THE NEW MEDTECH POLICY: INDUSTRY VIEW

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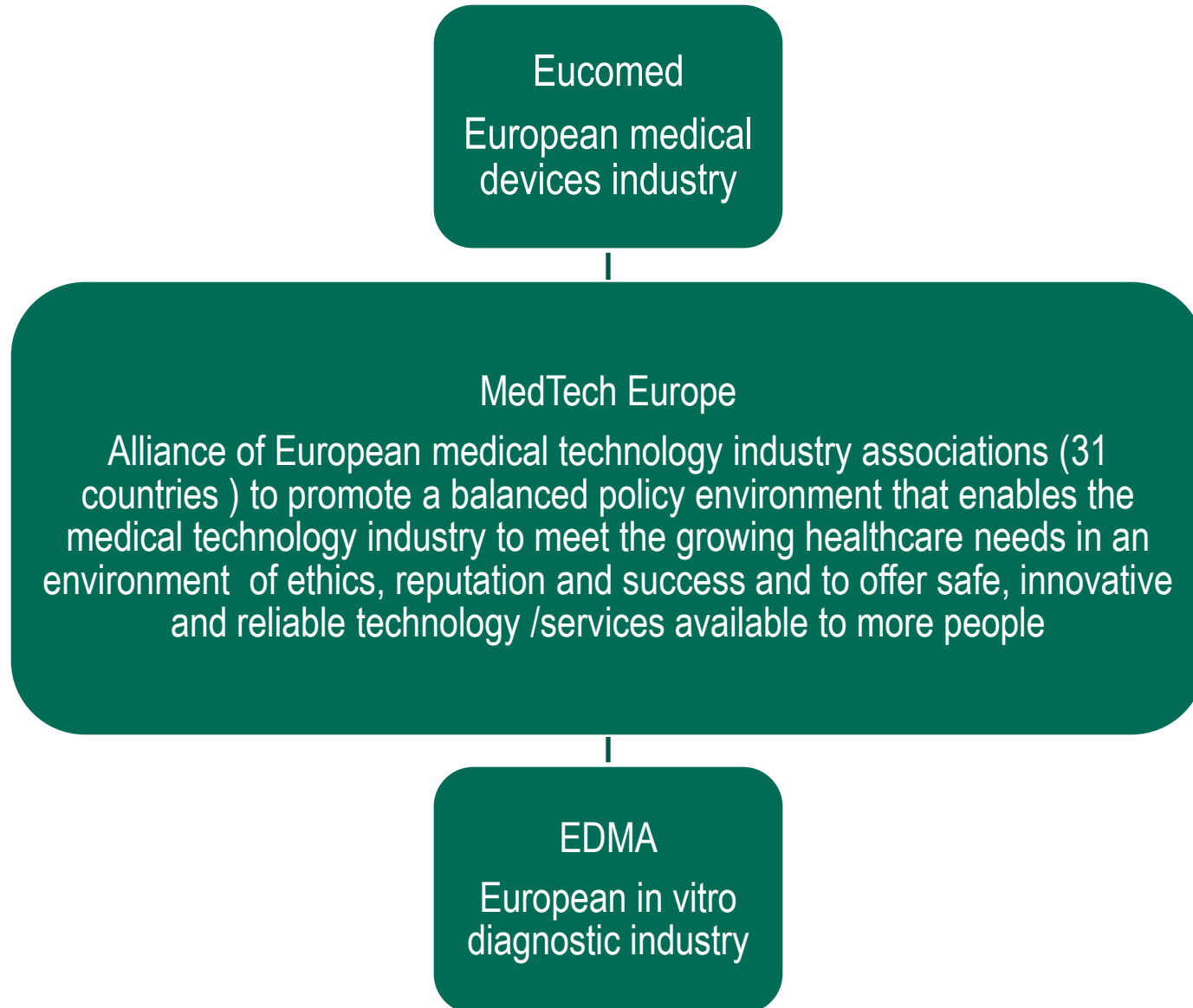
EHRA Summit 2016

European Heart House, Thursday 14 April 2016

AGENDA

- **About MedTech Europe, EDMA and Eucomed**

- **Background on the New Code of Ethical Business Practice**

- **MedTech Code of Ethical Business Practice** :

