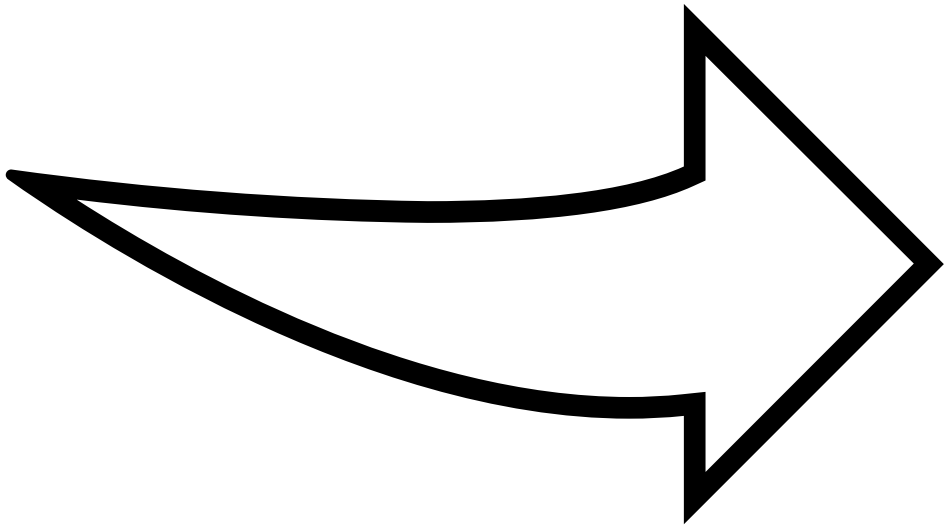
United Kingdom

Medical device regulation state of play

James Pink

Before the UK exit from the EU



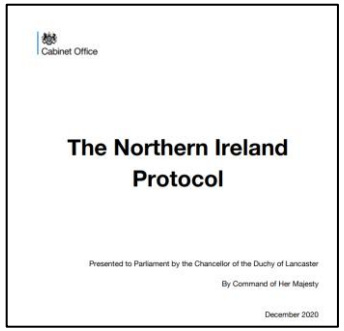
CE

The UK exit from the European Union

Impact on medical device regulation in the United Kingdom

UK Exit from EU transition timeline

2019
29th March


Cabinet Office

The Northern Ireland Protocol

Presented to Parliament by the Chancellor of the Duchy of Lancaster
By Command of Her Majesty
December 2020

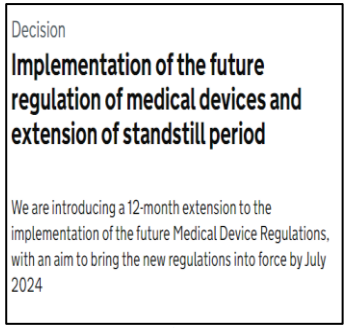
2020
10th December

Medicines and Medical Devices Act 2021

CHAPTER 3

Explanatory Notes have been produced to assist in the understanding of this Act and are available separately

2021
11th February


Decision

Implementation of the future regulation of medical devices and extension of standstill period

We are introducing a 12-month extension to the implementation of the future Medical Device Regulations, with an aim to bring the new regulations into force by July 2024

2022
13th June

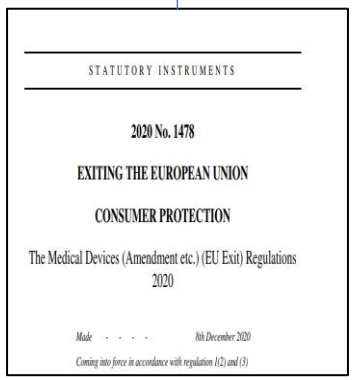

Press release

UK and EU to formally adopt the Windsor Framework

The UK and EU will meet to formally agree the Windsor Framework at the Withdrawal Agreement Joint Committee, chaired by the Foreign Secretary and the European Commission Vice-President.

