1. THE BIGGER PICTURE
   • OTC – Primary Care – Speciality Care

2. CH INNOVATION WITH A ...’BUT’
   • Switches ...but
   • Line Extensions ...but

3. KNOWN DRUGS – MADE BETTER
   • Cocoa → Cough
   • Haemoglobin → oxygenate wounds
   • Ibuprofen → reinvented

4. CH – Challenges to overcome
   • Make or buy (closed or open innovation)
   • Symmetry vs. Asymmetry
   • Brand vs. Product
1. The Bigger Picture

1980 - 2000

- **Primary Care**
  - H2s
  - NSAs
  - PPIs
  - Statins

- **Specialty Care**

2000 - 2020

- **Primary Care**
- **Consumer/OTC**

- **Specialty Care**
  - Oncology
  - Rheumatology
  - Virology
  - CNS
  - Immunology
  - Rare Diseases

- **Speciality Care growth is price driven (More Money spent on smaller patient populations)**
- **Considerably less NPD in Primary Care (and less switch targets in the future)**
Consumer Healthcare Trends

Fundamentals remain positive

- ageing population
- Budgets shift towards Self-Care & Self-Pay (of minor episodic conditions)

But...

- Heterogeneity of OTC regulation has hardly changed
- Complexity and diversity of OTC distribution/retail conditions/access restrictions/advertising limitations etc. remains a feature of the industry

The industry is extremely focused on Strategic Growth and Share Grab but needs to step up its ambition to grow markets
2. INNOVATION ..BUT: “Switch”

Great Successes:
• Ibuprofen (Advil, Nurofen, Motrin, etc.)
• H2s (Tagamet, Zantac, Pepcid)
• Nicos (Nicorette, Nicoderm, Nicotinell, etc.)
• NSAs (Claritin, Zirtec, Allegra)
• Allergy inhaled steroids (Flonase, Nasacort etc.)
• PPIs (Prilosec, Prevacid, Nexium)
• EC (Plan B, Levonelle, EllaOne)

But...
1. Successes were very US centric; H2s, PPIs and NSAs were nowhere near as successful in Europe as they were in the USA
2. With Primary Care being de-emphasised by Big Pharma – switch candidates will ultimately be more scarce.
2. INNOVATION ..BUT: “Line Extension”

- Count Size
- Form
- Dose/ Strength
- Indication
- Flavour
- Speed/ Duration
INNOVATION BUT: “Line Extension”
INNOVATION ..BUT: “Line Extension”
INNOVATION ..BUT: “Line Extension”
INNOVATION ..BUT: “Line Extension”
Line Extensions have successfully grown many big OTC brands

But...

- less and less new products offer meaningful news
- Patients and pharmacists are increasingly irritated and confused by the tidal wave of XX Plus, XX Forte, XX Extra, XX Ultra, XX Max, XX Advance, XX ExtraAdvance, XX Express,
- Press and Public are beginning to criticise overly clever marketing segmentation of products which are practically identical
3. GENUINE INNOVATION

Known Drugs – Made Better

- **Known substances/molecules** – with established safety profile (even direct to OTC is an option if the indication is already OTC and if the chosen active has a well established safety – relative safety -)

- **Continuous improvement** of established drugs – (reformulations to effect absorption, pharmacodynamics, AE/safety profile, organoleptic, etc.)

- **Interdisciplinary understanding and application** of biological, chemical, physical principles
3. Known Drugs – Made Better

a) Can Cocoa treat Cough?

- Theobromine – an alkaloid naturally present in cocoa beans
- An API with past use in vasodilators and diuretics
- A chemical which has shown to be able to down regulate cough hypersensitivity
- A non-narcotic/ non-opioid alternative to codeine and dextromethorphan
- Licensed as antitussive in South Korea (2 phase IIIs, large phase IV, selling > 30 m capsules p.a.)
- EU development 1 challenge study + 1 phase III away from filing, Centralised Procedure eligibility confirmed, 10 years exclusivity.
- Direct to OTC possible/ desirable?
- Partnering in Rx seems more attractive/ Rx partners seem to be more attracted
3. Known Drugs – Made Better

b) Purified Haemoglobin to oxygenate wounds

- Chronic wounds are commonly hypoxic (oxygen deprived)
- Ambient oxygen cannot diffuse into wounds (less than 1 %)
- A novel solution (bespoke spray applicator) containing purified haemoglobin from porcine source has shown to carry oxygen deep into the wounds (CE Class III)
- Shown to heal more wounds faster, reduce pain, reduce exudate, save the NHS considerable amount of money per patient.
- Now on NHS tariff and NHS supply chain.
- Working on USA IND with possibility to obtain ‘breakthrough designation’ and ‘fast track’ review
- While technically OTC (MD) – the product skews towards Rx mechanics
3. Known Drugs – Made Better

c) ‘Lipid dissolved’ Ibuprofen reinvented

- Strong anti-inflammatory effect at lower dose in a) pulmonary, b) intestinal, c) RA inflammation as well as c) better GI tolerability in pre-clinical studies
- Comprehensive development programme resulting in full manufacturing scale up of lipid dissolved soft gelatine capsules
- UK marketing authorisation approved, EU and USA in progress
- Completed Phase III proving that 1200mg lipid dissolved ibuprofen is as effective (non-inferior) as 2400mg standard Ibuprofen (softgel capsules) in patients with flaring knee pain
- Improved GI tolerability shown in pre-clinical studies, noticeable in AE reports of Phase III study will be examined in subsequent clinical programme.
- Attracts more Rx interest than OTC interest – depending on geographies
4. Consumer Healthcare - Challenges to overcome

1. Closed or Open Innovation
   • Open innovation in CH is more of a lip service
   • >30% of big Pharma pipeline derives from third party
   • Has to be built into culture but also into financial models/ accounting practices

2. Symmetry vs. Asymmetry
   • OTC regulation substantially less harmonised and standardised than Rx
   • Need to accept that innovation may have to start with different legal status and label depending on geography

3. Brand vs. Product
   • Does a brand have to serve a product or a product to serve a brand
   • Both... but exclusively brand led approach can filter out bigger opportunities

4. ‘Why Not’ vs. ‘Yes But’ culture
   • Shocking level of absence of commercial functions
   • Internal evaluators look for gaps – not for solutions
   • Tasked to find risks – not possibilities

Tell me why I should engage – don’t tell me why I shouldn’t !!!