    - **Scope**

    - **What the new code is saying**

    - **Chinese wall**

    - **When the new code will be enforced**

    - **Conference Vetting System**

- **Operating in 2018 and after**

ABOUT MEDTECH EUROPE

Eucomed

European medical devices industry

MedTech Europe

Alliance of European medical technology industry associations (31 countries) to promote a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs in an environment of ethics, reputation and success and to offer safe, innovative and reliable technology /services available to more people

EDMA

European in vitro diagnostic industry

Adherence to strict ethical rules
is therefore crucial
to protect industry's relationship
with HCPs.

WHY DID THE EUROPEAN MEDICAL TECHNOLOGY INDUSTRY CHOOSE TO PHASE-OUT DIRECT SPONSORSHIP OF HCPS TO THIRD-PARTY ORGANISED EVENTS?

Inviting or directly supporting individual HCPs to attend a third-party organized educational event is perceived as creating a potential commercial bias. This in turn might affect the way the HCP uses or recommends a certain product, given the unilateral nature of the benefit.

As an industry we felt that publicly disclosing such support does not address the inherent conflict of interest of this direct sponsorship practice. This is why we have decided to phase out such support.

DIRECT SPONSORSPHIP VS EDUCATIONAL GRANT

Two types of industry support to Third Party Organised Events

"Direct sponsorship"

Companies select individual HCPs and **financially support their participation** to Third Party Organised Events.

Such financial support typically covers some or all of the travel, lodging and registration costs of the HCP.

"Educational grants"

Companies provide educational grants to **hospitals, medical societies** and other third parties **to support genuine medical education.**

These include educational grants provided to support HCP participation to Third Party Organised Event. **HCPs are selected by the receiver of the grant.**
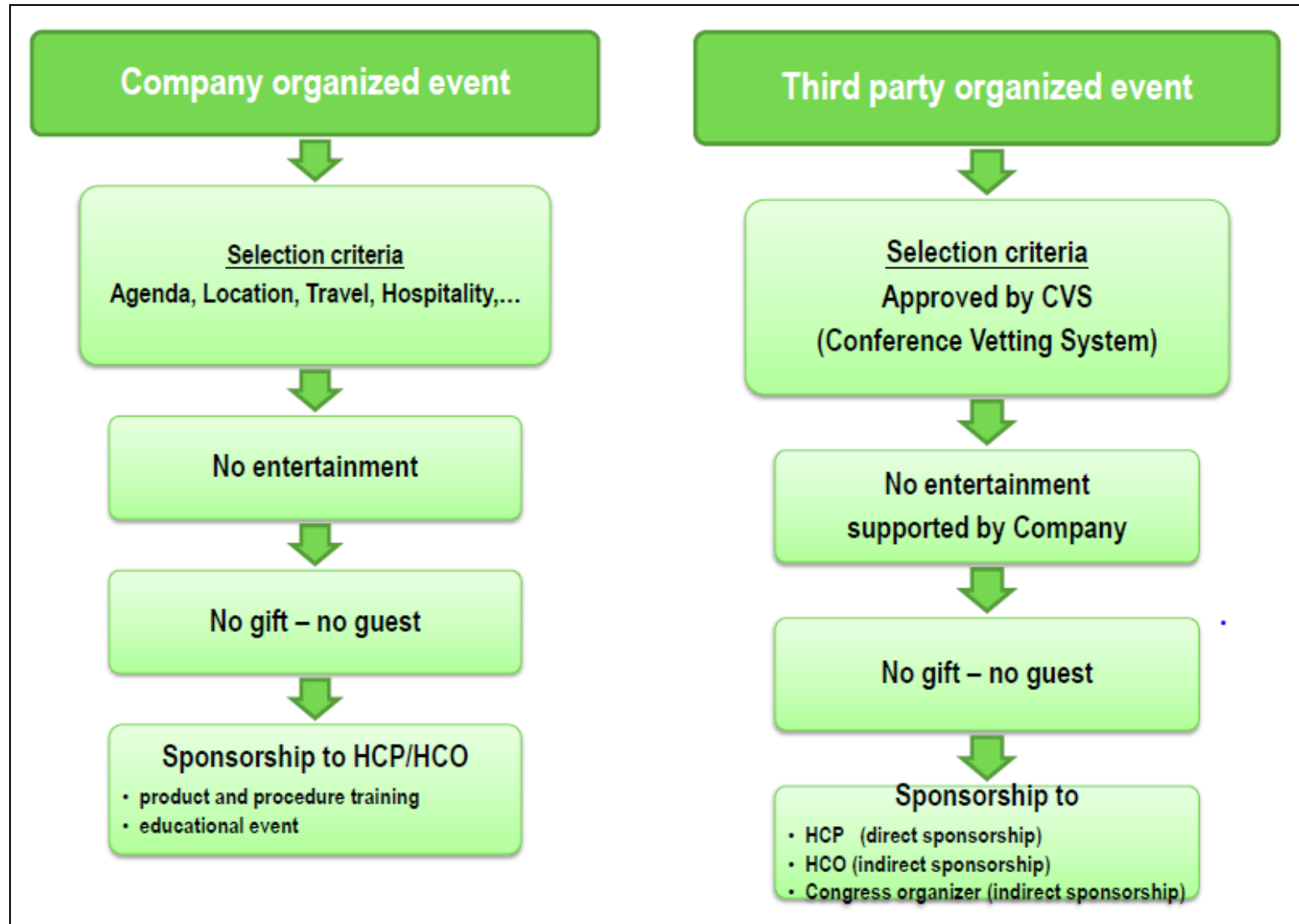
A new Code of Ethical Business Practice have been approved on December 2nd in Brussels, in a continuous effort to set high ethical standards for the medical technology industry across Europe.

