Medicines & Healthcare products Regulatory Agency

Current MHRA position on Sustainability themes in Devices manufacturing

IPAC-RS Sustainable Lifecycle Approaches

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Putting patients interests first

Patient first

“The MHRA aims to involve patients at every step of the regulatory process to ensure that the balance of risk and benefit is considered from all perspectives.

This will require developers to demonstrate that they have consulted patients in the development of new products and the design of clinical trials and investigations.

It also requires us to systematically involve patients and lay representatives in advisory committees while making regulatory decisions and to respond quickly when people report problems.”

Medicines and Healthcare Products Regulatory Agency: Corporate Plan 2023 to 2026

Consult and inform

Building compliance in

Early intervention – building compliance into product design

What is the cost involved in having a final product rejected by a regulator for a design or material selection issue?

What does “building compliance in” mean?

- Create a community of practice to promote a compliance mindset - present ideas as a group of stakeholders
- Follow (create!) industry best practices & standards
- Engage the agency early

- See also Outcomes-based Cooperative Regulation, OBCR, Prof Chris Hodges

What a medical devices regulator cannot do

What the MHRA cannot do

Act as a consultancy

Act alone (within reason)

- environmental considerations cut across regulators
- Health technology assessors (HTAs) and NHS procurement are part of the approval process in the UK
- international boundaries/memoranda of understanding (MoUs)/ mutual recognition agreements (MRAs) with other regulators

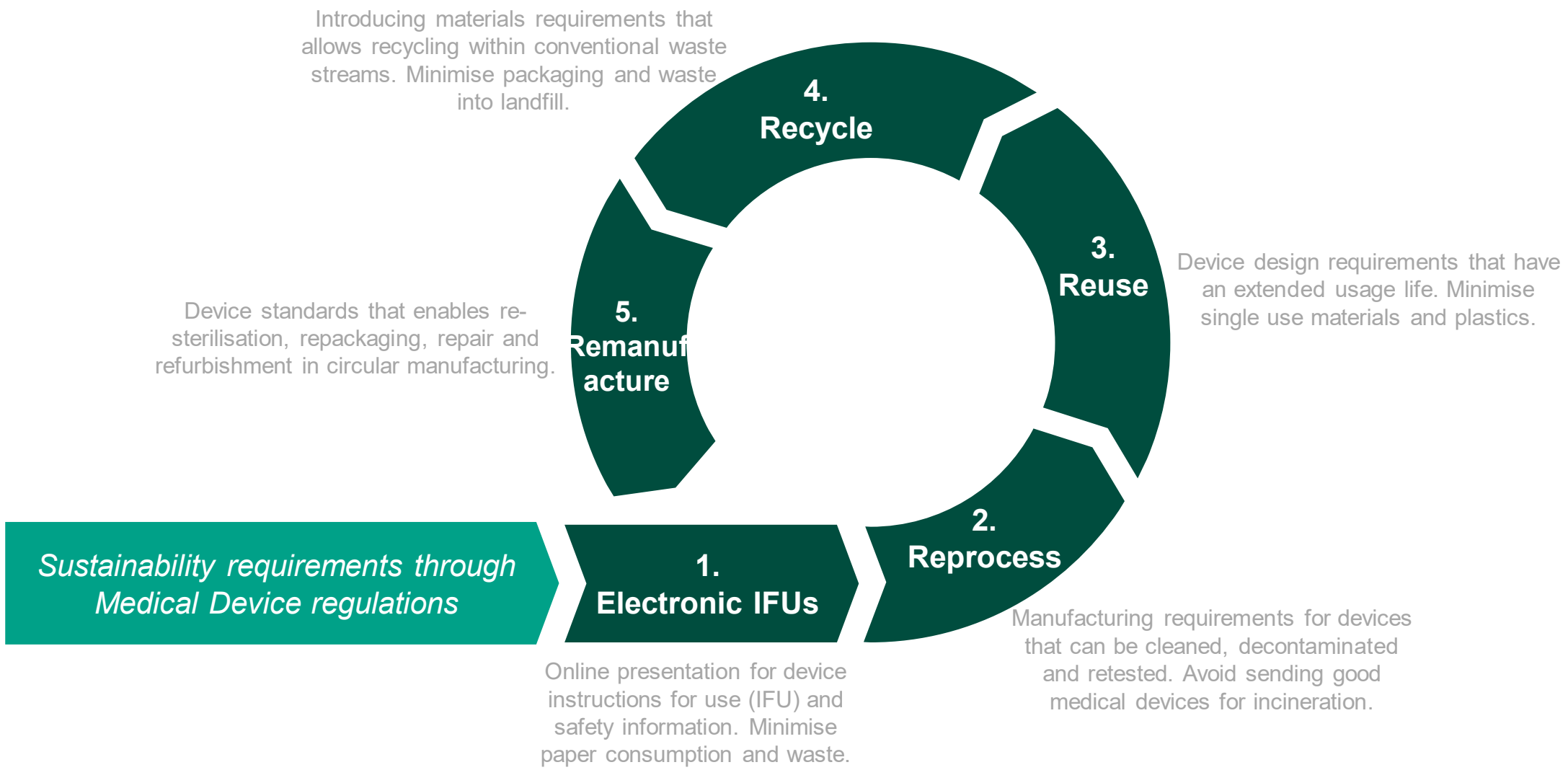
Approve a potential primary packaging material separate from the intended contents

