MedTech Europe
from diagnosis to cure

The EU Green Deal: Some Reflections on the Chemicals Strategy for Sustainability

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PANEL 2 – Green Chemical Policy, 15.30-17.00

About MedTech Europe

The European trade association for the medical technology industry including diagnostics, medical devices and digital health.

OUR MEMBERS

130+ multinational corporations*

*medical devices, diagnostics and digital health

50+ medical technology associations

Medical Technologies: Essential for Patient Care

MedTech Europe's Mission

To make innovative medical technology available to more people, while helping healthcare systems move towards a sustainable path.

- **Medical technologies = medical devices and *in vitro* diagnostic medical devices**
- These technologies are essential for the prevention, diagnosis, treatment and monitoring of thousands of serious diseases and other health conditions
- Hundreds of millions of EU citizens annually receive healthcare, enabled by our sector

Human Health and Chemicals Legislation
The Impact on Medical Technology Availability

- **Our sectorial legislation (Regulations 745/2017 and 746/2017) have specific chemical safety requirements**, covering more than 1,200 substances of concern and spanning the whole product-life-cycle, including the handling and minimization of waste

- **Chemical substances used in medical technologies are subject to most chemicals regulations**, e.g., REACH, RoHS, POP, BPR, OHS, WFD

- **In the recent past, our sector has been going through significant challenges stemming from the REACH Authorisation of 'triton' (OPE/NPE) substances and the REACH Restriction of microplastics**
  - The conditions proposed for downstream users (hospitals), such as collection and incineration of wastewater, were not feasible and impractical.
  - Europe risked a situation where life-saving technologies could still be made available but not 'used'..

Chemicals Strategy for Sustainability (CSS): Overview

Aims:

- **Strengthen** existing framework on EU chemicals policy
- **Achieve** EU's sustainability ambitions, **while** ensuring competitiveness

A key **pillar** under the **EU Green Deal**

Challenge: Restriction of larger groups of substances of concern within shorter periods of time

- Potentially serious impact on our sector, which typically has multiple long timelines for the **designs**, the **re-designs**, and the **regulatory approvals** of technologies

Opportunity: inclusion of the Essential Use concept

- Can potentially help Europe achieve its sustainability aims via a more **streamlined** process, that preserves healthcare systems' **access** to the benefits of *legacy* (i.e., existing) products

Essential Uses: The Concept

Montreal Protocol

- Multilateral Environmental Agreement
  - Aims to protect the Earth's ozone layer by phasing out the chemicals that deplete it
- Different background, scope and objectives from Authorisation and Restriction pillars of REACH
  - However, Montreal Protocol elements may assist to develop a similar concept under REACH?

- <u>Concept of Essential Use</u>
  - Identify sectors/products which fit the definition and criteria of essential use
  - Assess applications for continued use where use chemicals in those sectors/products are proven essential for society and when no alternatives are available

CSS: Some Views from MedTech Europe

Objectives of the medical technology industry

Medical technology
"classic essential use"

- Promote **sustainability**
- Support the **application of the 'Essential Use'** concept to our sector
  - Medical technology is a **"classic" essential use** for society
- Contribute to **streamlined regulatory processes** that achieve **proportionality** going forward

Challenges

- Data collection
  - *Substitution in existing products*: identifying and evaluating alternatives, complexities of (re)design, etc.
- Market Access Risk
- Continued availability of critical substances

Conclusions

Use of substances of (potential) concern in medical technology sector are in most cases essential

- Substance restrictions can have a significant detrimental impact especially for legacy products that healthcare systems need to retain in order to meet their duty of care of patients

Chemicals Strategy for Sustainability provides an **opportunity** to:

- Promote high sustainability of new generation green healthcare products
- Enable continued use of chemicals needed to keep legacy medical technologies available, in cases where there are no viable alternatives

…and thereby achieve a mutually-acceptable balance between the need for healthcare, competitiveness and environmental protection!