SCOPE OF THE NEW CODE
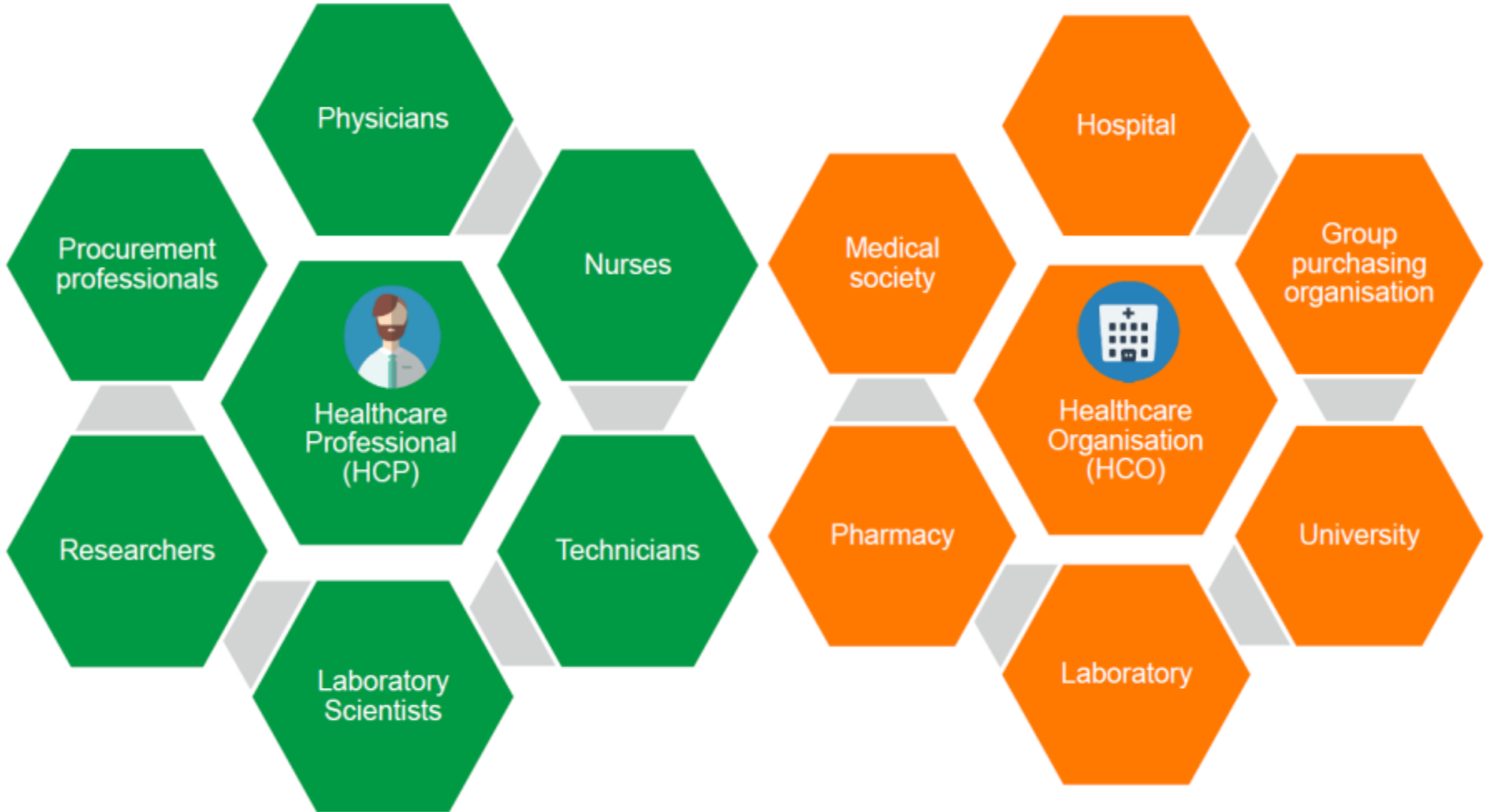
SCOPE OF THE NEW CODE

