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# COVID – 19
# Challenges and Opportunities for the Medtech Industry

May 2020

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# Overview

1. The Pre-COVID Landscape
    - MDR/IVDR
    - NBs
    - Re-certifications
2. COVID-19 Response
    - Regulatory flexibility
    - Manufacturing/Innovation
    - Supply chain
3. Post-Crisis Landscape
    - Healthcare delivery transformation

# Pre-COVID Landscape

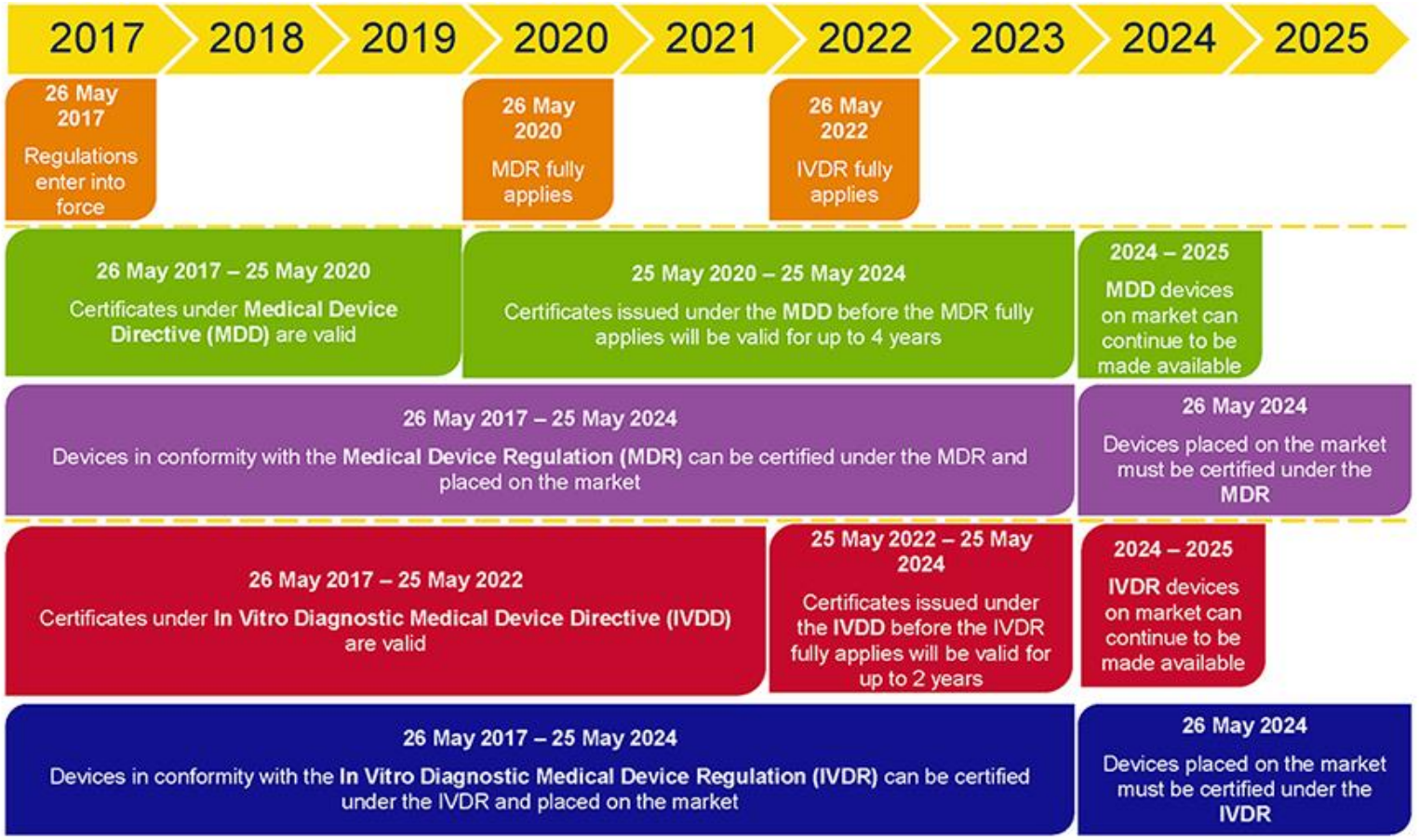
## Medical Devices

- **Outgoing Medical Device Directives**
- **Incoming Medical Device Regulations**
- **Notified Body Capacity**

