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Navigating the uncertainty

What to do if you cannot find a Notified Body

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Notified Body Conditions

- Finding a Notified Body for MDR is not a quick way forward even if you area an existing customer!
- Get a Notified Body for MDD is probably not possible anymore
  - If you have everything ready it is still theoretical possible
  - You should contact non MDR approved ones

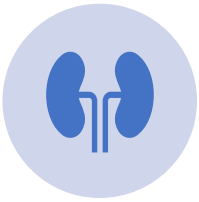
Covid slows down MDR implementation

- Most Notified Bodies have difficulties to do initial audits for MDR since these are not in the remote audit guidance.
- This however is decided on national level from the competent authority in the country the NB is registered.

The parts covered in this presentation

WHERE ARE YOU IN THE PROCESS?

LAST POSSIBILITY



WHAT CAN YOU DO?

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Where are you in the process?

Are you in any of the following situation?

- Expiring MDD certificate
- Lost your MDD certificate (e.g. Issues with your current NB)
- New in the market (startup to enter the market)
- Change in product intended use (now or planned)
- Significant change of the product

Will your notified body be able to keep your product code…. Things can change quick!

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Am I alone in this situation?

There are quite many companies across EU that face this scenario!

My personal experience last 3 month:

- 5 startups with almost ready products but fragmented quality systems in place, 2 finally found a NB!!
- 2 had a UK notified body and got issues with the new NB

  Still not solved
- 1 changed NB and got stuck in the middle….

However companies without problems do not contact me….

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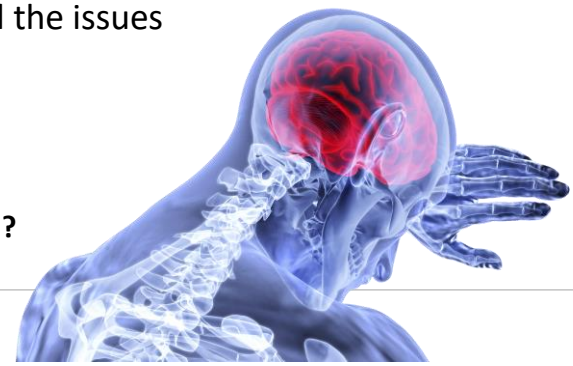
Navigating the uncertainty

Golden rule

- Work with what you can, prepare for the worst

- Draw up a few scenarios to understand the issues
  - Worst case
  - Best case
  - The most realistic way

What are the options if this happen to you?



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Last possibilities

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Last possibilities before May 26

Ensure that you have everything ready!!!!!

- Contact Notified bodies both for MDR and MDD.
- Change intended use to become a class I product in MDR
  - Works for some products
  - Might have other implications on e.g. sales, existing customers etc

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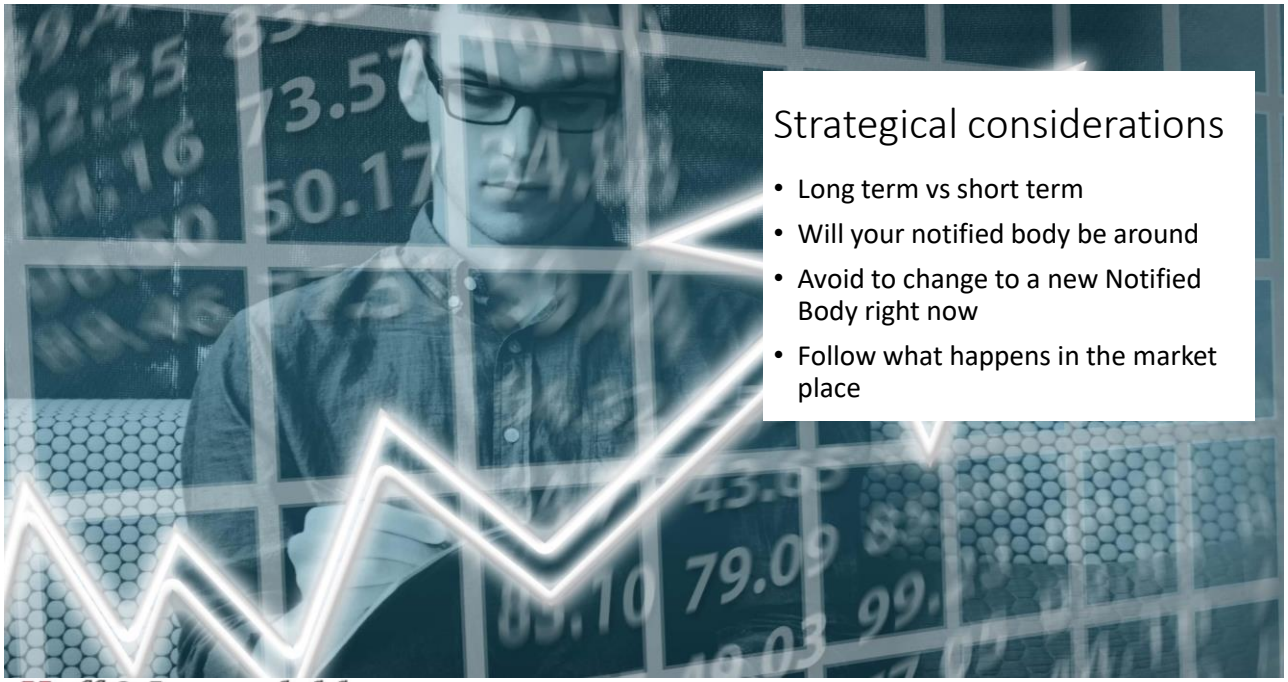