The new MedTech Europe Code regulates **all aspects** of the industry's relationship with Healthcare Professionals and Healthcare Organisations

Company organized event	Third party organized event
Selection criteria Agenda, Location, Travel, Hospitality,…	**Selection criteria** Approved by CVS (Conference Vetting System)
No entertainment	No entertainment supported by Company
No gift – no guest	No gift – no guest
Sponsorship to HCP/HCO • product and procedure training • educational event	**Sponsorship to** • HCP (direct sponsorship) • HCO (indirect sponsorship) • Congress organizer (indirect sponsorship)

WHAT IS THE NEW CODE ENFORCING?

2018

"Direct sponsorship"

"Educational grants"

Stronger rules

SCOPE OF THE NEW CODE

- Mission to make safe, innovative and reliable technology and related services available to more people

    - Advancement of Medical Technologies: Collaboration and creativity for innovation

    - Safe and Effective Use of Medical Technology: appropriate instruction, education, training, service and technical support

    - Research and Education: serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services

- The 5 Principles

    - Principle of Image and Perception

    - Principle of Separation

    - Principle of Transparency

    - Principle of Documentation

    - Principle of Equivalence

- The Code also introduces a common independent enforcement mechanism.

EDUCATIONAL GRANT

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Companies

STOP
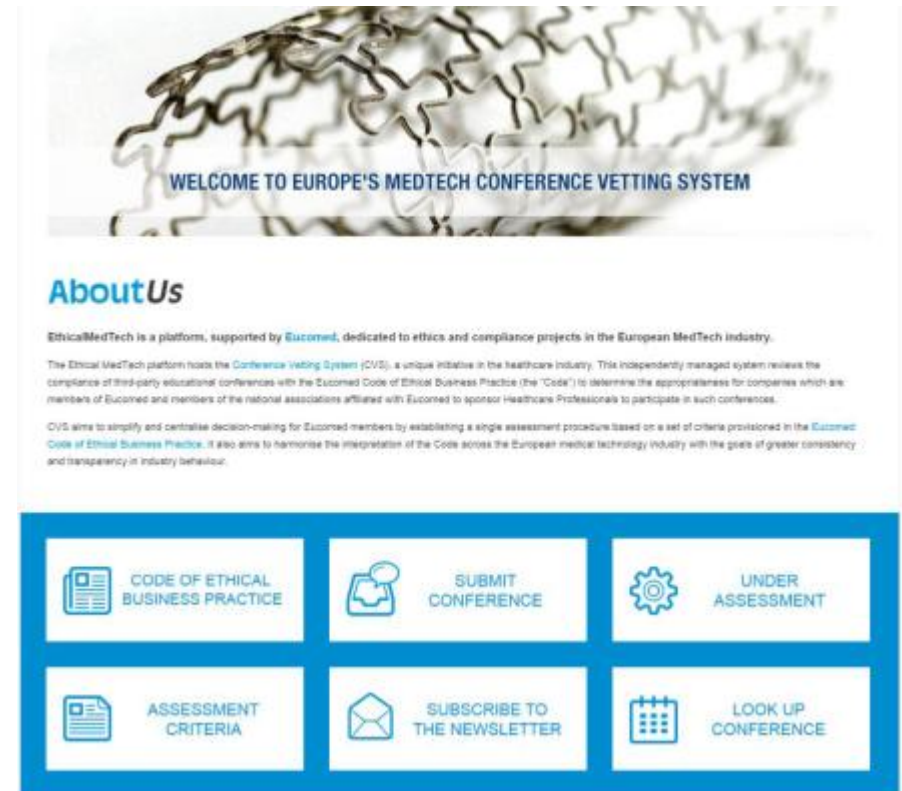
TRANSPARENCY
Independent Medical education

