COMPLIANCE MATTERS

Chugai Pharma UK Approach to Aggregate Spend & Disclosure on a Budget

Presentation by **David Eves**

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Chugai Pharmaceuticals

- Japanese company formed in 1925
- Chugai Pharma UK launched first product in 1994 in oncology
- Strategic partnership with Roche in 2002
- Joint promotion in Rheumatoid Arthritis
- 42 staff + R&D + marketing companies in the UK
- Presence in UK & Ireland
- Turnover > £10M

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David Eves

- Joined 1994
- Director of Medical Affairs
- Training Manager
- Compliance Officer

- Manage compliance declaration spend for all UK HCP spend
- Manage cross border engagements and spend
- Ensure ABPI compliance
- Ensure IPHA compliance
- Audit spend and methodology
- Certification
- Disclosure

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Background

- Declined budget proposal for an automated spend capture system
- Identified current internal finance system (Navision)
  - An industry standard enterprise resource planning system
  - Identify payment options
  - Payee identification
    - Places of work and personal
    - Maximum three payment codes
  - Assess financial traffic
  - How many engagements
  - Types of engagements
    - Bank transfer, credit card payment, cash

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Assessment of types of spend

- **Traffic**
  - **c. 400 payments in 2011 that would require disclosure**
- **Lines of traffic relating to HCPs**
  - **Promotional x 2**
  - **Marketing x 2**
  - **Medical Affairs**
  - **R&D**
  - **Co-promote**
  - **International**

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Assessment of Assumed Risks

- **Traffic light system to measure risk**
  - **Low/No risk = no spend**
  - **Medium risk = marketing, R&D**
  - **High risk = promotional**

Actual Risk in 2012

- **Low risk = no spend but requires twice annual check**
- **Medium risk = Promotional**
  - **Effective approval system, low actual spend, trained**
- **High risk = Marketing, R&D**
  - **Higher spend per engagement**
  - **Fees for services**
  - **Advisory Board Meetings**
  - **Investigator Meetings**
  - **Trial costs**
  - **Flat fee payments from certain affiliates**
  - **Administration staff**
  - **R&D perception of the Code**

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Models

The TukTuk Method

- It works!
- Manual
  - Finance Manager
  - Database Administrator
  - Compliance Officer
- Low maintenance
- No start up costs

- Navision + database
- Risks
- High hidden costs in labour
- Complex sub-categorisations
- Only possible for small/medium company with limited spend traffic

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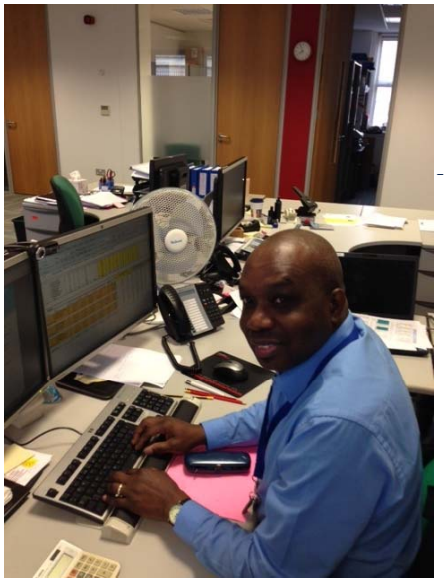
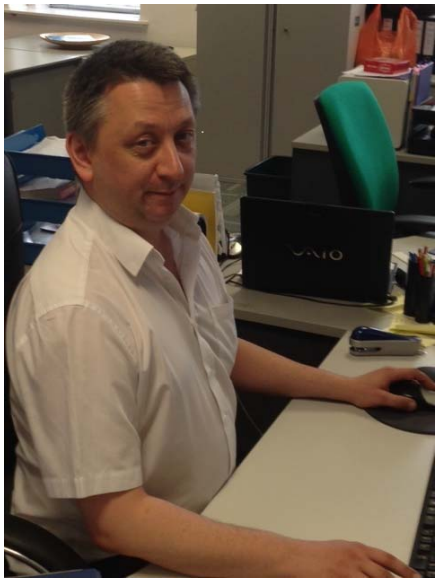
Those involved





Linval
Information Manager

Paul
Assistant Accountant

David
Compliance Officer

What Needed to be Captured

- Change in process for all payment types to include compliance spend categorisation
  - Meetings & Sponsorship
    - Third party
    - Non third party
    - Payments to a third party company
  - Payments to an institution
  - Fees for services
  - Patient organisations
  - Joint working