From: Foreign, Commonwealth & Development Office and The Rt Hon James Cleverly MP
Published 24 March 2023

2023
24th March


STATUTORY INSTRUMENTS

2020 No. 1478

EXITING THE EUROPEAN UNION

CONSUMER PROTECTION

The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020

Made - - - - 8th December 2020

Coming into force in accordance with regulation 1(2) and (3)

2020
8th December


Guidance

Regulating medical devices in the UK

What you need to do to place a medical device on the Great Britain, Northern Ireland and European Union (EU) markets.

From: Medicines and Healthcare products Regulatory Agency
Published 31 December 2020
Last updated 1 January 2022 — See all updates

2021
1st January


Policy paper

Northern Ireland Protocol Bill: UK government legal position

Published 13 June 2022

Contents
Relevant rules of international law
The situation in Northern Ireland

The Foreign Secretary has outlined the Government's plans for primary legislation to address elements of the Northern Ireland Protocol (the "Protocol"). This statement summarises the position of the Government that such legislation is lawful under international law.

2022
21st October

2023
27th February

Legislation that applies in Great Britain

- Since 1 January 2021, there have been a number of changes. These are:

- a new route to market and product marking (the UKCA marking).
- all medical devices need to be registered with the MHRA before they are placed on the market
- Medical device manufacturers based outside the UK need to appoint a single UK Responsible Person for all of your devices, who will act on your behalf to carry out specified tasks, such as registration.
- CE marking will continue to be recognised in Great Britain until 30 June 2024
- certificates issued by EU-recognised Notified Bodies will continue to be valid for the Great Britain market until 30 June 2024
- the EU no longer recognises UK Notified Bodies
- UK Notified Bodies are not able to issue CE certificates - and have become UK Approved Bodies

Legislation that applies in Great Britain

Approved Bodies for Medical Devices and IVDs

Currently 4 organisations designated as an Approved Body:

	Medical Devices	Active Implantable Devices	In-Vitro Diagnostics
BSI	✓	✓	✓
DEKRA	✓		
SGS	✓		✓
UL			✓

Details of full scope here: Medical devices: UK approved bodies - GOV.UK (www.gov.uk)

- Recognise need to significantly grow capacity in UK AB sector
- Challenging to do this in parallel with implementation of regulatory requirements, both here and in other jurisdictions
- Requirements for Approved Bodies are set out in UK MDR 2002 and Regulation 920/2013 – must be able to demonstrate compliance
- We are being pragmatic in our approach to designation – balancing need to establish independent UK system against not creating unnecessary duplication

Legislation that applies in Great Britain

- Devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which, prior to the end of the transition period, gave effect in UK law to the directives listed below:

  - Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
  - Directive 93/42/EEC on medical devices (EU MDD)
  - Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)

- This means that the Great Britain route to market and UKCA marking requirements are based on the requirements derived from the above EU legislation.

- NI follow EU rules

- * To place MD/IVD on market in GB or NI – the extension to the MDR transitional period applies and sell-off rule removed for MD and IVDs.