Thank you

(*and please, stay safe!*)

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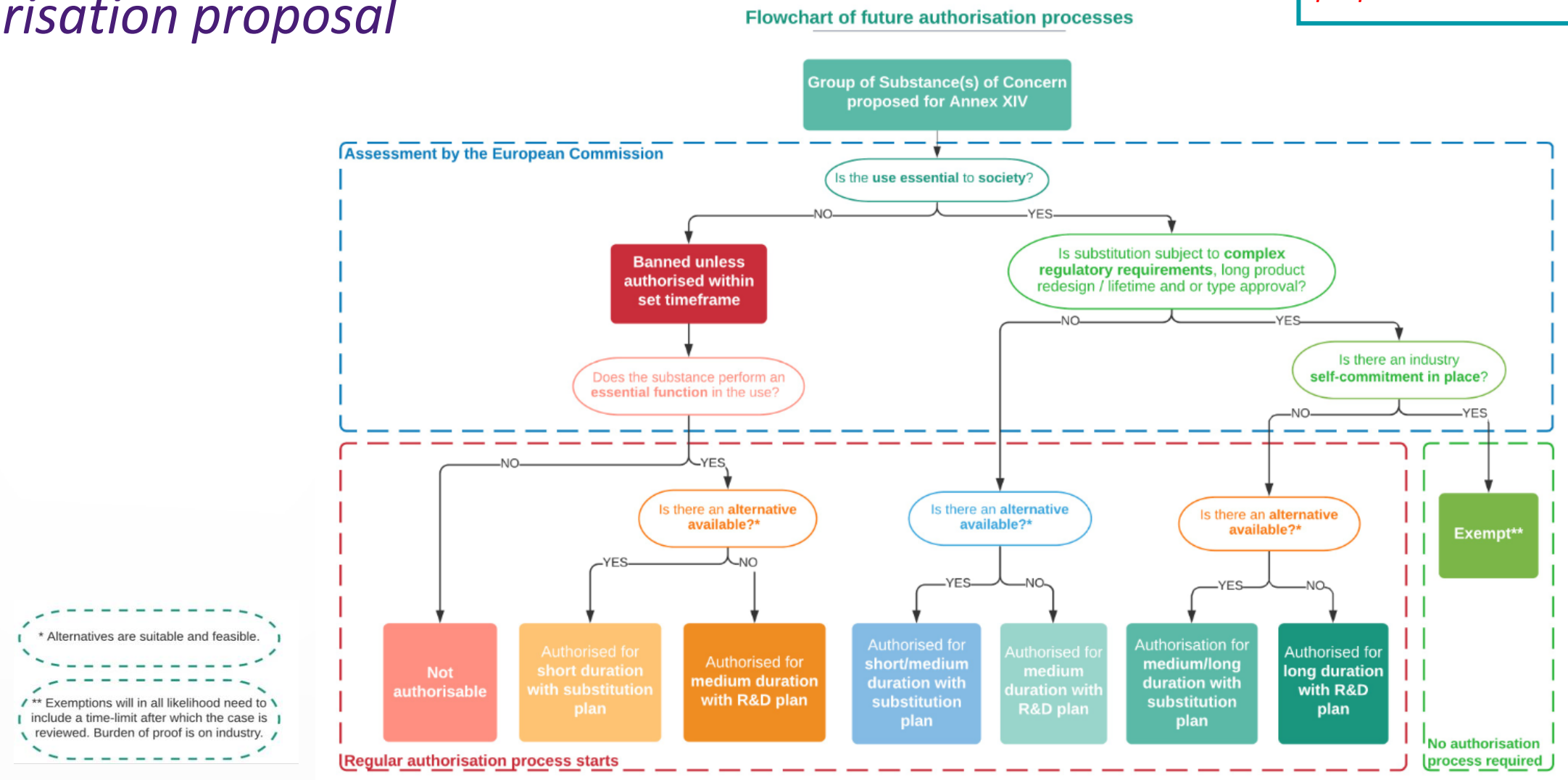
Backup Reading Material