Strategical considerations

- Long term vs short term
- Will your notified body be around
- Avoid to change to a new Notified Body right now
- Follow what happens in the market place

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What can you do now?

- If last possibilities does not work out

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Alternatives

National exemption – after May 25

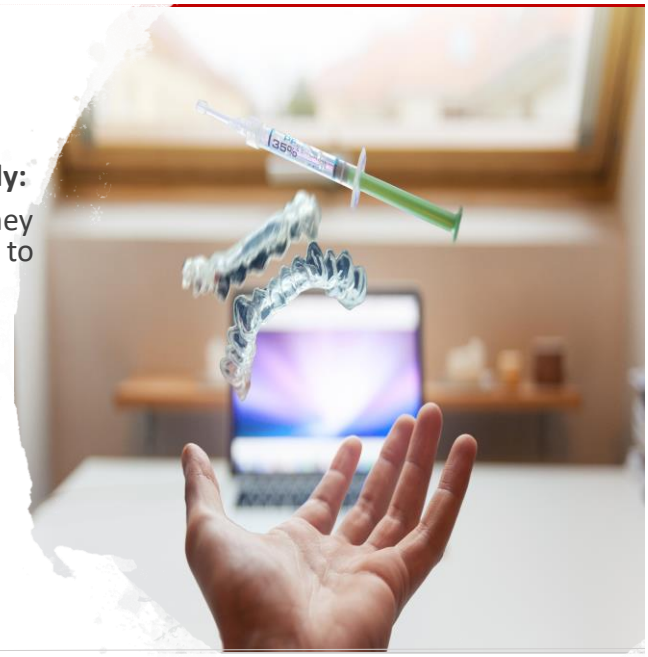
- Contact Läkemedelsverket
- Ensure you have contacted all MDR Notified Bodies and have documented this

Using article 59 (if implemented nationally)

Using article 59

The following criteria for derogation will apply:

- The manufacturer must demonstrate that they have tried what can reasonably be expected to get the device CE-Marked, as well as the reasons why this has so far not been successful;
- The device must be of vital importance;
- There are no substitutes (sufficiently) available;



Using article 59 cont

- There are no indications of risks of the device for public health;
- Derogations are only temporary and the timeline should be in line with the expected timeline for achieving CE Marking;
- There is an EU-wide relevance for extending the validity of the national derogations.

Using article 59

- If this work it will for sure be a burdensam process
- Have not been used (what I know about)

This process probably is the one that should have been used in the Covid situation last year!

Alternative strategy

Export outside EU

- Countries requiring free sales
- Compliance needs
- Timelines
- Navigating new barriers

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What you already should be doing

No excuse to not be ready in case a NB gets an opening!

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Key take away

- Monitor your NB to ensure they will exist/keep your code
- If you need a NB, contact them and document this
- Look for alternative strategies outside EU

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