element

Technical details – It got complicated ☺

Aspect	UK pre-Brexit	GB now	Northern Ireland pre Windsor agreement	Northern Ireland Post-Windsor agreement	UK next
Regulation	EU Directives	UK regulations	EU Regulations / UK Regulation amended NI protocol bill	Windsor framework translated in Law and NIP Bill scrapped	UK regulations
Mutual recognitions	EU recognitions	UKCA / CE (including new CE transitional Article 120)	UKNI / CE	UKCA / CE	UKCA / CE / MDSAP / Switzerland ???
Classification	MDD / IVDD / AIMD	Uk Regulation – Class I, IIA etc and Class A – D IVD.	EU Classification / UK classification if intended to place in GB	UK Classification / EU Classification if intended to place in Ireland / EU	
Conformity assessment	Class I Member State Other – Notified body EU	UK CAB and MHRA for certain CAB activities (ancillary medicines etc)	EU Notified body and EMA for certain CA activity / UK CAB and MHRA if intended to place in GB	UK CAB / EU Notified body if intended to place in Ireland / EU	Exciting ☺ May be MRA's
Quality Management Systems	Annex II – Annex VI EN ISO 13485 Harmonised	UK Regulation EN ISO 13485 Designated	Annex IX – XI MDR / UK Regulation if intended to place in GB	UK Regulation / Annex IX – XI	BS EN ISO 13485 designated MDSAP?
Safety and Performance Requirements	EU Annex I Essential requirements	UK Regulation	EU Annex I General Safety and Performance requirements (transitional periods) / UK Regulation if in GB	UK	UK Essential Requirements
Standards	Harmonised Standards	Designated Standards	Harmonised Standards EU / UK designated standards if intend to place in GB	UK Designated Standards / EU Harmonised standards if intended to place in Ireland	UK Designated Standards and others subject to MRA
Device identification	GMDN	GMDN	EMDN / GMDN if intend to place in GB	GMDN / EMDN if intend to place in Ireland / EU	GMDN
UDI	EU Directives	UK Regulations	EU Regulation (UDI-DI designated issuing entity) and UK Regulation	UK Regulation / EU only if intended to place in Ireland (EU)	UK Regulation
Registration	Member State	Public Access Registration Database (PARD)	EUDAMED / PARD if intended to place in GB	PARD / EUDAMED if intended to place in Ireland / EU	PARD – Maybe somehow share other databases to avoid duplication?
In-market representative	Either Manufacturer in EU or Authorised Rep	Responsible person	EU Authorised Rep and Responsible person if intended to place in GB	Responsible Person or EU Authorised Rep if intended to place in Ireland	Responsible person
Post-market surveillance and vigilance	Manufacturers incident reporting – Member State coordinated.	MORE (Manufacturers online reporting environment)	EUDAMED / MORE	MORE / EUDAMED if intended to place in Ireland / EU	MORE+
Labelling	EU Directives	UK Regulations	EU and UK regulations	UK and EU regulation if intended to place in Ireland / EU	UK Regulations

UK transitional regulations

- The current Medical Device Regulations 2002 (UK MDR 2002) states that the acceptance of CE marked devices on the Great Britain market ends on 30 June 2023. This has now changed. The transitional arrangements set out in the government response outline an extension to the recognition of CE marked medical devices placed on the Great Britain market, which is intended to be reflected within the UK MDR 2002, once it is amended.

- “Manufacturers will be able to continue to place CE marked devices on the Great Britain market after 1 July 2023. From July 2024, the transitional arrangements will apply for CE and UKCA marked devices placed on the Great Britain market.”

UK transitional arrangements

- The government intends to introduce legislation by Spring 2023 that will bring into force the transitional arrangements and post-market surveillance requirements as outlined in the government response. Bringing into force the new post-market surveillance requirements ahead of the wider future regulatory regime reflects the government's priority of improving patient safety as part of the future Medical Device Regulations.

UK transitional arrangements

- Focus groups are ‘expected to run for the 6-8 mths prior to laying down the SI.
- To note, under the World Trade Organisation (WTO) Technical Barriers to Trade agreement, the Secretary of State will be required to share the draft regulations on the future medical device regime for comment.
  - The period for comments must last for at least 60 days prior to the regulations being laid in Parliament.
  - The draft regulations will be published by the WTO and will provide an opportunity to all our key stakeholders to review and comment on the draft legislation before it comes into force.
- It is considered by some that the SI timelines will shift backwards, taking into account the above two points.

