Association of British Healthcare Industries

# Medical Device Regulation - what industry wants

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I. The medical technology sector

II. The current regulatory system

III. The Commission proposal

IV. The political process

# ABHI

## STRATEGY

Advocating policies that allow members to operate in a favorable business environment

### UK MARKET

**Policies** that support the rapid evaluation, reimbursement and adoption of medical technologies by UK healthcare systems

### INTERNATIONAL MARKETS

**Policies** to provide an effective gateway to foreign markets

### REGULATION & STANDARDS

**Policies** for simple and smart regulation, providing patients with safe, effective, high quality and innovative medical technologies

### ETHICS & PRINCIPLES

**Policies** to ensure business is conducted in the right manner

# ABHI's role in Regulation

ABHI founded 1989 to address EU Medical Device Legislation

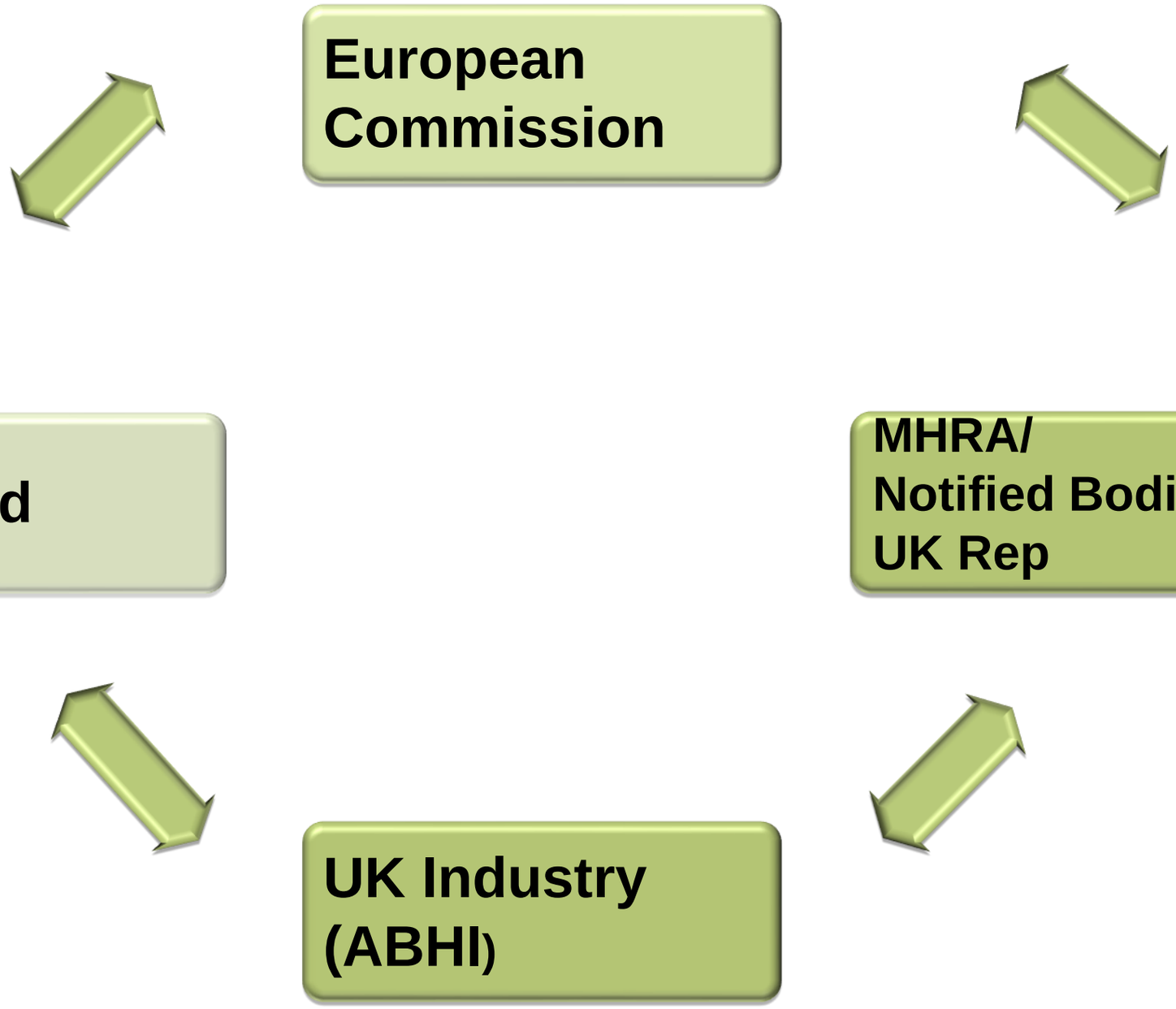
European dimension to ABHI activity in this area