# The Medical Device Directives

- **These Directives, which have been in place for 25 years, were scheduled to be superseded on 25 May 2020.**
- **On 26 May 2020, the Medical Device Regulations were due to come into effect, with the In-Vitro Device Regulations to follow two years later.**

# Pre-Covid Timeline to MDR/IVDR



## MDR – Key Principles

**A significant strengthening of the regulatory framework around medical devices and, in particular, their post-market surveillance.**

- Scope and Classification - Scope expansion and new classification rules
- Clinical Evidence - Retreat from equivalance and focus on clinical investigation data
- Economic Operators - Obligations for importers, distributors and Authorised Representatives
- EUDAMED/Post Market Surveillance – Increased requirements in post-market follow-up

# MDR Delay

## Pre-Covid concerns

https://www.bhsm.ie/insights-news/covid-19-could-bring-welcome-relief-to-irelands-burgeoning-medical-device-industry/


- Notified Bodies
- Lack of EC Guidance
- Re-certification delays
- Market contraction and disappearance of devices

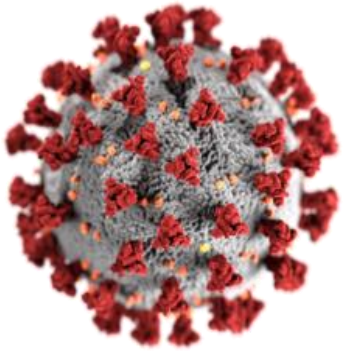
# MDR Delay

## Realignment of Priorities from the EC

- MDR implementation was delayed until 26 May 2021 on 20 April 2020. The EU Parliament's press release stated the following:

*"Given the current pressure on national health authorities and manufacturers of medical devices, there is a fear that there could be shortages or delays in getting the medical devices needed to fight COVID-19, were they to follow the new rules of the Medical Devices Regulation from May this year"*

# COVID Impact



## Realignment of Healthcare Priorities

- Healthcare systems across the globe have redirected very substantial resources to COVID-19 response efforts.

- There is unprecedented demand for PPE, ventillators and other critical medical supplies, while demand for some devices has contracted significantly.

- Regulators have had to act to facilitate the increased supply of existing products alongside the development of new products in a time sensitive environment.

# Regulator Response

## PPE vs Medical Device

The regulation of face masks and gloves differs depending on the product type and its intended purpose.

- PPE

Face masks and gloves intended to shield against hazardous substances are considered PPE – regulated under EU 2016/425

- Medical Devices

Face masks and gloves designed for use in a clinical setting are class I medical devices, subject to the Medical Device Directive and require Notified Body oversight if to be used in  a sterile setting.

(Dual purpose products are considered to fall under both of the above)

# Regulator Response

## Harmonised Standards

The European Commission has adopted decisions on harmonised standards for certain medical devices.

The agreed standards allow device manufacturers to demonstrate conformity to the Medical Devices Directive and provide companies with direct access to the internal market for their products. The standards cover the devices listed below:

- Medical face masks
- Surginal drapes, gowns and suits
- Washer-disinfectors
- Sterilisation

The available standards can be accessed free of charge here:
https://www.nsai.ie/covid-19/

# Regulator Response

## PPE

The European Commission has issued guidance to facilitate the increased production of PPE in Europe. That guidance identifies two scenarios in which PPE may be placed on the market where conformity assessments have yet to be finalised, or even commenced.

1. Adequate Safety

If national market surveillance authorities find that the relevant products ensure an adequate level of health and safety in accordance with the requirements of EU law, they may authorise these products even where conformity assessment procedures and the affixing of CE mark have yet to be finalised.

# Regulator Response

## PPE

### 2. Exceptional Circumstances

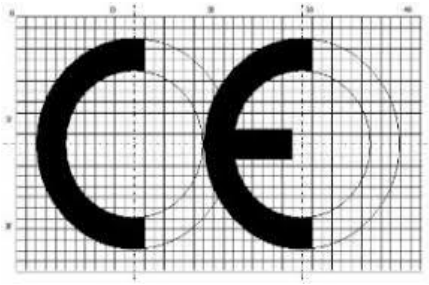
Where conformity assessment procedures have yet to be commenced and there is no CE mark, products may be placed on the market if all of the following criteria are met.

- The products are manufactured in accordance with one of the EN Standards/WHO guidelines
- The products are purchased by Member State authorities
- The products are only available to healthcare workers
- The products are only available for the duration of the crisis
- The products do not enter regular distribution channels

The new conformity routes for PPE can be accessed here.