Overview of Statutory Instruments (SI)

Statutory Instruments	Description
Transitional Arrangements	Intended to amend the end of the standstill date (30 Jun 2023) in the current UK Medical Device Regulations 2002 (UK MDR 2002) and introduce the transitional arrangements for CE marked devices
Post-market Surveillance	Bring into force the new post-market surveillance requirements for CE marked and UCKA devices as laid out in the government response to the public consultation
Future Medical Device Regulations	This SI will bring into force the wider medical device regulations as laid out in the government response to the public consultation

Timelines for SI

Statutory Instrument	Laying of Statutory Instrument (expected)	Implementation date (expected)
Transitional Arrangements	Spring 2023	Spring 2023 (*Immediate effect*)
Post-Market Surveillance	Summer 2023	Winter 2023/ Early 2024 (*6-month implementation period)*
Future Medical Device Regulations	Winter 2023	Summer 2024 (*6-month implementation period)*

Northern Ireland and the Windsor framework

Northern Ireland pre-Windsor framework

Northern Ireland Protocol left Northern Ireland within the EU single market with the consequence that the EU law remained applicable in Northern Ireland whilst UK law applied in the rest of the UK.

- MHRA able to authorise medicines for Northern Ireland only on the basis of EU Directive 2001/83.
- Novel medicines, including innovative cancer medicines that were required to be authorised by the EMA in the EU, could not be authorised for Northern Ireland by the MHRA but could circulate in Northern Ireland on the basis of a European Union marketing authorisation.
- Since almost all such medicines are supplied to Northern Ireland from Great Britain, **some manufacturers were choosing not to launch novel products in Northern Ireland** as it is a very small market which might not justify the commercial investment in a separate pack.

