Swiss as 'third country'

Strategic planning for the worst

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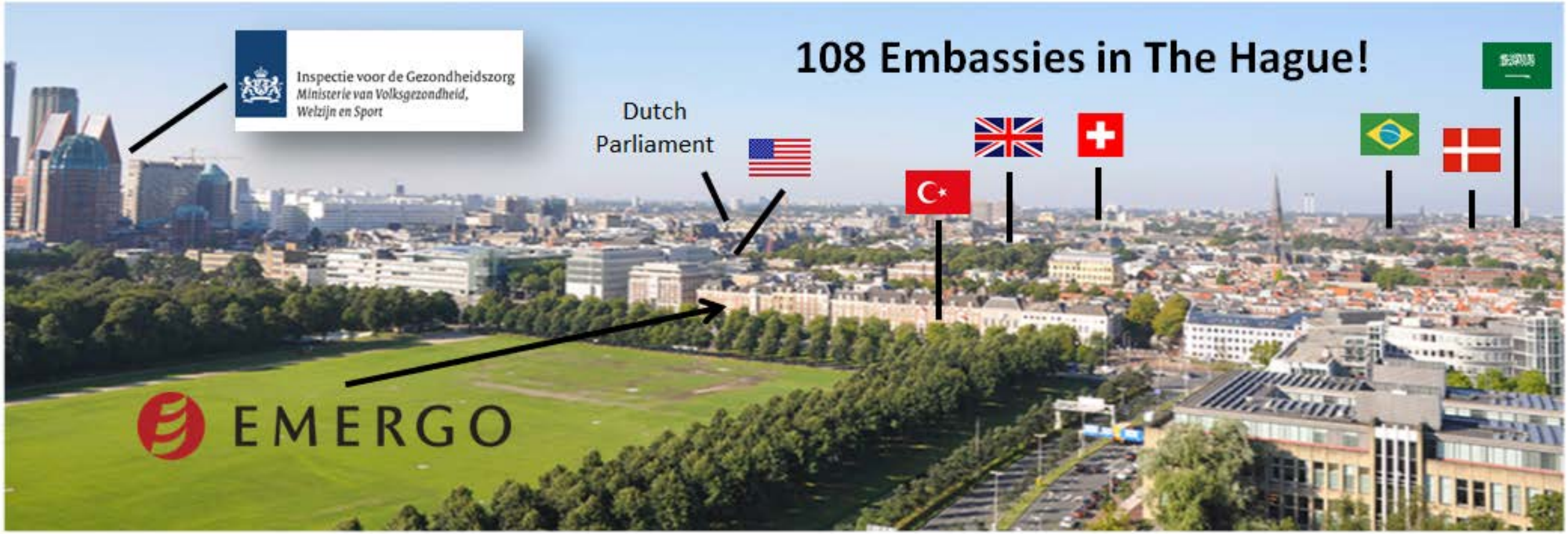

The Hague, The Netherlands

What you can expect today

- Main differences EU versus non-EU manufacturer
- Lessons from Brexit: agile risk management
- Planning for controlled risks

EU manufacturer versus non-EU manufacturer

- Free movement of Medical Devices, if placed on the market by:
  - EU manufacturer
  - Importer, from non-EU manufacturer engaging an Authorized Representative (AR)
- Details must be supported by documents (Declaration of Conformity, label etc.)

Note: under the MDD an EU manufacturer may appoint an AR, under the MDR this is not allowed

Three perspectives on importation

1. Customs: held accountable for taxes and tariffs
2. Logistics: first to physically receive the products after they have crossed the border
3. MDR: has certain administrative responsibilities

These three types of importation are not correlated

Certificates

- For MDD or AIMDD certificates:
  - No name of AR on certificate required
  - If the manufacturer remains on same location, but moves out of EU: this is NOT a significant change that would trigger new certification
- For MDR certificates:
  - Name of AR required on certificate for non-EU manufacturers
  - Adding such name later may trigger additional auditing
  - Devices MDR certified before My 26th, 2020 are not covered by an MRA and should *probably* need an AR and Importer

