

Gabor Danielfy Memorial Keynote Address

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Pharma on trial?



Trust – it starts here...



Trust is vital for successful collaboration



COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS



efpia

European Federation of Pharmaceutical
Industries and Associations



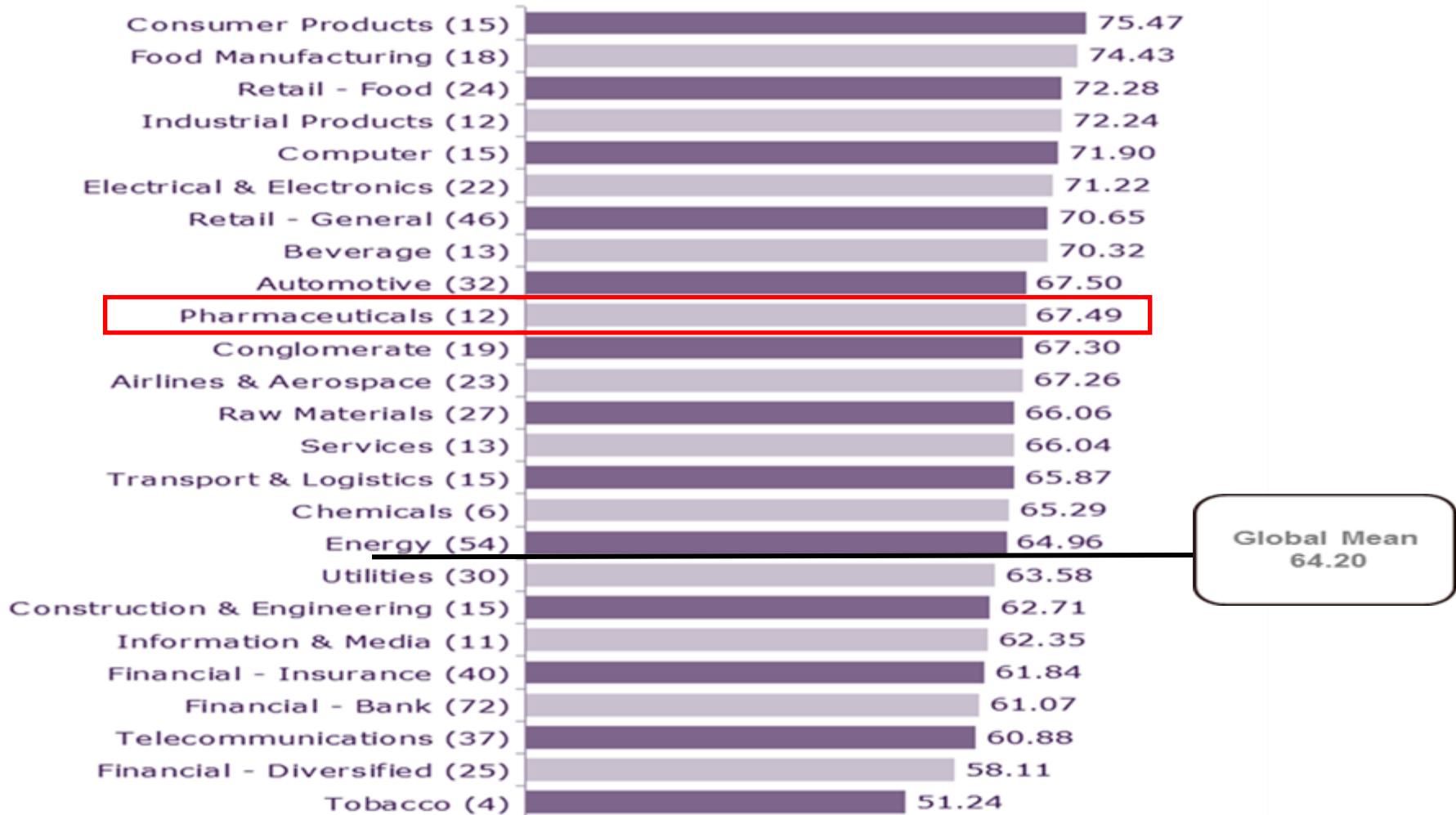
“Improving the sustainability of healthcare systems through better adherence to therapies: a multi-stakeholder approach”