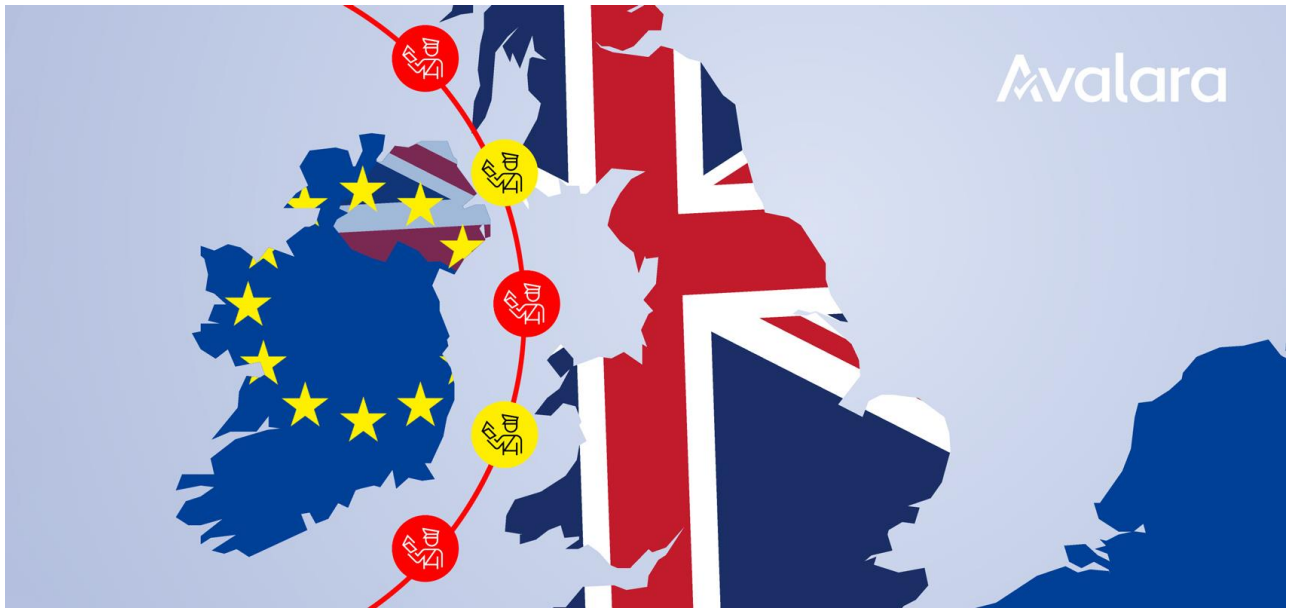
Northern Ireland pre-Windsor framework

	Type of good (see list of product areas below)	Accepted marking or combination of markings*
Placing goods on the market in Northern Ireland	Manufactured goods being placed on the market in NI using an EU conformity assessment body	CE
	Manufactured goods being placed on the market in NI using a UK-based body	CE and UKNI
Placing goods on the market in Great Britain	Manufactured goods being placed on the GB market until the end of 2022	UKCA or CE
	Manufactured goods placed on the GB market from 1 Jan 2023	UKCA
Placing qualifying Northern Ireland goods on the market in Great Britain (unfettered access)	Qualifying Northern Ireland goods being placed on the GB market under unfettered access	CE or CE and UKNI
Placing goods on the EU market	Manufactured goods being placed on the EU market	CE

*You may use combinations of the product markings listed in each box and your goods may be acceptable with more than one marking. For example, a product with both the CE and UKCA markings can be placed on the EU market. However, for the EU market the CE mark must appear without the UKNI indication as goods bearing the 'CE and UKNI' marking are not acceptable in the EU market. This means these goods must be manufactured to EU rules and cannot be assessed by a body based in the UK.

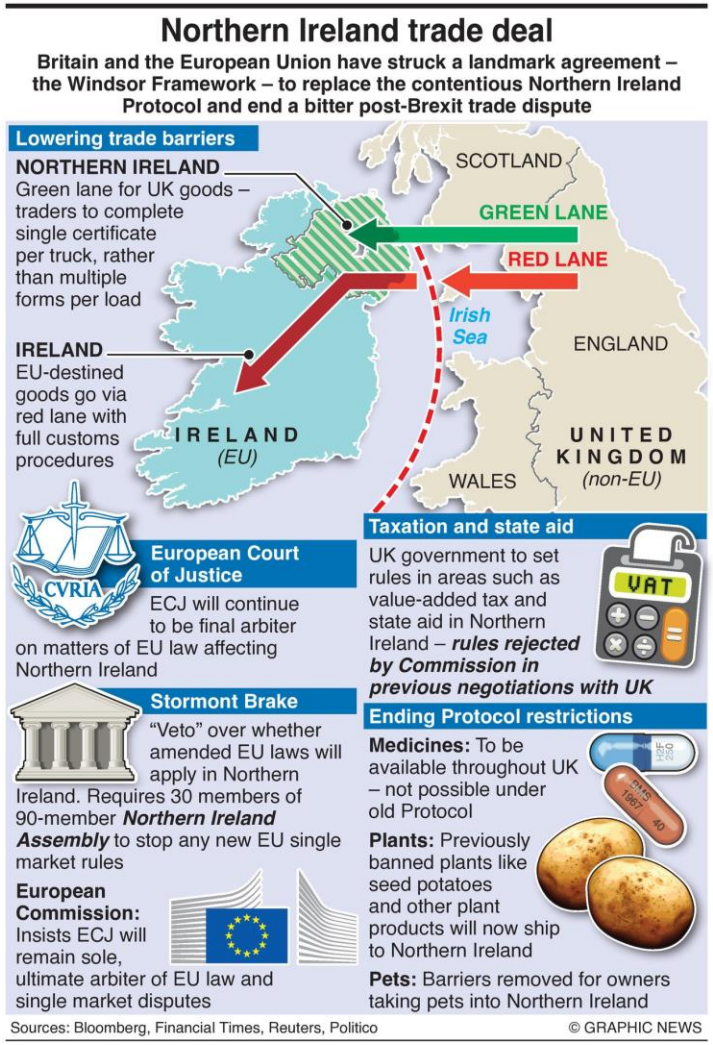
CE UKNI

UKCA



[Brexit Northern Ireland VAT and EORI numbers (avalara.com)]

