Market Round-up

V33 – 25th January, 2019

General Market News:

- Plans to give generic drugs companies more freedom to manufacture new medicines in the EU more quickly moved closer to becoming law
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- Up to 900 ***Pfizer*** staff to ballot for industrial action
  LINK

- The European Commission has expanded the use of **Orkambi** to include children with cystic fibrosis (CF) aged two years to five years.
  LINK

- ***Novo Nordisk*** has announced that **Ozempic,** a new once-weekly GLP-1 analogue injection for the treatment of type II diabetes, is now available in the UK.
  LINK

- ***GSK*** Chairman **Philip Hampton** steps down as company preps for split-up
  LINK

- ***Sanofi*** and ***GSK*** have joined up with a project collecting genomic and health data from 500,000 participants in Finland, which could help to develop **personalised medicine**.
  LINK

- ***Astellas*** and ***KM Biologics*** to end distribution agreement in Japan
  LINK

- ***MSD*** gives ***Vertex Pharmaceuticals*** exclusive rights to DNA damage inhibitors
  LINK

- Cost hike of €450m for **children's hospital** 'very disturbing' with the PAC to hear €50m of overrun for St James's site is to come from the health budget this year
  LINK

NCPE *Drug Updates*

- The NCPE recommends that ***bene-Arzneimittel's*** **Pentosan Polysulfate Sodium** (elmiron®,) not be considered for reimbursement at the submitted price.
  LINK

- A full HTA is recommended to assess the clinical effectiveness and cost effectiveness of ***EUSA Pharma's*** **tivozanib** compared with the current standard of care.
  LINK

- A full HTA is recommended for ***Pierre Fabre Medicament's*** **Encorafenib (Braftovi®), binimetinib (Mektovi®)**
  LINK

Biosimilars/Biologics:

- The FDA has approved a new biosimilar of ***Roche's*** breast cancer drug **Herceptin,** from ***Samsung Bioepis*** & ***MSD*** ahead of the original drug's US patent expiry in June.
  LINK

Drug Approvals/Filings:

- ***Pfizer*** looks to move **Tafamidis** forward with FDA Priority Review
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- The first therapy to win approval for cancer patients in remission with minimal residual disease in Europe is ***Amgen's*** BiTE immunotherapy, **Blincyto**.
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- ***Novartis'*** **crizanlizumab** gets FDA breakthrough designation
  LINK

Brexit:

- The Irish Government has published the next phase of Brexit 'No Deal' legislative planning which also includes Healthcare.
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- The European Commission confirms that a no-deal Brexit will see hard border in Ireland
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- Scramble for UK warehousing to stockpile goods as no-deal Brexit edges closer
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