# Regulator Response

## HPRA Approvals/Derogation



- The HPRA has developed a process for the urgent assessment of non-CE marked devices in Ireland in the context of COVID-19 which would allow their use in the interests of the protection of health.

- The scheme is available to both manufacturers and consultant physicians who can access the scheme by way of written application.

- The relevant application forms can be accessed through the HPRA website.

# Regulator Response

## Criteria for Derogation

When assessing an application for derogation, the HPRA will consider the following:

- The degree of criticality of the use of the device
- The availability of substitutes
- Documentation of compliance with a harmonized standard or other technical solution
- Reports of tests performed by competent bodies
- Indications from vigilance/market surveillance

Any derogation authorized will be time limited and the relevant device must be registered with the HPRA through their website.

# Regulator Response

## Off-Label Use

Pursuant to guidance issued by the EC, where the off-label use of an existing device is deemed necessary, a careful risk/benefit assessment to the patient must be carried out. That assessment will typically include the following:

- A documented risk assessment on the use of the device
- Consideration of the ethical and legal principles
- The implementation of precautions to minimize risk
- Review of the risk assessment at suitable periods
- Obtaining approval from the HPRA where required.

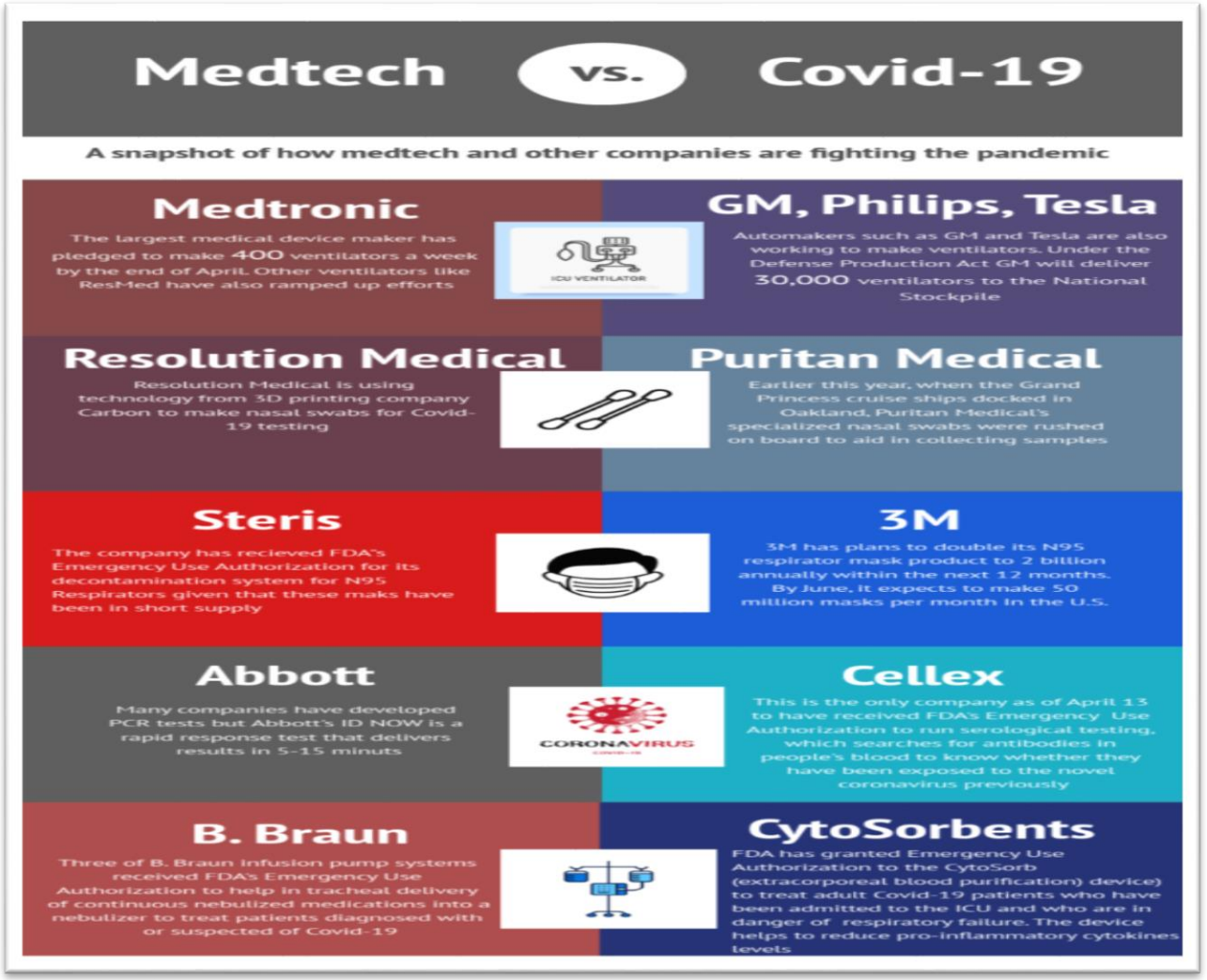
The patient must also be informed of the use of the off-label device during any consent process.