Windsor framework – 27th February 2023



- Rewriting the Treaty with new 'Stormont Brake' means UK can veto new EU goods laws if they are not supported by both communities in Northern Ireland
- New green lane removes border in Irish Sea
- Northern Ireland to benefit from same VAT, food and drink **and medicines** as the rest of the UK

- It delivers free-flowing trade in goods between Great Britain and Northern Ireland

Windsor framework

- The MHRA will be able to approve all drugs for the whole UK market enabling all types of medicines to be supplied in single packs, within UK supply chains, with a single licence for the whole UK. The **EMA will no longer have any role** in approving medicines for Northern Ireland.
- Meanwhile, the EU has published a draft Regulation whose main effect is to declare that medicines to be **authorised by the EMA pursuant to the provisions of Regulation 726/2004 shall not be placed on the market in Northern Ireland**. The medicinal product concerned must be conspicuously **labelled "*UK only*"**
- Simplification of the VAT and excise arrangements for Northern Ireland means that Northern Ireland's position within the UK's VAT and excise area is guaranteed while still maintaining frictionless arrangements for businesses, including healthcare and life sciences businesses, in Northern Ireland trading with the EU.

Windsor framework Green and red lane

The current process

- The goods are checked at ports in Northern Ireland on arrival
- They can then be moved into the Republic of Ireland once checked

The new plan

- The goods are split into two different lanes
- Goods destined for Northern Ireland go into the **Green Lane** meaning they wouldn't have to be checked and would require minimal paperwork
- Goods destined for Ireland and the EU go into the **Red Lane** and checks are carried out

Windsor framework implications

Stormont brake

- Under the protocol, some EU law applies in Northern Ireland, but politicians had no formal way to influence the rules
- New agreement reduces proportion of EU rules applied in Northern Ireland to less than 3%
- European Court of Justice continues to be the final arbiter in disputes over these remaining rules
- Deal introduces a "Stormont brake" which allows the Northern Ireland Assembly to raise an objection to a new goods rule
- Process would be triggered if 30 MLAs (representatives in the Stormont) from two or more parties sign a petition
- The brake cannot be used for "trivial reasons" but reserved for "significantly different" rules
- Once the UK tells the EU the brake has been triggered, the rule cannot be implemented
- It can only be applied if the UK and EU agree
- This new process is not subject to oversight by the European Court of Justice oversight
- Disputes would be resolved through independent arbitration
- The EU has its own safeguard - if Northern Ireland starts to diverge significantly from the bloc's

The future state

The United Kingdom future medical device regulations

Future regulation timeline

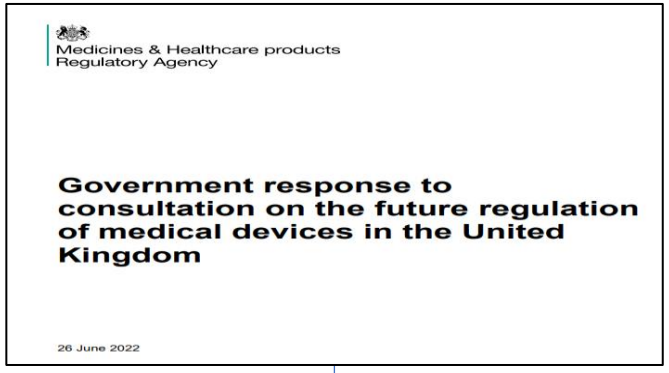

Consultation outcome

Consultation on the future regulation of medical devices in the United Kingdom

From: Medicines and Healthcare products Regulatory Agency and The Rt Hon Sajid Javid MP

