Summary

- Everyone is learning
- Opportunities for engagement welcome
- NB opinion critical issue for manufacturers preparing submissions for 2020
- Clarification needed for notified bodies also
- Resource and timing issues
Acknowledgements

- Mark Chipperfield, Corvus Device
- Tim Chesworth, AstraZeneca
- Elizabeth Baker, John Wilkinson and Ian Hudson, MHRA
- Ilona Reischl, AGES
- Armin Ritzhaupt, Sabine Haubenreisser, Agnès Saint Raymond, EMA
- Theresa Jeary, LRQA
- John (Barr) Weiner, FDA
- Bob Laughner, MedImmune
- Paul Jansen, Haselmeier
- Doug Mead, Janssen
- Serge Mathonet, Sanofi, EBE DDC group lead
- Suzette Roan, Sanofi
- Amanda Matthews, Pfizer
- April Kent, Amgen
- Vikas Jaitely, Merck Group
- Rita Purcell, Niall MacAleenan HPRA
- Shayesteh Furst Ladani, MedTech and Pharma Association

THANK YOU!
Additional information
Combined ATMPs

Figure: Advanced Therapy Medicinal Products (ATMP)
Source: PEI
New action plan to foster development of advanced therapies

Actions address specific challenges identified by stakeholders

The European Commission’s Directorate-General for Health and Food Safety (DG SANTE) and the European Medicines Agency (EMA) have published today a joint action plan to foster the development of advanced therapy medicinal products (ATMPs). The main aim is to streamline procedures and better address the specific requirements of ATMP developers.

ATMPs are medicines for human use that are based on genes or cells. These therapies offer ground-breaking new opportunities for the treatment of disease and injury. They are particularly important for severe, untreatable or chronic diseases for which conventional approaches have proven to be inadequate.

ATMPs can be classified into four main groups: gene therapy medicinal products, somatic cell therapy medicinal products, tissue engineered medicinal products and combined ATMPs. EMA has received 18 marketing authorisation applications since the ATMP regulation came into force in 2009. Nine products have been approved.
Opportunities for facilitation by independent, professional organisations...

Workshops with industry collaboration groups and regulators

- **RAPS** Regulatory Affairs Professionals Society
- **RAPS in US:**
  - Building the Scientific Bridge for Combination Products, Nov 2017 - RAPS Education Workshop
  - Understanding the Draft Guidance on Postmarketing Safety Reporting for Combination Products - An Interactive Analysis with FDA and Industry Webcast, 31 May 2018

- **TOPRA** The Organisation for Professionals in Regulatory Affairs
  - MedTech Special Interest Network with DDC topic
  - F2F EBE meeting at TOPRA Office, London April 2018