SOME RULES FOR THE GRANTS

- In more details, this is how the rules for educational grants will change:

- Grants will be **publicly disclosed**, ensuring increased transparency of the funds allocated to medical education.

- Conferences receiving support will still need to comply with **specific requirements** and with the Conference Vetting System.

- Grants can only be provided to legal entities but **never individuals** and will require a **written contract** and other related documentation in accordance with the rules of Third Party Organized Educational Events and Grants and Charitable Donations.

- Companies will be able to define the **category of HCPs** (i.e. group of nurses or group of young healthcare professionals) which should be eligible for the grant but **not individual HCPs.**

- Companies must have an internal and independent process based on **objective criteria** to assess the grant requests

CONFERENCE VETTING SYSTEM

- This independently managed system **reviews the compliance of third-party educational conferences with to determine the appropriateness** for companies **to sponsor Healthcare Professionals** to participate in such conferences http://www.ethicalmedtech.eu.

WHEN?

- The MedTech Europe Code of Ethical Business Practice will become binding for all Eucomed and EDMA corporate members by **1st January 2017**. Corporate members will have one more year to implement the phase-out of direct sponsorship of HCPs to third-party organised events, which will be effectively banned by 1 January 2018.

- Given the significance of this change, there will be a transition period with corporate members of Eucomed be required to **phase out direct sponsorship between now and 1st January 2018**

CONCLUSION

- A new **Code of Ethical Business Practice** has been **approved** on December 2nd

- The new code is a clear message from the medical technology industry that we want to safeguard and protect our relationship with healthcare professionals by adopting a clear and strict self-regulation. It will be a priority for us to work on the practical details of these changes with medical societies and healthcare professionals to ensure they are properly implemented.