Published 16 September 2021

2021
1st September

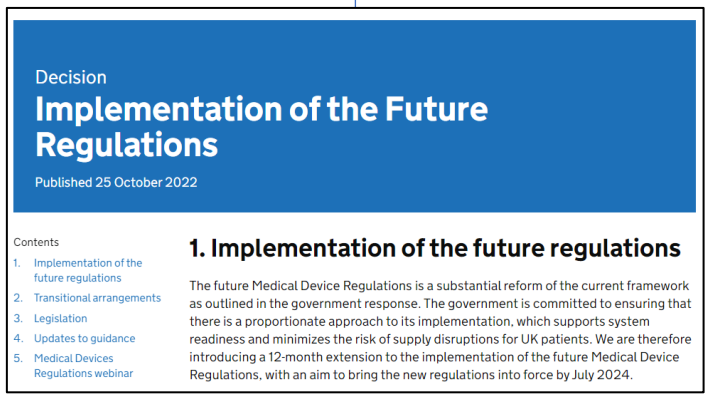

Medicines & Healthcare products Regulatory Agency

Government response to consultation on the future regulation of medical devices in the United Kingdom

26 June 2022

2022
26th June

2022
25th October


Decision

Implementation of the Future Regulations

Published 25 October 2022

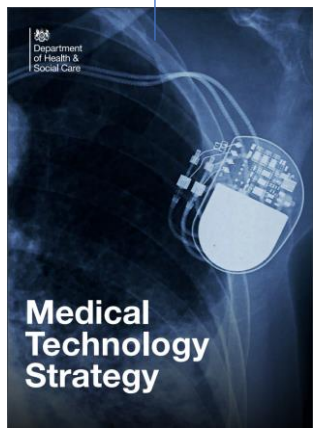
Contents

1. Implementation of the future regulations
2. Transitional arrangements
3. Legislation
4. Updates to guidance
5. Medical Devices Regulations webinar

1. Implementation of the future regulations

The future Medical Device Regulations is a substantial reform of the current framework as outlined in the government response. The government is committed to ensuring that there is a proportionate approach to its implementation, which supports system readiness and minimizes the risk of supply disruptions for UK patients. We are therefore introducing a 12-month extension to the implementation of the future Medical Device Regulations, with an aim to bring the new regulations into force by July 2024.

2023
3rd February



UK life sciences Council regulatory reform

- The advisory group has agreed that aligned proposals will be published on three priority areas:

1. International recognition
2. Routes for innovation
3. System capacity.

UK life sciences Council regulatory reform

- 9 Proposals : Advisory Group Reform Proposals - GOV.UK (www.gov.uk) Including:

- *Ensure the supply of safe medical devices through expanded recognition*
- *Building on current product recognition routes from the EU, rapidly explore building a UK product regulation equivalence route for the approvals of medical devices to include other trusted jurisdictions such as the US for a greater proportion of products.*
- *Explore greater flexibility over the requirements for physical UKCA markings on parts, instructions and labels before products can be marketed in the UK. Make greater use of registration and traceability mechanisms to ensure patient safety.*
- *The MHRA has already announced its intention to expand recognition for medicines, and create a new recognition framework by the end of 2023. Aim to align changes to the Medical Devices Legislation to the Medicines legislative timeline if possible*

