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Market Round-up

V15 – 31st August, 2018

General Market News:

- ***GSK*** is buying ***Novartis*** out of their **consumer healthcare** joint venture for $13 billion
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- ***Novartis*** announces new data that show **Entresto® (sacubitril/valsartan)** can be initiated early & safely in hospitalized patients after an acute heart failure episode
  LINK

- ***JW Pharmaceutical*** signs global out-licensing agreement for their novel **atopic dermatitis** drug candidate, JW1601, with ***LEO Pharma***
  LINK

- **NICE** says 'no' to ***Gilead's*** **Yescarta** in draft guidelines
  LINK

- ***Bayer*** and ***Johnson & Johnson's*** plans to expand the scope of blood thinner **Xarelto** have hit a setback after the drug failed to hit targets in two studies in venous thromboembolism and heart failure studies.
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- ***Bayer*** has filed a marketing application in Europe seeking approval for **larotrectinib** as treatment for TRK fusion cancer.
  LINK

- ***Amgen*** files for once-weekly regimen for myeloma drug **Kyprolis**
  LINK

- ***Pfizer*** recalls **Advil** due to dosage mislabelling
  LINK

- ***Vertex*** has announced it is committed to getting **Orkambi** free on NHS
  LINK

- ***Novartis*** highlights early initiation of **Entresto** is safe for many heart failure patients
  LINK

- ***Pfizer*** drug reduces death rate in patients with hearts damaged by protein clumps
  LINK

- ***Novartis*** to boost ability to manufacture new cancer drug in Europe
  LINK

Biosimilars:

- $70 million patent infringement verdict against ***Hospira Inc.*** upheld over its biosimilar version of ***Amgen's*** anemia treatment **Epogen**
  LINK

- ***Pfizer*** calls for FDA guidance to address false and misleading biosimilar adverts
  LINK

NCPE Drug Updates

- A full HTA was recommended for ***MSD's* Keytruda® (Pembrolizumab)** to assess the clinical effectiveness and cost effectiveness of pembrolizumab compared with the current standard of care.

- Full pharmacoeconomic assessment recommended on ***Roche's*** MS Drug **Ocrevus® (Ocrelizumab)**

Drug Approvals:

- European regulators have approved ***Novartis'* Kymriah** and ***Gilead's* Yescarta**, enabling patients to access **CAR-T therapies** across the region for the first time.
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- ***Novartis*** says EU approves **Tafinlar** in combination with **Mekinist**
  LINK

- FDA approves ***Shire's* Takhzyro** for Hereditary Angioedema
  LINK

- Dublin-based ***Jazz Pharmaceuticals*** are celebrating news of European approval of its leukaemia drug **Vyxeos**.

- The FDA has approved ***Bayer's* Jivi** drug for the treatment of haemophilia A
  LINK

Brexit:

- All sides need to re-learn the art of compromise in Brexit negotiations - and they do not have long to do it.
  LINK

- Stockpiling medicine for Brexit could cost the UK Billions
  LINK

Further Reading:

- Big pharma takes a gamble on NHS experiment
  LINK

- **"Sláintecare scepticism is understandable, but it is our best hope"**... article by Anthony Staines Professor of Health Systems in Dublin City University
  LINK

- **"Pandemrix victims left out in the cold".**
  Vaccinations save millions of lives each year, but failure to compensate in those rare cases when they harm recipients creates a dangerous breach of public confidence.
  Article from Business Post, 25th August
  Imagine listening to the medical experts and getting your child vaccinated. Imagine that your child was one of those exceedingly rare statistics and had an adverse reaction to that vaccine. Imagine you were then ignored and that successive governments refused to acknowledge that wrong.

This is the reality facing the parents of children who suffered an adverse reaction to the Pandemrix swine flu vaccine.

In a world where the public health benefits of vaccination are abundantly clear, theirs is an unusual story. It makes for a difficult juxtaposition at a time when public health authorities are battling outbreaks of measles and fighting hard to reverse a fall in uptake of the HPV vaccine, which protects against cervical cancer.

Vaccines have undoubtedly been one of the greatest public health achievements. The World Health Organisation (WHO) estimates they avert 2-3 million deaths every year. But sometimes, ever so rarely, things can go wrong. The Pandemrix vaccine, which is no longer on the market, is one of those rarities.

Pandemrix was approved in response to a global outbreak of swine flu. Vaccines undergo rigorous testing but – such was the scale of the panic about the pandemic in 2009 and 2010 – this vaccine was rushed to market and approved without undergoing the usual regulatory scrutiny.

