Safer Europe without Falsified Medicines

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Is Europe ready?

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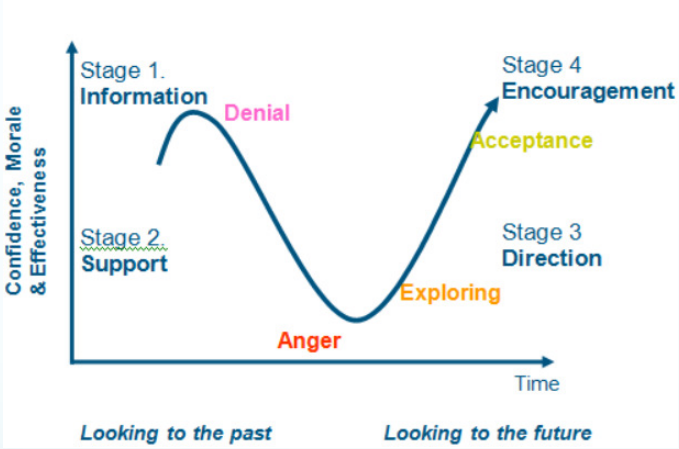
Implementing FMD: a huge challenge - and a fantastic opportunity!

- Implementing the FMD and DR across Europe is extremely complex and a huge challenge as we heard over the last days
  - A complex and heterogeneous supply chain
  - So many stakeholders that need to be on the same page and strive for the same goal
- The stakeholders working together could be a paradigm shift
  - Certainly not easy, sometimes almost hopeless…but
  - We could demonstrate the possibility for other causes - practice makes perfect?

A *very* big investment in a strong defence system – we can not afford any breaches!

- **ALL** parts of the system must be connected and work properly
- All stakeholders must do their part – each bring an essential piece of the big jigsaw
- A breach *will* be exploited and all the efforts and money spent could be for nothing

Key challenges – symbols



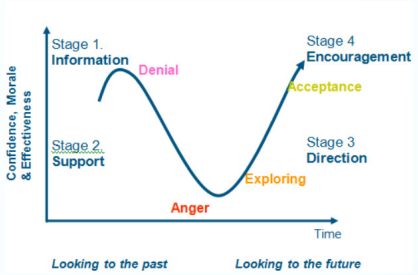
The change curve

The ball

The onion

Priority issues for speeding up implementation and recommended action - 1: *Face facts!*

- Accepting the FMD is a reality and get started on what needs to be done!
  - No point on spending time and energy trying to be exempted!
  - No point in claiming falsified medicines is not a problem!
  - No point in counting on an extended timeline!



➡ COM and NCAs must be very clear in their communication to each stakeholder about their accountability; do the "telling"

➡ All NMVOs need to put a lot of effort into communication –"facilitate" (the role is not "asking, selling or negotiating"!)

Priority issues for speeding up implementation and recommended action – 2: *Focus!*

- There are so many possibilities and ”nice-to-have” distracting from the primary goal
  - for additional functionality or use of the EMVS, e.g. Aggregation, data usage…
  - for extending the scope, e.g. bed-side scanning, patient verification, e-prescription
  - fix other issues or put in additional requirements

➡ Focus on ”the ball” to make the goal 9 Feb 2017. Again, ALL stakeholders must help here

➡ When we have a successful implementation that meets the DR, *then* all the other opportunities can be pursued

Priority issues for speeding up implementation and recommended action – 3: *Complexity*

- The complexity can be underestimated from a single stakeholders point of view
  - Early in the learning curve and starting too late because there are dependencies that are not understood – or respected
- The complexity can be overwhelming and almost paralysing - especially when not harmonised across Europe

➡ EMVO and the NMVOs is working hard to provide guidance and templates, need to manage "information overload" and make it easier to navigate

➡ COM and the NCAs must help to simplify implementation requirements, provide clarity and harmonise across Europe

Conclusion

Europe can be ready –

IF we ALL make a strong commitment and effort!