Share confidential information given during scientific advice to one applicant

Approve/Not Approve a medical product solely on the basis of its environmental credentials

Environmental Sustainability through Medical Device Regulations

Five Provisions in UK Medical Device Regulations



Existing guidance that MHRA assessors currently refer to
for medicinal products and drug/device combinations

- ICH Q3E: Guideline for Extractables and Leachables (E&L) (currently under revision)
  - See ICH Website for details
- Human Medicines Regulations 2012, which refers to
  - Annex I, Directive 2001/83/EC (relating to medicinal products for human use)

Plus:

- Appendices XIX and XX in British Pharmacopoeia
- General chapter 2.4.35 in European Pharmacopoeia (soon to be updated regarding elemental impurities)
- Ph. Eur. 3.2.2 Plastic Containers and Closures for Pharmaceutical Use

Ph. Eur. 3.2.2

“For selection of a suitable plastic container, it is necessary to know the full manufacturing formula of the plastic, including all materials added during formation of the container so that the potential hazards can be assessed”.

“Recycling of excess material of well-defined nature and proportions may be permitted after appropriate validation”.

Case Study

Scenario: A plastic material used in primary packaging is sourced from oil-based raw materials (methanol, ethane etc)

- A change is made to supplement the feedstock with 30% plant-based raw material (again the basic molecules). This creates a bulk plastic product ready to mould into packaging product with the same properties indistinguishable from the original. (validated by chemical id, properties), AND
- The material is supplied using the same SKU/product number downstream.

Question:

- Should the pharmaceutical manufacture report this change - and if so via what mechanism - annual etc?
- Or is it sufficient to be managed though the existing QMS?

Case Study Assessment

The packaging material has not changed either in composition or properties. It is only necessary to submit a variation if there is a change

- this would be true if the SKU/product number registered in the dossier had changed
- Unless – unlikely – the starting materials of packaging materials are recorded in the dossier

There would be no need:

- to submit stability studies as it is the same material.
- for E&L studies as these should be unchanged.

Caveat: if the MAH considers that a change may affect the quality/safety/efficacy of the product *even if it is not one of the changes that they need to declare* as per the variations guideline, they can still submit this variation under an unforeseen categorisation

Refer to EC Guideline of 16 May 2013 B.II.e) Container closure system

Responsiveness and enablement

- Legislative timetables are **not** conducive to speed

(Bill, committee, draft, first, second readings, committee, report, third readings, amendments, Royal Assent)

  - Secondary Legislation (Statutory Instruments) a little quicker!
- Mandatory Guidance not necessarily conducive to Innovation
  - One-to-many
- Guidelines / best practice
  - One-or-many-to-many
- Early scientific advice
  - One-to-one

Example of working within existing legislation - how can we interpret:

Human Medicines Regulations 2012

Schedule 8 Part 1, Para 4

(data/evidence to accompany an application for a UK marketing approval)

"An evaluation of the potential environmental risks posed by the medicinal product, including an assessment of its environmental impact and a description of the proposed arrangements for limiting that impact on a case by case basis.“ ?

MHRA sustainability policy

And next steps

MHRA Corporate Plan 2023-2026

Financial Year 2024/25

“**Deliver a sustainability strategy for medical products** in conjunction with international regulators, which contributes to addressing the climate change emergency”

“Enhance our access to scientific evidence to inform our decision-making by building on existing and forming new partnerships to establish a network of Centres of Excellence in Regulatory Science, made up of academic and key scientific and research bodies nationally and internationally.”

Link to MHRA Corporate Plan 2023-26

Take-aways

The MHRA wishes to be an enabling regulator with respect to our response to the environmental crisis

Our primary and legislative remit is to ensure the safety, quality and efficacy of medical products for patients.

We welcome cooperative, many-to-many innovative approaches

Medicines & Healthcare products Regulatory Agency

Thank you

Any questions?

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