Background briefing

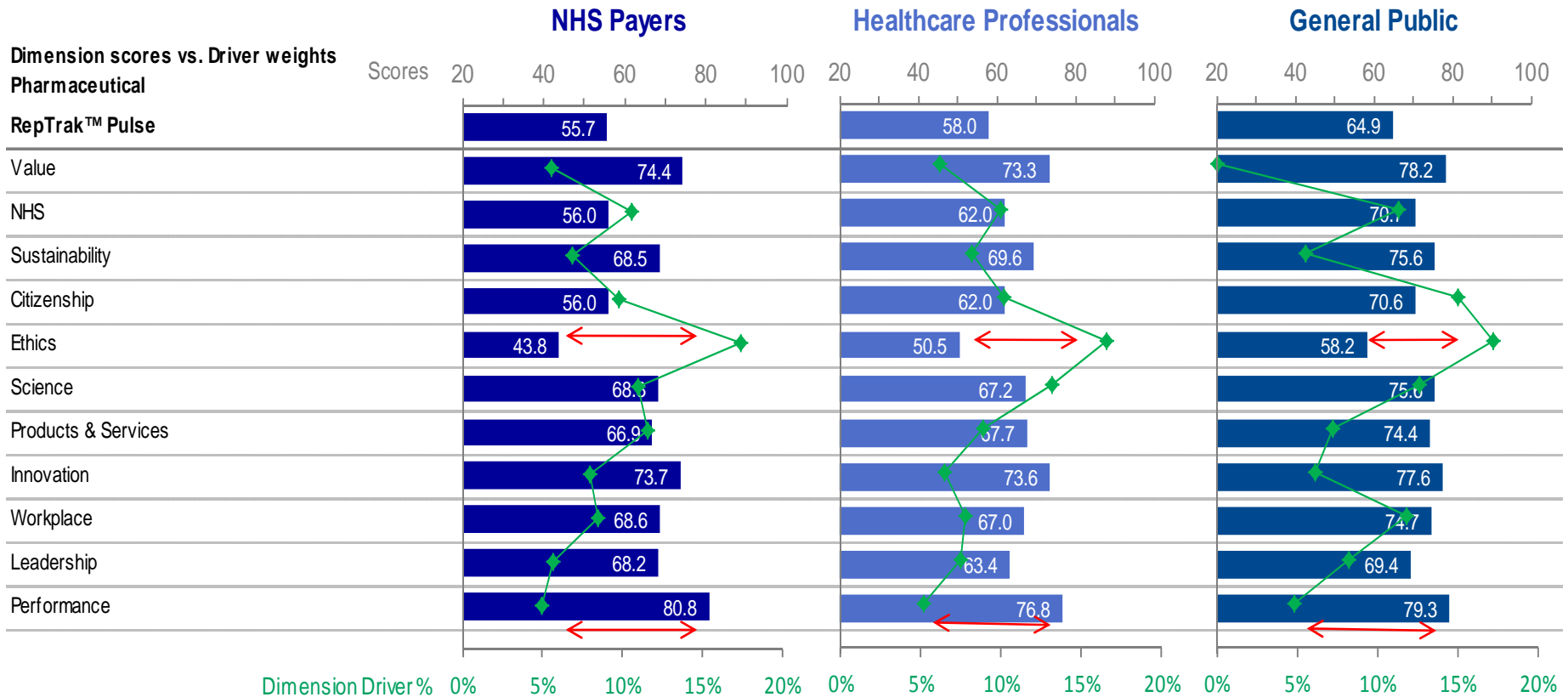
Introduction: why does adherence matter?

“Drugs don't work in patients who don't take them”¹ – as the former U.S. surgeon general C. Everett Koop said. However, policy makers, health managers and healthcare professionals...

Where are we now.....



Dimension Scores – Performance vs. expectation



- Industry performance on different drivers of reputation
- Health stakeholders' expectations of industry's performance
- Show where there is misalignment between industry performance and health stakeholders' expectations of industry

So, what can be done?



Clinical trial transparency



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- UPDATED: J&J in 'game-changing' data disclosure plan
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- Europe to vote on greater trial transparency
- Court annuls EMA data decision

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J&J reveals more on transparency policy
Published on 03/02/14 at 01:24pm



Johnson & Johnson's pharma subsidiary Janssen has given Pharmafile more details on its new transparency policy, which will see both historical and future data made available to third parties.

J&J sets new pace for sharing trial data

Chooses Yale to act as independent clinical data request review body

Johnson & Johnson (J&J) has enlisted Yale University to review requests from researchers to access clinical data held by its pharma business Janssen.

It is the first time a pharma company has taken the step to introduce a third party independent reviewer as pressure grows on the industry to improve transparency of drug data following concerns that some drugs, such as Roche's Tamiflu, were not as effective as their manufacturers claimed.

Yale, through its Yale School of Medicine's Open Data Access (YODA), will act as an independent body to review and make final decisions regarding all requests for Janssen's clinical trial data for its treatments, including clinical study reports (CSRs) and de-identified patient-level data.

J&J has also set up a new website (www.clinicaltrialstudytransparency.com) to enable researchers to make online requests for data access.

Richard Lehman – an adviser to the YODA project – said the move was a “game-changer” for pharma.

“This is a new standard for responsible and independent data sharing”

He said: “The project will be wide open and will provide help to companies who want to follow in J&J's footsteps. It will leave organisations who are still discussing whether data sharing is even a good thing looking very out of date.”

Other companies making headway in improving transparency include GSK, which along with joining the AllTrials campaign, has set up an online system to provide researchers with access to anonymous patient-level data about its medicines.

J&J is the first company to make a commitment of this kind, however, with CMO Dr Joanne Waldstreicher explaining the company's decision represented a “new standard for responsible, independent clinical data sharing”.

As for how the collaboration with Yale will work in practice, J&J said that YODA members may reach out to Janssen researchers with questions during its review of a request, but the final decision on data sharing will be made by YODA.