Today we:

- Monitor developments in the regulatory system
- **Influence the regulators** in the UK and at European level

  (with Eucomed)
- Provide a limited advisory role to members

# The Virtuous Circle



# I. The Medical Technology Sector

'It's bigger than you may think'

# Medical Technology in Europe

Eucomed
Medical Technology

The industry employs close to **500,000** people

**22,500** medical technology companies in Europe

**80%** of medical technology companies are **SMEs** employing less than 250 people

First in filing patent applications in Europe: one patent application filed every **38 minutes**

Sales in 2009: **€95 billion**

**>30%** of the global sales of medical technology

The European industry is growing at **>5%** per annum

**Fast innovation**

an average a product will be superseded by an improved version within **18-24 months** of introduction

**500,000** medical technologies currently available to healthcare professionals

**Global sales** of medical technology **>** the GDP of Sweden or Switzerland

Spending on medical technology accounts for only **4.2%** of total healthcare expenditure

www.eucomed.org

Eucomed 2011

Eucomed
Medical Technology

# Our Vision on Regulation

Industry wants a clear predictable  and effective regulatory system specifically tailored for medical devices that:

•Guarantees the highest level of safety for patients

•Ensures timely access to the latest innovative technologies

•Enjoys the trust of its stakeholders

•Contributes to the sustainability of national healthcare systems

•Results in a dynamic environment, which encourages and keeps research & development and innovation in Europe

# II. The Current Regulatory System

# Weaknesses of the current system

- **Fragmentation:** divergent interpretations and applications of rules across EEA
- **Regulatory gaps** for certain products: Scope, reprocessing
- **Lack of transparency**
- **Shortcomings in implementation**
  - Market surveillance / post-market controls
  - Vigilance
  - Functioning of Notified Bodies
- **Damaged confidence** in safety the system: PIP and MoM

# The consultation 2008-2011

- 2008 - initial Recast Paper
- 2009 – changes in the Commission
- 2010 – the Exploratory Process
- 2011 – Commission Communication
- PIP and HIP
- 2012-  the MDR Proposal

# Immediate Measures following PIP

- Intended to bring forward key measures before implementation date
- Mainly concerns NBs including a Regulation due end 2012
- Also, Recommendation on unannounced inspections
- And there will be more

# III. The Commission Proposal

# The Commission Proposal

**We ask three questions of each proposed measure:**

•Does it increase Patient Safety (avoid PIP)?

•Does it maintain or improve the current access patients and doctors have to life-saving technologies?

•Does it encourage innovation (sustainable healthcare systems) ?

# Improvements in Notified Bodies (NBs)

**Current system**

- Control and oversight largely on voluntary and national approaches
- lack of transparency, trust and legal certainty

**EC proposal**

- More rigorous designation, audit and control by Member States and Commission
- Member States fees for designation and monitoring of NBs
- NB enhanced compliance powers – right and duty to carry out: periodic NB audits, unannounced inspections, physical or laboratory testing on MDs, certificate suspensions, withdrawals or restrictions

# Vigilance

**Current system**

- Lack of coordinated exchange of information on reported incidents
- Considerable variations re responses to incidents
- Duplication of efforts & increased inequalities re health protection

**EC proposal**

- Better coordination between national surveillance authorities
- Centralized reporting
- Empowerment of healthcare professionals and patients to report serious incidents at Member State level

Creation of EU database for centralisation of notifications

# Transparency and Traceability/UDI

**Current system**

- Confidentially requirements seen as too restrictive, lack of transparency
- Decreased level of public trust in the system and CE-marking

**EC proposal**

- Extended database on MDs providing more information available on the quality and safety of devices on the market
- Introduction of UDI system to enhance post-market safety, reduce medical errors, fight against counterfeiting, enhance purchasing and stock management by hospitals
- Implant cards

# UDI – A (rapidly) Emerging Issue

- UDI is cross-discipline – Patient Safety / Supply Chain
- New legislation proposed in 2012
  -FDA and EU (in MDD Revision)
- ‘All devices’ to carry a machine-readable identifier
- Main purpose:  patient safety (traceability)
- But will be used for ‘commercial’ purposes
- ABHI can influence development through Eucomed & GHTF
- Programme will accelerate after PIP
- BUT key concerns are:
  - **Proliferation of systems**
  - **‘reciprocity’ – will healthcare authorities and providers be equipped to interact with industry?**