# How has Industry Responded to COVID?


## Production

There is now unprecedented demand for respirators, PPE and ventilators. Supply is unable to meet demand.

- 3M have doubled production of N95 respirators to 100 million units per month.
- Medtronic has significantly increased ventilator production and aims to produce 1,000 units per month by the end of June 2020.
- Non-medical device manufacturers are now re-purposing to assist in the production of PPE.
- A number of drinks manufacturers are also producing hand sanitizer.


Medtech vs. Covid-19
A snapshot of how medtech and other companies are fighting the pandemic
Medtronic
The largest medical device maker has pledged to make 400 ventilators a week by the end of April. Other ventilators like ResMed have also ramped up efforts
ICU VENTILATOR
GM, Philips, Tesla
Automakers such as GM and Tesla are also working to make ventilators. Under the Defense Production Act GM will deliver 30,000 ventilators to the National Stockpile
Resolution Medical
Resolution Medical is using technology from 3D printing company Carbon to make nasal swabs for Covid-19 testing
Puritan Medical
Earlier this year, when the Grand Princess cruise ships docked in Oakland, Puritan Medical's specialized nasal swabs were rushed on board to aid in collecting samples
Steris
The company has recieved FDA's Emergency Use Authorization for its decontamination system for N95 Respirators given that these maks have been in short supply
3M
3M has plans to double its N95 respirator mask product to 2 billion annually within the next 12 months. By June, it expects to make 50 million masks per month in the U.S.
Abbott
Many companies have developed PCR tests but Abbott's ID NOW is a rapid response test that delivers results in 5-15 minuts
CORONAVIRUS
Cellex
This is the only company as of April 13 to have received FDA's Emergency Use Authorization to run serological testing, which searches for antibodies in people's blood to know whether they have been exposed to the novel coronavirus previously
B. Braun
Three of B. Braun infusion pump systems received FDA's Emergency Use Authorization to help in tracheal delivery of continuous nebulized medications into a nebulizer to treat patients diagnosed with or suspected of Covid-19
CytoSorbents
FDA has granted Emergency Use Authorization to the CytoSorb (extracorporeal blood purification) device) to treat adult Covid-19 patients who have been admitted to the ICU and who are in danger of respiratory failure. The device helps to reduce pro-inflammatory cytokines levels

# How has the Industry responded to COVID?

## Collaboration

The crisis has created an environment in which collaboration between companies, countries and across industries has become essential.

- Medtronic publically shared the design of one of its ventilators to allow for cross-industry evaluation of the options for rapid manufacture.
- In the United Kingdom, companies such as Rolls Royce have collaborated with established Medtech specialists to increase their production of ventilators.

# How has the Industry responded to COVID?

## Innovation

The Irish Medtech industry is now engaged in a multitude of project to develop solutions for multiple aspects of the crisis.

- Last week, 7 NUIG rapid response research projects were announced. T
- NUIG's 'Inspire Team' developed an adjustable split ventilator.
- Carebots have been developed to help manage the dispensing of pharmaceuticals.
- Development, sourcing and validation of rapid-test COVID-19 Kits
- Track and trace mobile technology is being developed and deployed to assist both in the effectiveness of social distancing and the tracing of contacts in the event of a COVID-19 diagnosis.

A tracker of COVID-19 projects can be accessed here.

# How has the Industry responded to COVID?

## Supports for Innovation

Early stage companies engaged in the development of innovative healthcare solutions are likely to affected by the financial fallout of COVID-19 disproportionately, given their reliance on funding and investment.

Various supports have been put in place by the government to support scaling and start-up enterprises. The detail of those supports can be found here.

It is worthy of note that investors are still willing to engage as evidenced with Irish company ‘Lets Get Checked’ having just raised 71 Million US in order to develop their home diagnostics offering.