J&J's plans don't just stop with pharma products and the company intends to introduce a data sharing process for its medical device and consumer products.

Disclosure of transfer of value



Responsible Transparency

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The pharmaceutical industry recognises that it has a responsibility to show leadership in advancing responsible transparency. The industry supports measures that will enhance relationships between industry, healthcare practitioners, patients and citizens at large and advance public health.

The EFPIA Code

The Disclosure Code has been approved by the General Assembly on 24 June 2013. The final edited versions of the Code has been submitted to Compliance Committee comments, and has been reviewed by legal counsel.

[read more](#)

EFPIA HCP/HCO DISCLOSURE CODE

EFPIA CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

Adopted by the EFPIA Statutory General Assembly of 24 June 2013, and requiring implementation in national codes by 31 December 2013.

FINAL EDITED VERSION
Following General Assembly Approval

Updates

- 31 OCT 2013
Signing OTT: EFPIA Member Companies Submit Letters Agreeing to Advance Transparent Relationships with the Medical Profession
- 22 OCT 2013
Transparency and Industry Interactions with the Medical Profession - Commitment Letters published
- 05 SEP 2013
EFPIA Response to EMA Consultation on the Publication and Access to Clinical-Trial Data
After finalising its comments on the EMA Consultation on the Publication and Access ... [Read more](#)

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Congresses and Medical education



Shared principles for interaction with HCPs

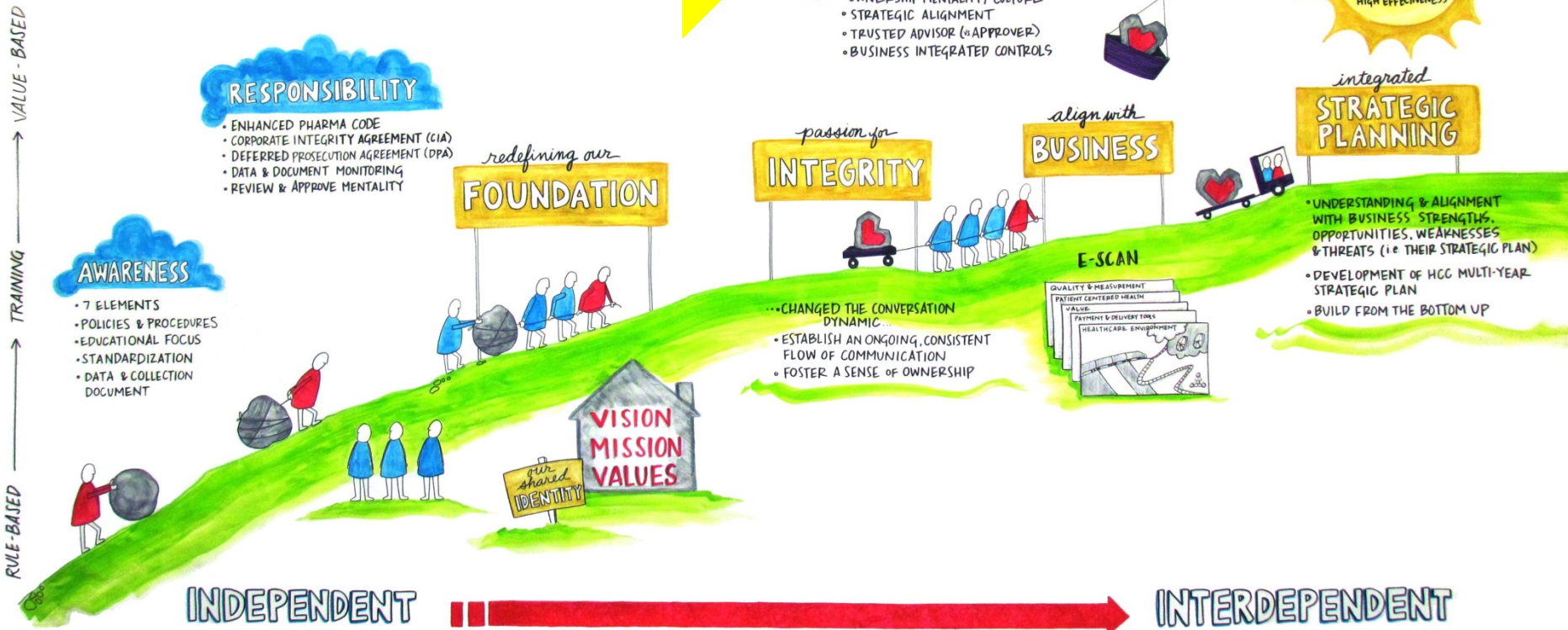


- Lawful promotion of regulated products
- Compliance with health care and anti-corruption laws, regulations and industry codes
- Medical and governmental decisions that are free from improper industry influence

Ultimate goal: improve the quality of patient care



The Compliance Journey



We must communicate better...



Industry ambassadors...



One issue is an issue too many, but...



Trust – it ends here...





Thank You



PHARMACEUTICAL COMPANIES
OF *Johnson & Johnson*