Efficient communication between Legal Manufacturer, Economic Operators & Notified Body

MDR Support Panel

sitem-insel

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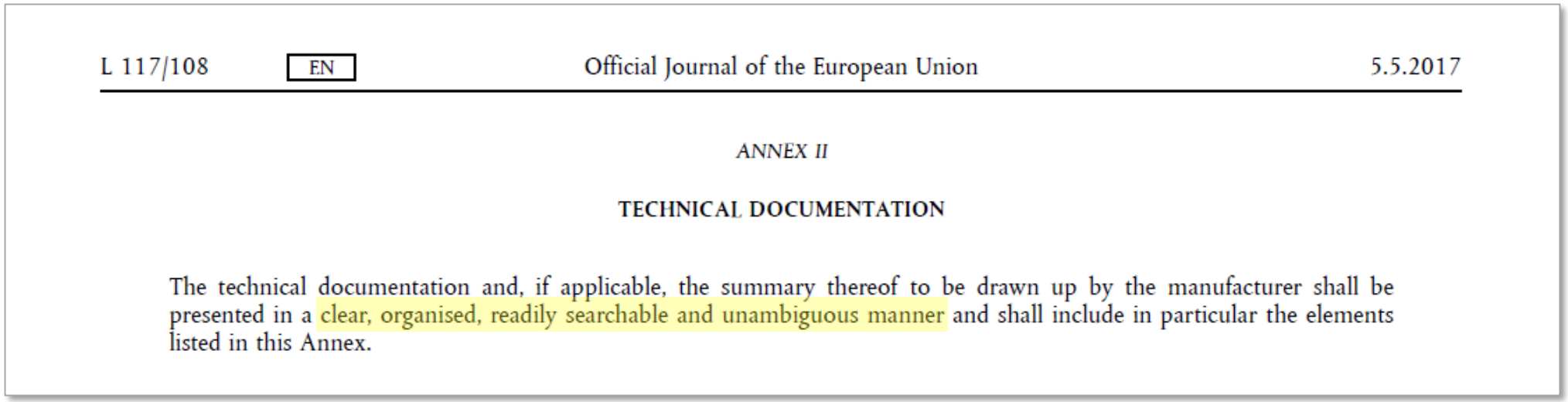
MDR & NBs require a structured & readily searchable Technical Documentation



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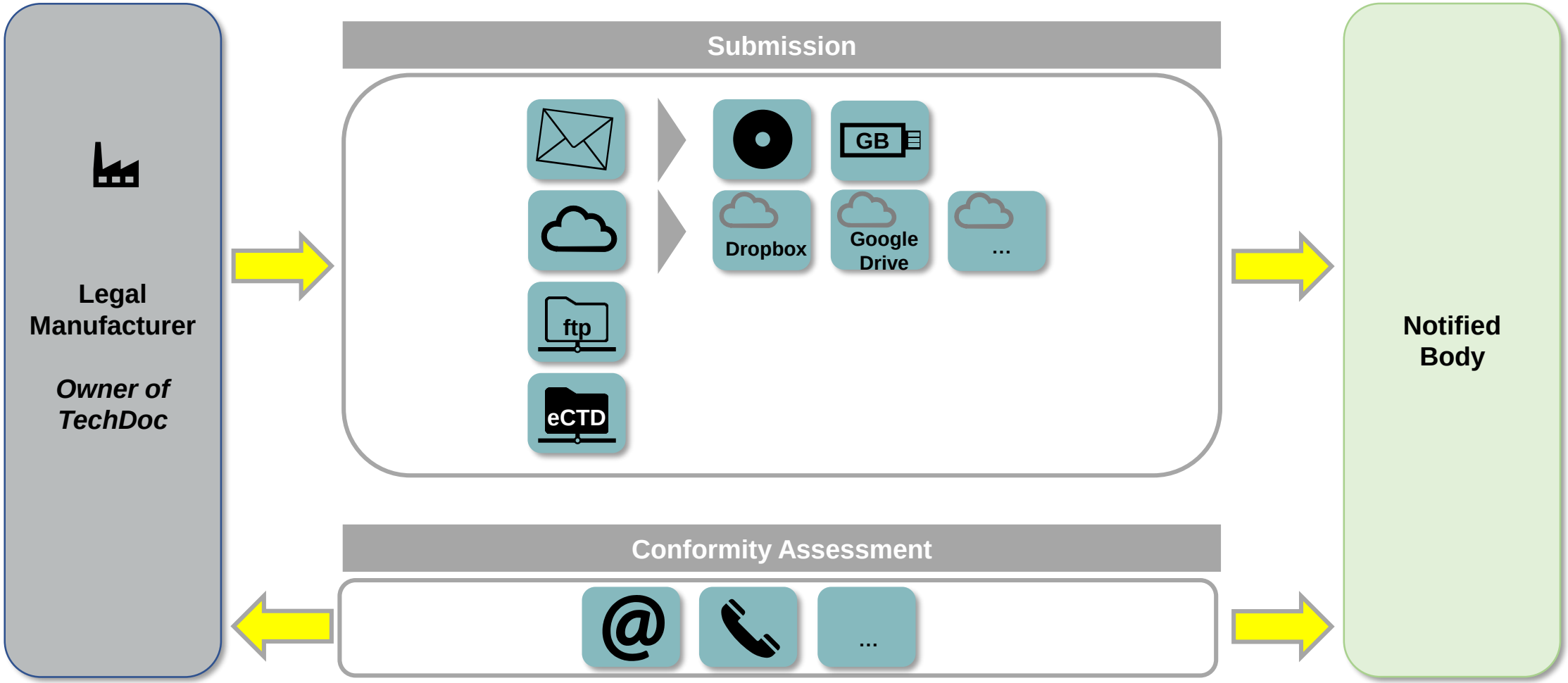
ANNEX II