# How has the Industry responded to COVID?

## Supply Chain

This has become a serious issue in the fight against coronavirus.

- Distributors do not have inventory
- Healthcare providers do not have the pre-existing relationships to buy directly from manufacturers
- Air travel is significantly restricted
- The requirements of navigating customs on both import and export to and from unfamiliar jurisdictions

The EC has also introduced an Export Authorisation Scheme for PPE, restricting such export in order to ensure that adequate supply remains available in the EU.

EC guidance on the scheme can be found here.

## Supply Chain

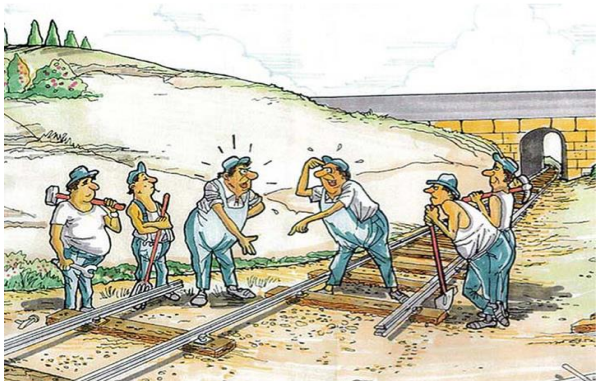
Contracting Authorities are also taking steps under existing EU Regulations and National laws to procure the necessary supplies equipment necessary in our response to the crisis.

The following points are worthy of note:

- Contracting Authorities may enter into contracts without competition or advertising in emergency situations such as COVID-19
- Contracting Authorities may also extend or modify existing contracts without the need for a further procurement process in emergency situations such as covid-19.

The Office of Government Procurement has issued guidance on the issue which can be accessed here.