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Monthly Review Meeting

- **High risk**
  - **Marketing**
  - **R&D**
  - **International travel**
  - **Affiliate spend**
    - **Creation of Engagement Approval System**

- **Medium risk**
  - **25% of all promotional staff**

- **Low risk**
  - **Twice yearly sample of low risk**
    - **e.g. administration staff**

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Monthly Review Meeting

- Review <u>every</u> payment made by the individual that month
  - Requires / does not require declaration
  - Ensure accurate categorisation
    - e.g. Advisory Board Meeting
  - Match finance paperwork to database
  - Cross reference HCP identification

- Conclusions
  - Track from paperwork to database
  - Track database to paperwork
  - Re-train staff on requirements
    - 'Think like an auditor'

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Engagement Approval System

- Captured all cross border planned engagements
  - Included Ireland / Northern Ireland
- Ensured engagement is appropriate to local and UK codes
- Ensured fair market transfer of value
- Required local and UK approval
- Certification for all cross border engagements where a UK HCP is involved
- Captured actual spend retrospectively
  - Issues with currency conversion

- Replaced by Roche iHCP system in 2014

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A Typical Engagement

- Different payments generated by different parts of the business
  - Accommodation , travel, fees for services, subsistence, local customs
- Different currencies
- Payments presented at different times
- Variable payment rates
  - Preparation, work, disturbance allowance
  - Local code requirements regarding allowance, esp. EU

- Speed of response to request
  - Minimum of 6 weeks requested

Product Co-promotion

- **Most spend within the co-promote**
  - **Which company declares spend?**
  - **Do we separate spend by product?**
  - **Principle of 'Follow The Money'**
    - **Each company discloses own spend and gives explanation**
  - **How to give the public meaningful information**

Engagements

- **2012 (235 / £408,300)**
  - **Payments to Institutions**
    - **9 - £170,000**
  - **Fees for Services**
    - **87 - £175,000**
  - **Sponsorship**
    - **137 - £63,000**
  - **Patient Organisations**
    - **2 - £300**
  - **Joint Working**
    - **0**

- **2013 (183 / £185,727)**
  - **Payments to Institutions**
    - **6 - £70,000**
  - **Fees for Services**
    - **89 - £91, 688**
  - **Sponsorship**
    - **£87 - £23, 421**
  - **Patient Organisations**
    - **1 - £618**
  - **Joint Working**
    - **0**

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2012 Spend

- Database accuracy within £8 due to currency conversion
- Separated UK and Ireland spend
- Submitted draft spend to ABPI as requested
  - Feedback very useful
  - Added descriptive around aggregate spend
- Feedback on information given on website
- Briefing document for all staff
- Agreed pathways for all enquires

- Total calls and enquires = 0

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2013 Spend

- New on-line payment system – CONCUR
- Required changes in new system to capture and sub categorise spend
- Train all staff / line managers
- Access issues for compliance

2013 Spend

- Access for cross referencing granted in January 2014
- 8 weeks of manual labour
- Completed work mid March
- All spend cross checked, externally reviewed
- Written methodology

- Briefing documents
- Shared information with ABPI
- Went live 31st March

Issues

- Ensure access and reduce manual load for 2014
- Share ownership with Finance
- Ensure readiness for 2015 individual capture
  - Changes in contract template
    - Is the contract fit for purpose?
  - How and when to inform HCP
    - e.g. certified letter to confirm payment and disclosure requirements to be sent on day of payment
  - Managing withdrawal of consent
    - Managing re-aggregated spend
    - Working with HCPs who decline / withdraw consent
  - Global HCP identifier

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Issues

- Sponsorship
- Understanding the requirements
  - Colleagues
  - HCPs
- Ensuring max hourly rates are meaningful for all contacts
- Increasing institutional requirements
- Country specific requirements
- Country specific events
- Readiness for central platform

Issues

- Separation of promotional and non promotional activities
- Does the public understand disclosed information?
- Does the HCP understand?
- Has there been a reduction in engagement due to disclosure?
- Disclosure of R&D / Investigator Initiated Studies
- Ensuring EFPIA compliance across the EU

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Conclusions

- It has been possible to manage code-required spend capture and disclosure on a shoestring
- Highly manual with significant hidden costs
- Not feasible for the future

- A positive experience
  - Has standardised all aspects of the company
  - Encouraged discussion regarding the purpose of transparency
    - Who is central to the outcomes
  - Better understand EFPIA requirements on this journey
  - Ready to buy in to effective CRM and spend capture systems
    - Use this year to prepare for 2015 and beyond
    - Ensure system harmonised to the needs of a central platform

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Thank you

Any Questions