The situation for 'early' MDR certificates is very unclear

Uncertainty regarding signing of MRA

- Setting up an AR and Importer before it is certain the MRA is not signed may be unnecessary:

  Wasted time and money as a worst case outcome

- Waiting until there is certainty may leave too little time:

  Loosing access to EU market as a worst case outcome

You need to balance both outcomes over time

Lessons from Brexit: manage uncertainty in six steps

1. Map alternative outcomes
2. Map timelines for transitioning
3. Analyze risks, especially the unacceptable outcomes
4. Create parallel pathways if possible
5. Map the optimal route, with stop/go moments, alternatives etc.
6. Prepare mitigations for worst case scenarios

Example from Brexit: UK based Notified Bodies

- January 2018: European Commission communicates certificates of UK based Notified Bodies will become void in case of a no-deal Brexit
- Step 1: map alternative outcomes:
  1. No-Brexit, soft Brexit
  2. Hard Brexit after transitional period
  3. No-deal Brexit on March 29th, 2019
- Step 2: Map timelines
  1. No changes required → no timelines
  2. Switch during transitional period → start around March 29th
  3. Hard stop on March 29th, no time to switch

UK Based Notified Bodies (2)

- Step 3: analyze risks – first two outcomes are not to mildly critical, third outcome can be fatal.
- Step 4: create parallel pathways:
  - Remain with current Notified Body *for some time*
  - Prepare for a switch to other Notified Body
- Step 5: optimal route. Switching NB takes time, determine how much and decide when there must be certainty regarding the current Notified Body
- Step 6: Worst case mitigation; prepare for placing extra stock on the market shortly before Brexit (device is physically produced and ownership changed. Supply and payment can follow later)

1. Swiss MRA issue: map alternative outcomes

1. MDR MRA is signed; status of Swiss MFR remains the same
2. MRA is not signed, with an interim agreement of a grace period (officially not yet being discussed)
3. MRA is not signed; status of Swiss MFR changes on May 26th, 2020

2. Map timelines for transition

1. If MRA signed: no need for any change
2. In case of a transitional arrangement: changes are needed, but there is some time for that
3. In case of a hard cut, there is little time to act

3. Analyze risks

- If MRA signed, or with a transitional period, no action needed or there is time to act; preparing now could waste time and money
- If MRA is not signed there will be a hard cut from the Date of Application of the MDR **for all devices**, including legacy – MDD and AIMDD certified – devices. Risks:
  - EU based importer and AR required, and indicated on label, in documents etc.
  - Loss of Swiss NB certification. This may also result in the loss of the grace period for legacy devices!

4. Create parallel pathways

- Route 1: maintain current situation as long as possible
- Route 2: prepare for the situation without the MRA with as little investments as reasonably possible

5. Map the optimal route

1. Certificates: crucial – **change now**, because this may result in keeping the grace period (no guarantees though…)
2. Appointing of AR: consider ‘delayed start’ option and get new versions of Declaration of Conformity, Label etc. through Document Control. This helps in a ‘late’ switch.
3. Search for potential importers, discuss conditions and negotiate agreements with at least one. Ensure a ‘delayed start’ option.
4. For ‘early’ MDR certified devices: appoint AR and importer ad these to MDR DoCs and certificates
5. Understand your bottlenecks (e.g. label change may be more difficult for direct marking)

6. Risk mitigation

- Prioritize your product port folio, you may have to sacrifice devices
- Prioritize your markets, you have to move production capacity and/or stock from one market to another
- Agree with EU importers or distributors that extra stock can be placed on the market
- Note: if a device is supplied to a swiss based distributor prior to the crash out, it has been placed on the EU market. However, once that distributor becomes a non-EU legal person these devices must be placed on the market again.

Any help coming…European Commission maybe…?

- The EU is involved in all sorts of their own issues…


I THINK THEY'VE GOT PROBLEMS BACK THERE IN HELVETIA
WELL, IT'S ABOUT THEIR TURN
GAUL
HELVETIA
?!

Thank you!

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