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The EGG
BRUSSELS

THE MEDTECH EUROPE CODE AS A BUSINESS ENABLER



A MedTech Europe event

The MedTech Forum

bringing HealthTech stakeholders together

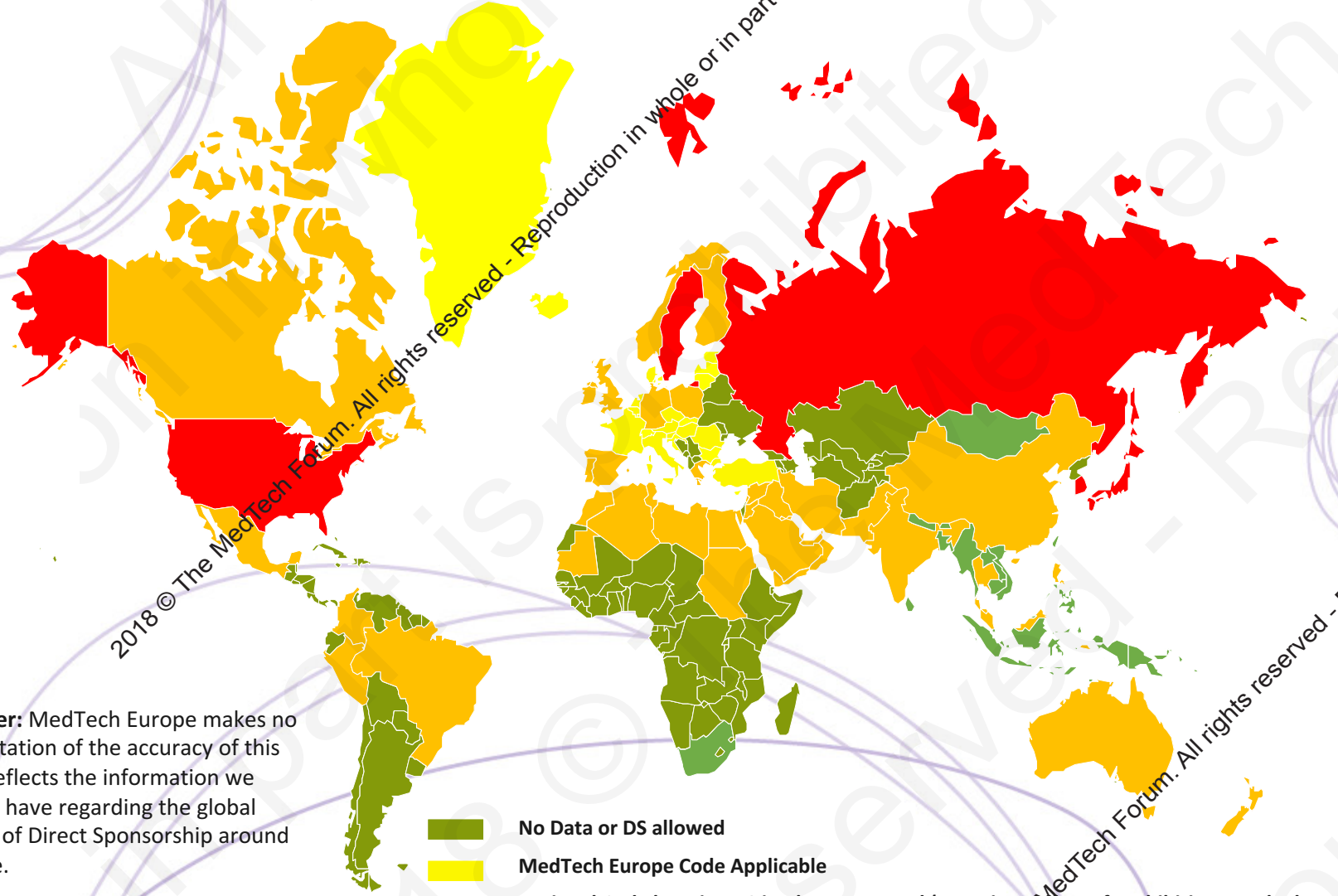
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1. Why an industry code? What is industry trying to achieve?

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2. Focus on HCP education - Prohibition of direct sponsorship



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Disclaimer: MedTech Europe makes no representation of the accuracy of this map. It reflects the information we currently have regarding the global situation of Direct Sponsorship around the globe.