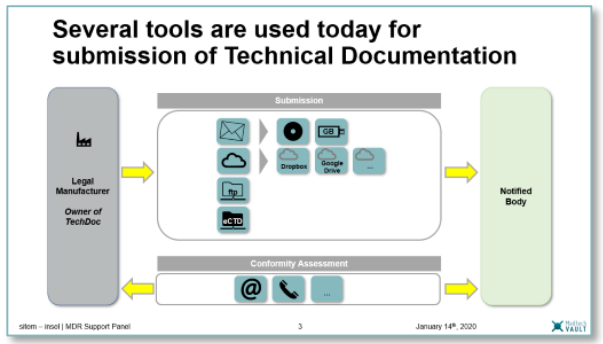
TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

Several tools are used today for submission of Technical Documentation



Are these tools really suitable for your future?



MDR challenges & future requirements of LM

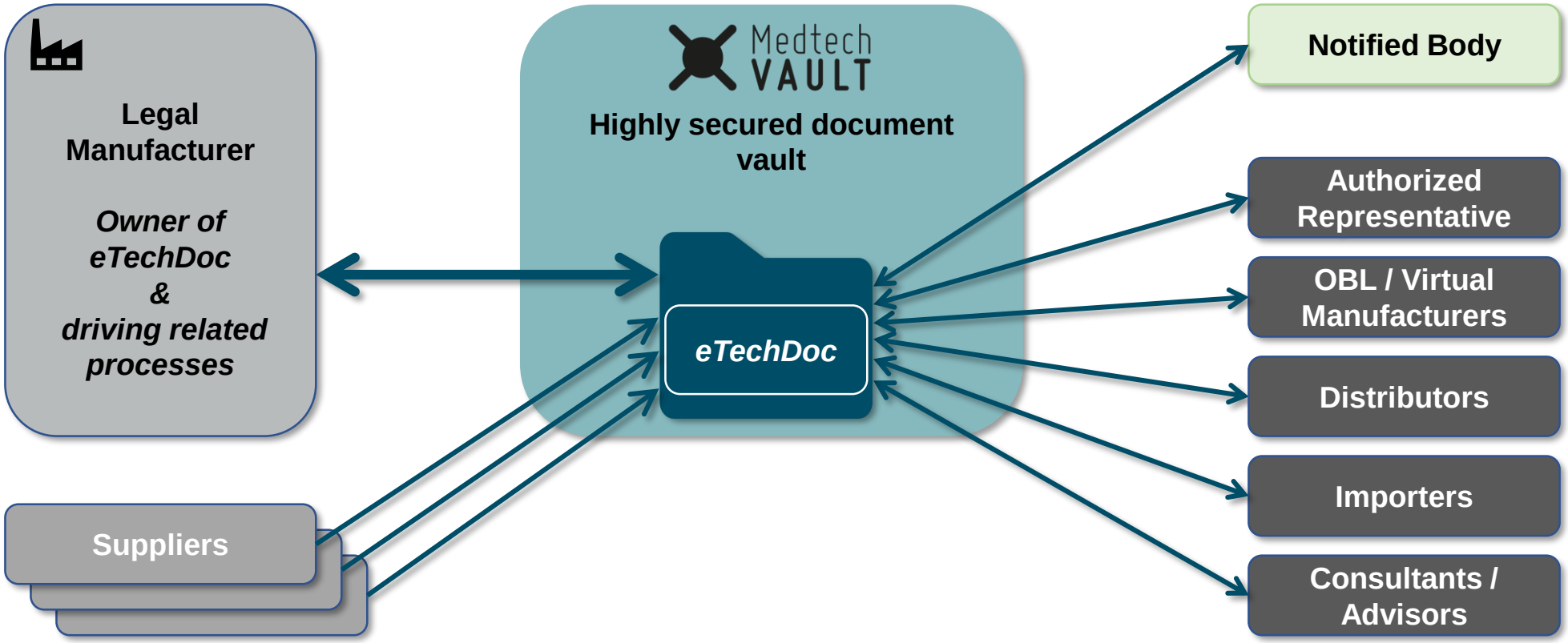
- Future business model
- Confidentiality requirements; in general & of supplier information
- Readily availability of TD upon request by CA / NB
- Trackability during conformity assessment & life cycle management / re-certifications
- Broader use of same TD content for multiple purposes such as other regulatory bodies, distributors, importers, etc.

In fact, the Legal Manufacturer has only 2 options

A. Maintain existing process by employing more regulatory staff
   - if you can get them in the first place
   - costly

B. Use an existing smarter tool that addresses the shortcomings of the current processes / tools, for example MedtechVault

MedtechVault is a solution to efficiently integrate all Economic Operators & the NB



MedtechVault is an add-on to your ERP system & QMS

MedtechVault can support your MDR readiness

Suitable for MDR challenges & future requirements of LM

- ✓ Future business model
- ✓ Confidentiality requirements; in general & of supplier information
- ✓ Readily availability of TD upon request by CA / NB
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- ✓ Broader use of same TD content for multiple purposes such as other regulatory bodies, distributors, importers, etc.

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