# Reinforced clinical evidence

**Current system**

- Already legal requirements under current EU law; last improvement in 2007 (Directive 2007/42/EC)

**EC proposal**

- Clearer requirements for clinical evidence
- General rule that class III and implantables should be evaluated on the basis of clinical investigation data
- New system of centralization of notifications and reporting system for severe adverse event
- Increased protection of subjects undergoing clinical investigations
- Extended post-marketing clinical follow-up

# Governance

| | |
|---|---|
| Current system | - Good but suffers from fragmented implementation |
| EC proposal | - Improved cooperation and coordination between Member States<br>- New Medical Device Coordination Group of MSs<br>- EC coordinating role to assist MSs manage the system<br>- Increased resources at EU level (DG SANCO, JRC) |

# New legal instrument & scope

**Current system**

- 3 Directives, fragmented implementation
- Issues related e.g. borderline products or devices for aesthetic purposes

**EC proposal**

- 2 Regulations, delegated and implementing acts
- Wider and clearer scope, e.g. to include implants for aesthetic purposes, devices containing or being made of non-viable human tissues
- Relabeling and repackaging by parallel importers
- Distance sales: diagnostics/therapeutics and associated services
- Clarification re medical software

# Reprocessing of Single Use Devices

| | | |
|---|---|---|
| Current system | - | It is not explicitly covered by the current legislation; some labeling requirements |
| EC proposal | - | SCENIHR recommendation followed: reprocessors assigned the same duties as manufacturers; some products will be allowed reprocessing only after appropriate evaluation from EC and MSs; MSs left free to prohibit reprocessing on their territories |

# Standards & Guidelines

**Current system**

- Inefficiencies in development and severe disparities in implementation of guidelines

**EC proposal**

- Better management of development and harmonized implementation of EU guidance now formal responsibility of the new Medical Device Coordination Group
- Possibility of ‘Common Technical Specifications’ where no standards exist

Need for full stakeholder involvement via a formal advisory committee

# Economic Operators

**Current system**

- Not all economic operators included
- Not aligned to New Legislative Framework

**EC proposal**

- Clearer roles and responsibilities for manufacturers, authorized representatives, importers and distributors
- Inclusion of diagnostic services and internet sales
- ‘Qualified Person’ concept introduced to strengthen product safety

Problems may arise when considered across all organisational models and supply chain structures

# Fees

**Current system** - Industry pays government differently in each Member State in a variety of ways

**EC proposal** - Now explicitly expressed – national approaches

Appropriate and sustainable funding model that demonstrates benefits for both the regulator and the regulated

# Stakeholder Involvement

**Current system**

- Medical Devices Experts Group (MDEG) open to representatives from valid stakeholders (industry, patients, physician groups)

**EC proposal**

- No explicit reference to a stakeholder advisory committee

MDEG should be kept and given explicit reference in the legislation

# Classification

**Current system**

- Risk-based classification: Class I (lower), Class IIa, Class IIb, Class III (Higher)

**EC proposal**

- Merger of AIMD and MDD texts; devices covered by AIMD become de facto Class III
- New rules (Class III): certain devices incorporating nanomaterial, devices for aphaeresis, devices ingested, inhaled or administered rectally or vaginally ….

Already safe products should not be unnecessarily burdened with increased bureaucracy and costs

# Early Scientific Advice

**Current system**

- Lacks early independent scientific advice on medical technology to Member States, European Commission and innovators

**EC proposal**

- Mention of Joint Research Centre and Member State Experts
- But no ability to offer early scientific advice

Greater access at EU level to sound independent scientific advice would greatly benefit MedTech SMEs