Medical Technology strategy – February 2023

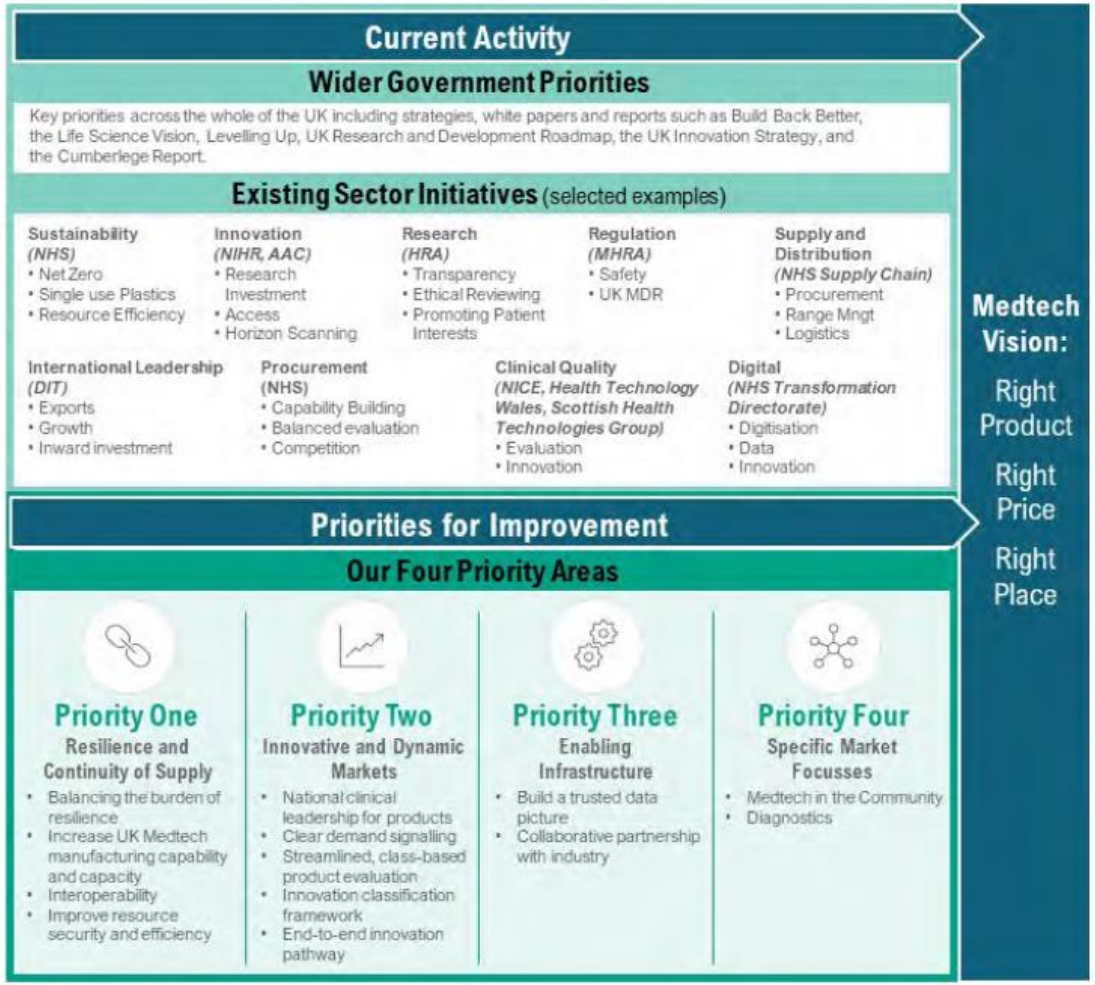


Figure 4: Current activity and identified gaps for strategy priority areas that contribute to the medtech vision.

Future state regulation

> From 2024, [the MHRA] will move to a different [regulatory] model, which will allow rapid, often near-automatic sign-off for medicines and technologies already approved by trusted regulators in other parts of the world such as the United States, Europe and Japan. At the same time, it will set up a swift new approval process for the most cutting-edge medicines and devices to ensure that the UK becomes a global centre for their development. With an extra £10 million of funding over the next two years, they will put in place the quickest, simplest regulatory approval in the world for companies seeking rapid market access (HC Deb, 15 March 2023, c841)"

The Right Honourable Jeremy Hunt MP, Chancellor of the Exchequer. 15th March 2023 budget statement

Simulations

1. Signal from National Health Service around shortage of appropriate wound dressings for venous leg ulcer
2. Novel software as a medical device intended to predict myocardial infarction in order to triage cardiovascular disease treatment waiting lists

QUESTIONS

Medical device regulation state of play

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