

Digital Communications & Outreach Challenges

BELA Inclusive Healthcare Industry Roundtable

Michael R. Clarke, JD, CCEP

Deputy GC & Global CCO, ConvaTec



Discussion Areas

- Background
- Rules for digital communications and marketing
- Impact of “pandemic marketing”
- Utilizing patient advocates or ambassadors
- Sales and marketing use of ephemeral apps for expanded marketing communications
- Incorporation of social media influencers, social media use and compliance monitoring;

ConvaTec Group Plc

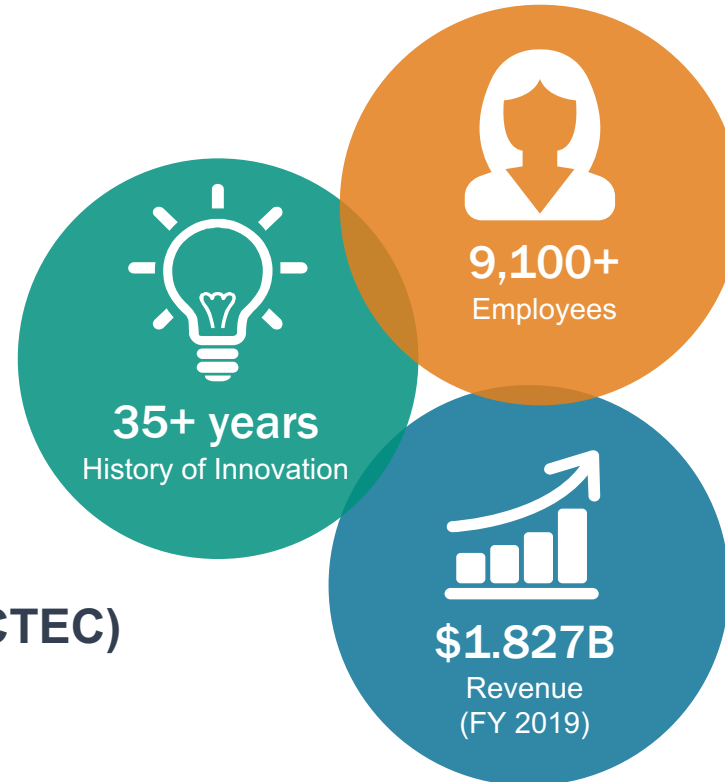
A global medical products and technologies company, focused on therapies for the management of chronic conditions

With leading positions in:

- Advanced Wound Care
- Ostomy Care
- Continence & Critical Care
- Infusion Care

Listed on the London Stock Exchange (LSE:CTEC)

Subsidiaries include: Unomedical, Amcare, Home Services Group, EuroTec





Our Vision

**Pioneering trusted medical
solutions to improve the
lives we touch**

Global Presence



- Key**
- Americas
 - Europe, Middle East and Africa (EMEA)
 - Asia Pacific
 - Manufacturing and R&D Centres
 - ◆ Corporate and Regional Offices

Caveat:

Desired Solutions & Best Practices



The New Way

- Remote working environments have made compliance functions reconsider operating practices and compliance guidelines and regulatory requirements
- Regulations are starting to consider the newer mode of doing business, and companies are reevaluation of existing policies, procedures, and business practices to reconcile them with changed ways of operating
- Life sciences companies are reviewing their compliance activities as an integral part of their overall business strategy; focusing on numerous areas, including:
 - Virtual interactions with health care professionals: new ways to educate and update
 - Digital transformation: using technology to enhance compliance monitoring

HCP Interactions – Speaker Programs

- November 2020: Office of Inspector General (OIG) of the Department of Health and Human Services issued a Special Fraud Alert related to speaker programs;
 - Alert highlighted OIG's skepticism on educational value of speaker programs
- Included compliance considerations for designing & executing programs

HCP Interactions – Speaker Programs (continued)

- The OIG alert identifies characteristics potentially indicating inappropriate intent and possible violations of the Anti-Kickback Statute:
 - Company-sponsored speaker programs where little or no substantive information is actually presented
 - Alcohol is available, or a meal exceeding modest value is provided to program attendees
 - The program is held at a restaurant or other location not conducive to the exchange of educational information
 - HCPs attend programs on the same or substantially the same topics more than once
 - HCP speakers or attendees are selected based on past or expected revenue that the speakers or attendees may generate by prescribing or ordering the company's products
- OIG recommendation: continue virtual sessions and avoid events with the above risks

Global digital DTC marketing concerns

- Regulatory requirements for life sciences marketing approvals in the different countries where we maintain a presence
 - U.S. Food & Drug Administration (FDA)
 - China's National Medical Product Administration (NMPA)
 - UK's Medicines and Healthcare products Regulatory Agency (MHRA)
- Similar trade association regulations limit marketing outside of approved indications for use of therapeutic products
 - AdvaMed
 - MedTech Canada
 - MedTech Europe, f/k/a Eucomed

Global digital DTC marketing concerns (cont.)

- Restrictions or guidance may extend to the audiences to whom we are permitted to communicate and in a particular manner
 - HCPs, rather than direct to patients
 - Marketing information rather than direct selling in APAC
- N. Asia issue: use of patient ambassadors
 - Users of therapeutic products interacting with hospital or clinic patients
 - Concern about direct selling via use of
 - QR codes;
 - Ephemeral apps; other tools

Poll Question #1

Do you allow your employees to use internet apps, such as WhatsApp or WeChat for business communications?

- Yes
- No
- Considering it
- Only for certain employees

Poll Question #2

Have you created an internal, company-based app for use by customer-facing employees?

- Yes
- No
- Not yet, but planning to

Internet communications & patient advocates

- Thoughts on incorporating QR codes to access product sales sites
 - Triggering global concerns about direct selling from industry to patients
 - Local or regional law analysis prohibiting direct to patient selling
- Ephemeral apps for expanded marketing communications
 - WeChat to communicate about therapeutic informational programs
 - Concern about expansion beyond original audience

Poll Question #3:

How do you manage your company's social media presence?

- Only static posts, no comments or feedback
- Posts with active engagement of responses
- Trying to figure it out

Social media use & monitoring

- Management of sites
 - Active management; two-way communication
 - Maintain static presence, with no comments or other engagement
 - Concern: adverse event postings
 - Reporting requirements
- Use of contracted or non-contracted influencers
 - To appear on corporate website, using product
 - To appear on social media, discussing product

Questions and Comments