It was used in several European countries, where public health officials strongly encouraged at-risk groups to be vaccinated.

Some doctors expressed concern from the get-go, arguing that the clinical trials had not been sufficient to support the vaccination of tens of millions of people. Problems soon emerged.

As the British Medical Journal (BMJ) reported, concerns "were raised in Finland and Sweden about a possible association between narcolepsy and Pandemrix" in August 2010.

Narcolepsy is a debilitating neurological disorder that causes overpowering daytime sleepiness, often accompanied by sudden muscle weakness triggered by strong emotion (known as cataplexy).

"But a lack of reported cases in other countries led to speculation that any possible association might be restricted to these Scandinavian populations," the BMJ stated.

The World Health Organisation issued a statement indicating an increased risk of narcolepsy with Pandemrix in 2011. Major reputable medical bodies have concluded that the probability of developing narcolepsy is much higher in those who received Pandemrix than in those who did not.

In Ireland, a small number of people who received the vaccine developed narcolepsy. The support group for those affected, called Sound, was promised a sleep clinic at St James's Hospital some years ago. That has yet to open, although some progress is now being made and the support group is hopeful it will open early next year.

Sound estimates that about 80 people were adversely affected in Ireland. Most are now aged between 17 and 27, but some are as young as 11. The parents of a number of younger children have given up work to become full-time carers.

Some of the young adults affected are unable to work, while others have dropped out of college. Their future is, at best, uncertain. Parents have real concerns about their children's ability to earn a living and provide for themselves in the future.

Dozens of families have initiated legal action against the state, seeking compensation for what happened. They want to ensure their children have a more secure financial footing. Other countries have already compensated victims of Pandemrix. The Irish government is fighting these claims.

Ireland is one of very few countries in the EU which has failed to introduce a no-fault compensation scheme for the very small number of people damaged by vaccines. Such a scheme would benefit other patients too. Vaccines are not without risks and adverse events, though exceptionally rare, can occur following vaccination.

Take Guillain-Barré syndrome (GBS), a rare disorder in which a person's own immune system damages their nerve cells, causing muscle weakness and sometimes paralysis. It often follows infection by a virus or bacteria. Studies show that it is more likely that a person will get GBS after getting the flu than after vaccination. However, there is a one in a million chance it could occur after someone receives a flu vaccine.

At a population level, it is considered that these small risks are balanced by the benefits of widespread population immunisation. But this means that an individual may very occasionally bear a significant burden for the benefit provided to the rest of the population.

In recognition of this, most developed countries have implemented vaccine injury compensation programmes. Germany enacted such a programme in 1961. France implemented a similar scheme in the 1960s. Many other countries followed in the 1970s. Britain has one.

These programmes reflect a belief that it is only fair and reasonable that a community protected by a vaccination programme accepts responsibility for, and provides compensation to, those who are injured by it.

Ireland has failed to do this, even though a compensation programme was recommended as far back 2001 when the Joint Commission on Health recommended that a vaccine damage scheme be set up at the earliest possible date.

A vaccine damage steering group published its report in 2009. It recommended establishing an ex-gratia payment scheme with payments dependent on the severity of damage experienced by an individual. There is no sign yet of the scheme.

This time last year, Minister for Health Simon Harris said his department was examining whether a vaccine compensation programme could be rolled out in Ireland. Last week, the Department of Health failed to respond to questions asking it to outline what work, if any, it has carried out on this.

In June, the government announced that it had asked the expert group led by High Court judge Charles Meenan to examine how vaccine damage claims could be handled more sensitively. Recent history does not suggest concrete action will be forthcoming any time soon.

Dozens of families whose children have been adversely affected by Pandemrix have initiated High Court actions. By resisting efforts to compensate those who have been damaged, the government is sending out a worrying message. Its position – whether arrived at by design or through sheer apathy – is unhelpful and negligent.

Cases of measles in Europe have reached a record high. The health service has only recently begun to reverse a serious drop in uptake of the HPV cervical cancer vaccine. Scientists, doctors and public health officials are doing their utmost to convince parents to vaccinate their children against measles, cervical cancer and other preventable illnesses. They have a real fight on their hands.

At a time when the anti-vaccine movement is posing very real threats to public health, the state's immoral response to genuine victims of Pandemrix will surely only feed misguided anti-vaxxers and fuel the fears of the vaccine hesitant.