BSAC Round Table
The Impact of AMR on Antibiotic Production for Medicine

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• cefuroxime,
• cefotaxime,
• gentamicin,
• moxalactam,
• cephalexin,
• cefaclor,
• tobramycin,
• vancomycin,

• cefotetan
• meropenem
• mupirocin
• chlorhexidine,
• augmentin BD,
• gemifloxacin,
• inhaled tobramycin
• daptomycin…
• and others
Pharmaceutical Company
Changes 1980 - 2016

• Outsourcing - birth of big CROs – 1980s
• Empowered project teams – 1980s
• Virtual small and medium size pharma – 1990s
• Big pharma spin-outs – 1990s
• Preferred partnerships and increased use of CROs – 1990s
• Mergers and product swaps – 1990s
• Interims and insourcing – 2000s
2014/2015 Record Year for Biopharma

- 82 new drugs approved by the EMA
- Industry sales exceeded $1 trillion
- Innovative drugs continue to command high price
- Rare and orphan drugs – 40% FDA approved
- Fast track annual costs around $100,000
- NASDAQ bio index – rose 36%
- Biotech – rose 28%
Pharma Company Cost Structure

R & D → 17%
Cost of goods tab → 13%
Sales and marketing → 35%
General administration → 8%

Margin → 27%

Barry James 2003
"The rate of introduction of new and expensive drugs is accelerated, generic convergence is slowing and prices of many generics are rising and expensive drugs are now being introduced the conditions that affect many people rather than thousands"

Peter Bach, New England Journal of Medicine, 2015
"The pharmaceutical industry and biotech corresponding to the threat of antibiotic resistance with renewed efforts."

"In the next 10 years we will witness the development of completely new antibacterials."

Challenges in Developing New Antibacterial Drugs - 2009

- Limited progress so far
- Antibiotic success in R&D is complex
- Lack of progress has led to the loss of expertise
- Current commercial needs are uniformly unrealistic
- Big pharma now focuses on easier to discover drugs along with high attractive returns

• Significant investment in new technologies over the last 20 years have not resulted in new antibiotic introductions for gram negatives

• Introductions and relaunches of several old antibiotics with limited activity

• Antibiotics are considered difficult to research, identify, register, license and market effectively

Jim O'Neill sets out plan to overhaul the global antibiotics pipeline 14 May 2015

- Commit lump-sum payments to successful drug developers to support a viable market for the highest priority antibiotics

- "De-link" the profitability of a drug from its volume of sales:

- Jump start the innovation cycle in antibiotics by getting money into early stage research

- Catalyse discoveries into new drugs by supporting the antibiotics development process
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The Year Ahead for Pharma?

- Pricing pressures
- Merger and acquisitions
- Collaborations continue
- US biosimilar growth
- Patient centricity
- Increasing importance of emerging markets
- Digital pharma
Personalised Data and Diagnostics

- 14 years ago, human genome mapped
- Increase in pharmacogenomic data
- In 2015, 13% of US marketed drugs mentioned genes
- Challenges:
  - Basic science
  - Clinical adoption
  - Regulation
  - Pricing
Companies have committed to reducing the development of drug resistance through work to support antibiotics stewardship, increasing investment in R&D that meet public need with greater focus on research into new antibiotics, diagnostics, vaccines and other alternative treatments and improving affordable access to high quality antibiotics for all.
J & J Restructuring Plan

- To lose 3,000 by 2018
- 60,000 will be axed overall
- Savings of $20 million in 2016 alone
- Sales down 10%

These actions will deliver more value to customers and drive growth for our business - ? Acquisition?

Pharmafocus January 2016
What measures might improve price transparency while maintaining incentives to manufacturers investing in new drug development?
Progress in medicine does not focus on doing existing things more cheaply and simply, but on things that previously could not be done at all