# What happens when it's all over?

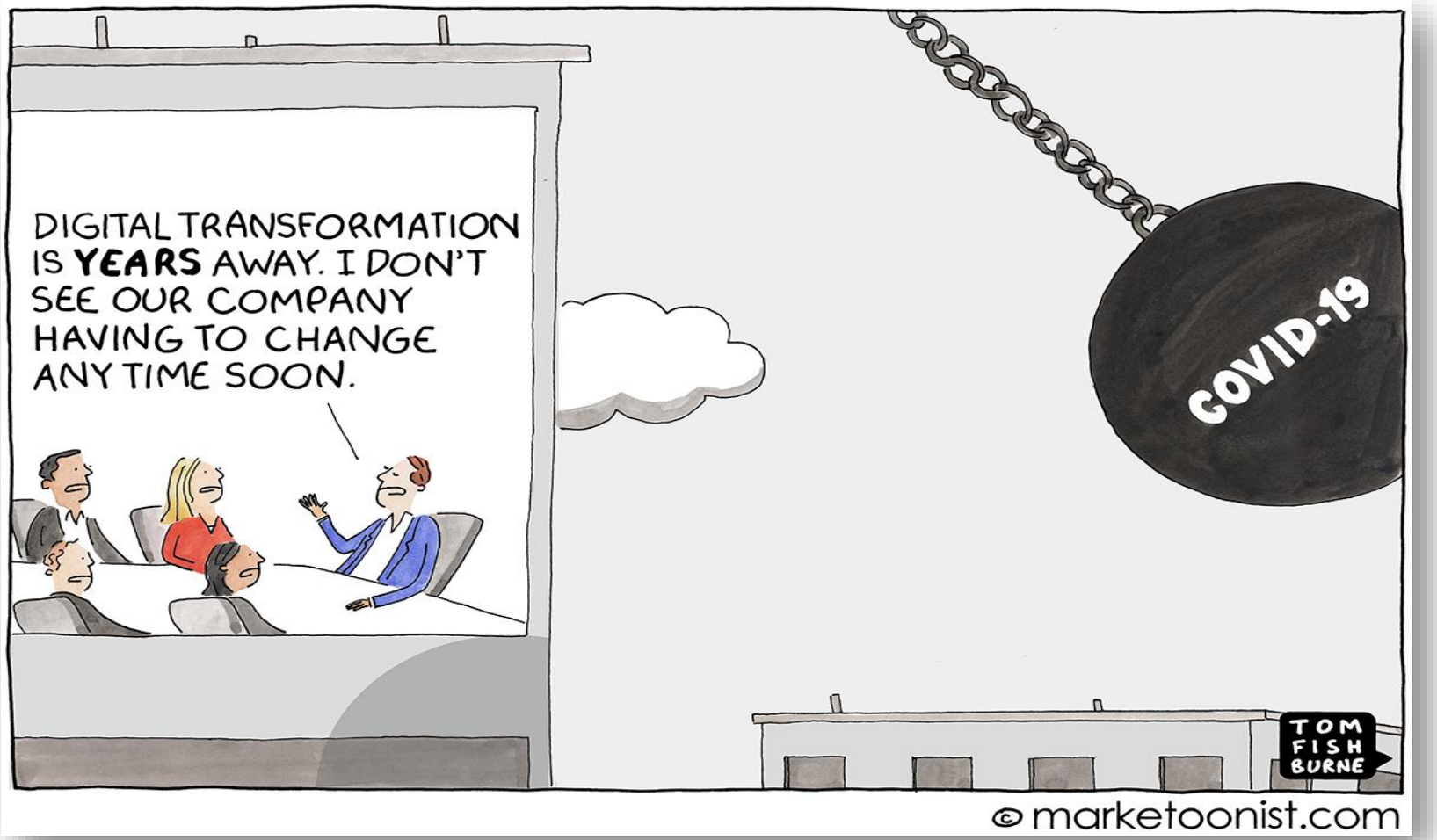


## MDR – Delayed by not derailed

Despite the twelve month delay, MDR is still likely to present significant issues for industry, given the resources that have been diverted to COVID-19 by Competent Authorities, Notified Bodies and all economic operators in the medtech supply chain.

Medtech Europe have called for a delay to both MDR and IVDR. Significantly, they have called for the length of the delays to be linked to end of the COVID-19 crisis, as declared by a relevant authority such as the World Health Organisation.

# Where do we go from here?



## Drive for Digitisation

The pandemic is likely to drive the healthcare sector to embrace new technologies which would previously have been resisted.

The next phase of digital healthcare could focus on increased interoperability between the many disparate systems used in healthcare with the goal of providing both healthcare professionals and patients with integrated data and services which are already common-place in retail and banking.

Work in this regard is already well advanced in Ireland under the direction of Martin Curley at Digital Transformation and Open Innovation and others such as John O’Brien at S3 Connected Health.

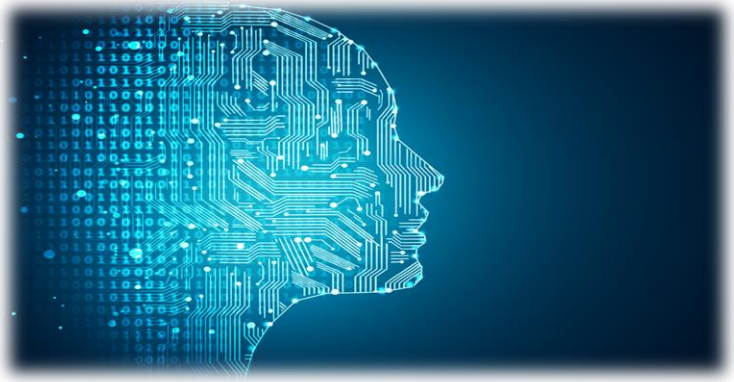
## Telemedicine and Home Diagnostics

In response to the pandemic, healthcare providers are expanding their use of virtual patient visits via telephone or video call.

The next phase of this trend would involve the monitoring of patient biological parameters through medical devices. The widespread use of telemedicine and tracking medical devices would decrease the need for patients to attend healthcare facilities, thereby reducing the risk of infection spread.

Developments in the development of the provision of remote healthcare must have regard to patient confidentiality and the complex regulatory framework which will apply when the pandemic has receded and MDR applies.

# Artificial Intelligence



Mynd You, a company based in Israel, have developed a voice bot and virtual care manager which acts as a hotline to assess risk, manage symptoms and provide guidance.

The technology utilizes AI-driven voice analytics during the call which are able to detect subtle changes in health and trigger proactive interventions as a result.

Similar technologies which deliver Cognitive Behavioural Therapy through app-based chat bots have been in existence for some time.

# Conclusions

## Potential outcomes of COVID-19 for the Medtech Industry

- Continued innovation and collaboration across industries
- Maintenance of inventory of essential products
- Strategies for product diversification in the event of demand drop-off
- The embrace of digital transformation in healthcare and the use of remote monitoring and telemedicine.

As an aside, the increased use of electronic processes and data capture will give medtech companies affected by MDR a significant competitive advantage with respect to the development of their post-market surveillance and post-market clinical follow-up requirements.

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