-  No Data or DS allowed
-  MedTech Europe Code Applicable
-  National Code banning DS in place or agreed (entry into effect of prohibition may be later)
-  DS prohibited by law or stakeholder agreement

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3. What does the future hold in terms of compliance and regulation?

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Back-up slides

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Industry's behaviour must respect high ethical standards & values



Reduce compliance/bribery risks – unilateral transfer of value



Uphold value and promote responsible industry image – Key priority



Harmonisation of requirements worldwide



Potential prevention of new laws – stringent self-regulation



Transparency will not end DS challenges by media and judicial authorities

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MTE Code – National associations' transposition status

Country	National Association	Status	Comments
Austria	Austromed	yes	AGM on the 29 March 2017. DS already not allow.
Belgium	BeMedTech	To be determined	Positive board decision to ban DS in 2016. Most likely implementation by 2020, but AGM decision pending.
Bulgaria	BAMDE	To be determined	No information
Czech Republic	CzechMed	To be determined	Discussions have started
	CZEDMA	To be determined	AGM most likely Q4 2017 or Q1 2018
Denmark	Medicoindustrien	Yes	Approval expected in 2018
	Dialab	To be determined	No plans yet
France	Snitem	To be determined	Statement by Board (Nov. 2015) not to transpose the Code
	SIDIV	To be determined	Discussions ongoing. Comms strategy for Q2 2018.
Finland	Sai Lab	To be determined	Board vote in Oct. 2017. AGM 17 Dec. 2017. 1 year transition, if adopted.
Germany	BVMed	yes	Board decision Oct. 2017 - Addendum to Article 8 Continued Medical Education, Section 2, No. 2 b; BVMed Code
	VDGH	To be determined	No plans for formal transposition but proactive promotion of the Code internally and externally.
	Spectari	yes	AGM approved new Code on 28 Sept. 2017
Greece	SIEVA	yes	Transposition of MTE Code approved on the 22 June 2017, enter into force January 2018.
Hungary	AMDM	yes	Revision planned for summer 2018 – recommendation as a best practice
	HIVDA	To be determined	Decision to partly implement the Code, awaiting clarification
Ireland	Irish Medtech Association	yes	Transposition in 2017, Code in full force as of 2018
	IMSTA	yes	Transposition in 2017, Code in full force as of 2018
Italy	Assobiomedica	To be determined	Intense discussions ongoing, internally and externally. Phase out included in the draft Code & full transparency
The Netherlands	NEFEMED	yes	GMH Code likely in July 2018
	FHI	yes	GMH Code likely in July 2018
	DIAGNED	yes	GMH Code likely in July 2018
Norway	MedTek Norge	N/A	Agreement with stakeholders, no transposition needed. Alignment with MTE Code already the case
	LabNorge	N/A	Agreement with stakeholders, no transposition needed. Alignment with MTE Code already the case
Middle East	MECOMED	yes	Phase out of direct sponsorship as of January 2018. Transparency in 2019
Poland	POLMED	yes	Adoption by AGM in 2017; 2018 in force
	IPDDL	yes	Adoption by AGM in 2017; 2018 in force
Portugal	APORMED	yes	AGM vote planned for Q4 2018 or Q1 2019
	APIFARMA	yes	Political discussions ongoing about structure, planned AGM for end 2017
Spain	FENIN	yes	Board approval on 20.12.2016, Transposition as of 2017
Romania	AFPM	No information	Discussions to start end 2016
Russia	IMEDA	yes	Analysis of MTE Code ongoing (translation available). DS not allowed by law
Slovakia	SK-MED	yes	Transposition with small adaptation. Implementation deadline 1 Jan. 2018
	SEDMA	yes	Transposition as of 1.1. 2018
Slovenia	SLO-MED	yes	Working group in place; planning of implementation measures and next steps
	SIEDMA	yes	Plan to do a direct transposition
Sweden	Swedish Medtech	N/A	Agreement with stakeholders, no transposition needed. Alignment with MTE Code already the case
	Swedish Labtech	N/A	Agreement with stakeholders, no transposition needed. Alignment with MTE Code already the case
Switzerland	Swiss MedTech	yes	Vote on the Code in June 2017
Turkey	Arted	To be determined	Request for exemption rejected. New position being developed
UK	ABHI	yes	Transposition already started, new Code in force as of January 2017. Phase out 1.1. 2018
	BIVDA	yes	Board decision in December 2016; Code in full force as of January 2018

v. Jan. 2018