Current Thinking on the Ideal Regulatory Process

Authorisation proposal

Disclaimer

proposal under development



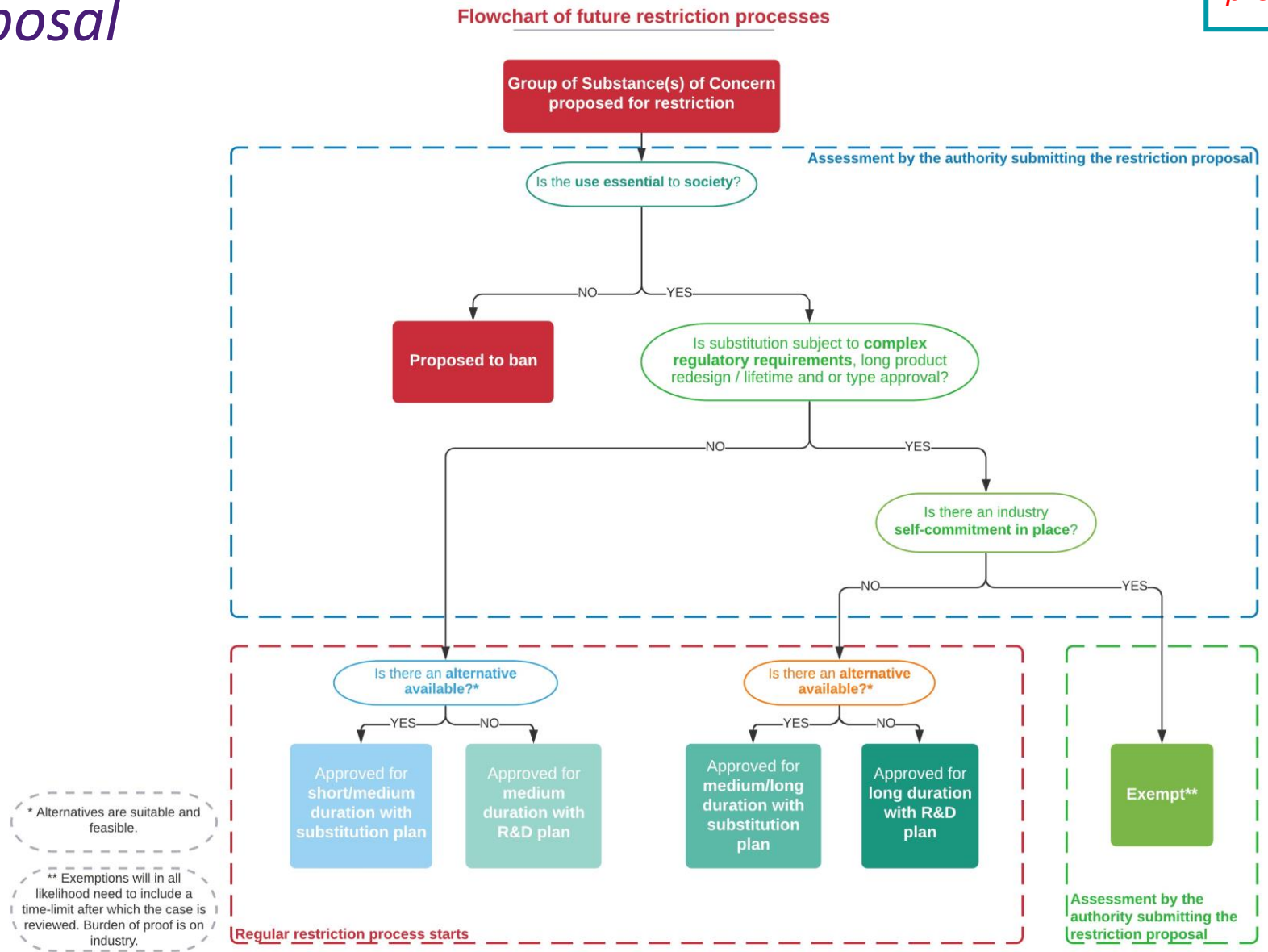
Note: The exemption should not cover only the IVDs and MDs but also their 'critical parts or components'.

Current Thinking on the Ideal Regulatory Process

Restriction proposal

Disclaimer

proposal under development



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