# Major Concern: Scrutiny of certain conformity assessments

**Current system**

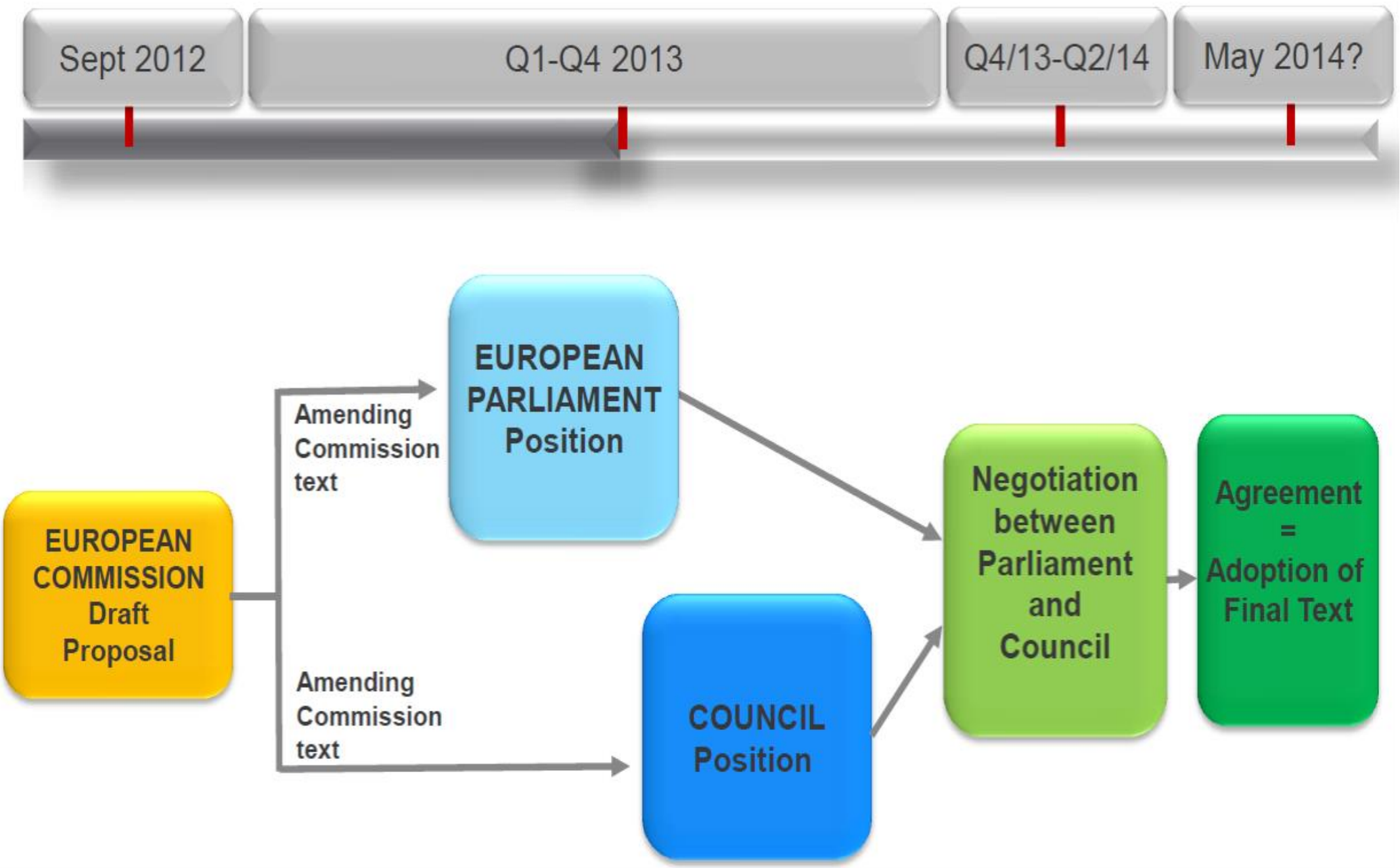
- Not included in the current legislation

**EC proposal**

- Medical Device Coordination Group (MDCG) to oversee in exceptional cases the work of NBs for new class III devices in case of novel technologies, specific public health threats or uneven evaluation by a NB
- NB notified Commission of all class III conformity assessment applications
- MDCG's comments made public in summary

- Add-on to existing approval process = bureaucratic burden without safety gain
- Delays between 6 months up to 1, 2, 3,… (?) years

# Overall Process



# The Political Process – current status

Report of ENVI Committee Rapporteur advocates

- Centralised pre market authorisation

Need for compromise

1 Compromise ENVI July or September

2 EP Q4

3 Council Q4

4 Council and EP Q2 14

MHRA broadly agrees with industry but need to ensure majority of Council support Commission Proposal

# What's been strengthened

| | | | | |
|---|---|---|---|---|
| More rigorous designation and audit of **Notified Bodies** | More **vigilance** and coordination between national surveillance authorities | More **traceability**, **UDI**, and implant cards | Clearer requirements for **clinical evidence** | More effective **governance** structure of Member States |
| *Wider and clearer **scope*** | *Increased regulation of **reprocessing of single-use devices*** | *More harmonized **guidance** and fully stakeholders' involvement* | *Clearer roles and responsibilities for **economic operators*** | |

# Medical Device Regulatory System

## How it will affect you?

- A tougher regime but based on the same principles
- Higher risk products: more evidence, more scrutiny?
- Fees payable to MHRA?
- Higher Notified Body fees
- Cost of UDI
- Enhanced control of importers and distributors

# THANK YOU