- Advisory Group on the Future of Medical Education

- This will be enforced as of January 1st 2018

I WAS ASKED TO….
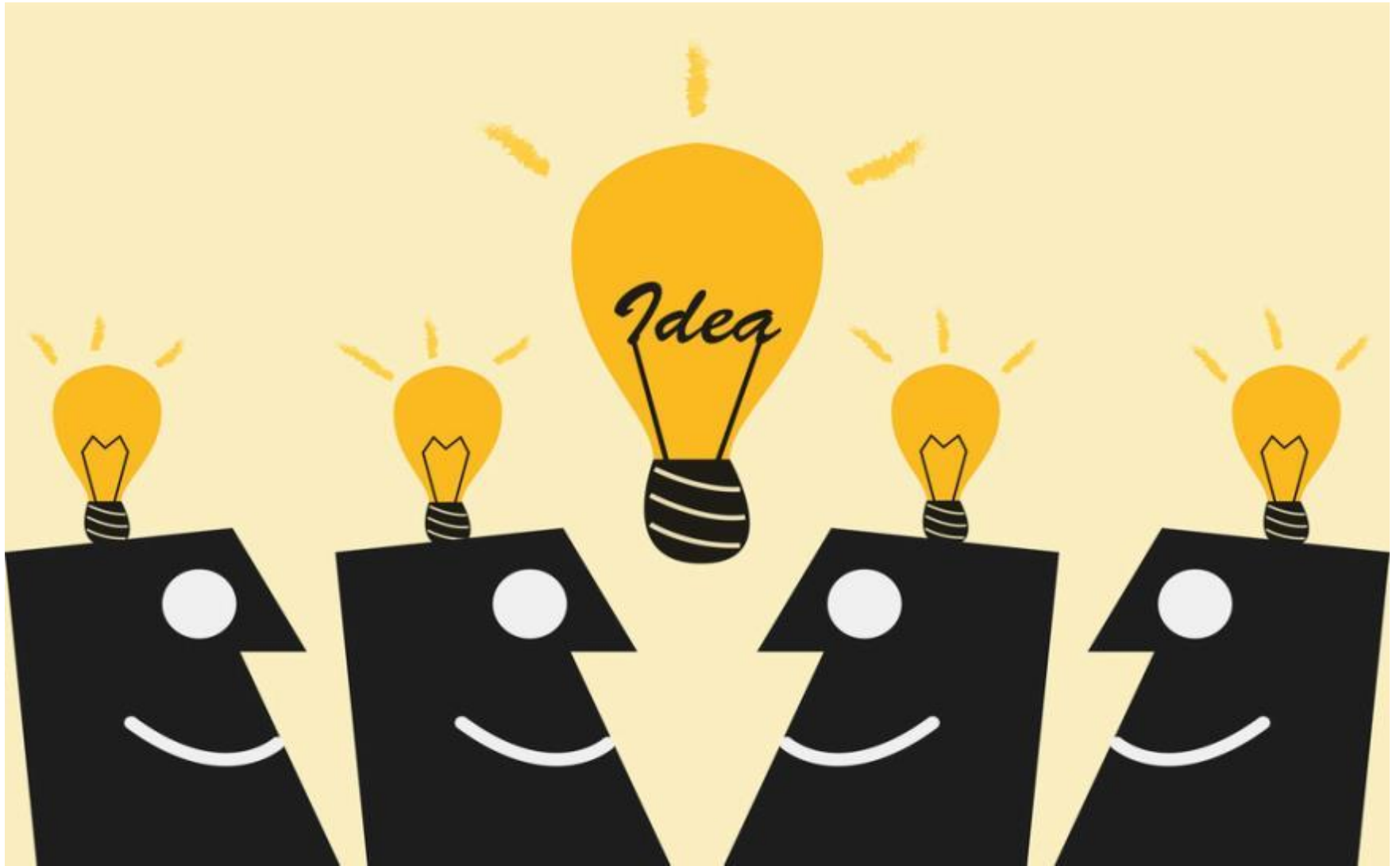
OPERATING IN 2018 AND AFTER…– INDUSTRY VIEW

- The industry is committed to continue supporting independent and genuine medical education

- No real decision taken and or communicated by industry:

    - Common path or individual?

    - Which approach/reaction to unrestricted grant?

    - Which balance between congresses and education?

    - Which congresses to support?

        - Third party organized Educational Conferences:

            - Grants

            - Exhibition

            - Satellite Symposia

        - Third party organized Procedure Training meetings

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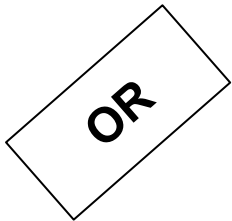
OPERATING IN 2018 AND AFTER…

- **<u>Third party organized Procedure Training meetings</u>**:
- From traditional congress to more educational congress (Curriculum concept)

  - More training villages = path of training villages

  - Session on the booth?

  - Invitation/day >> education through Live cases or VR

  - Segmentation

- EHRA current educational offering proposed and reinforced during congress

- Alumni events: i.e. PCHF

Just some personal ideas to start tomorrow's workshop

TOGETHER WE WILL SHAPE OUR EDUCATION

WHAT IS NOT IMPACTED?

Company organized event

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Selection criteria
Agenda, Location, Travel, Hospitality,…

↓

No entertainment

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No gift – no guest

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Sponsorship to HCP/HCO
- product and procedure training
- educational event