Dear Colleagues,

Here is the EFPIA Daily Briefing for 24 May 2016.
Any feedback would be most welcome.
Best wishes,
Faraz Kermani, Communications Manager (External Affairs)

**Regulatory**

**Pfizer says EMA lifts warning on its smoking cessation drug Champix**

(24/05/2016) (PharmaFile)

US pharma giant Pfizer says EMA has lifted a warning on its anti-smoking drug Champix (varenicline) after a study showed it did not appear to increase the risk of neuropsychiatric side effects.

**Janssen’s Darzalex gets conditional European Commission approval to treat multiple myeloma**

(24/05/2016) (PharmaFile)

Janssen says the European Commission has approved conditionally its biologic Darzalex (daratumumab) to treat blood cancer.

**Biosimilars**

**Sandoz’ biosimilar rituximab regulatory submission accepted by European Medicines Agency**

(24/05/2016) (FirstWord Pharma)

Sandoz, the global leader in biosimilars, announces that the EMA has accepted its Marketing Authorisation Application for a biosimilar to Roche’s EU-licensed MabThera (rituximab).
Arizona Governor Ducey Signs Bill Ensuring Patient Access to Interchangeable Biologic Medicines
(24/05/2016) (FirstWord Pharma)
The Biotechnology Innovation Organization (BIO) and Arizona BioIndustry Association (AZBio) commend Governor Doug Ducey for signing critical legislation to create a pathway for the substitution of interchangeable biologic medicines.

Clinical Trials

French authorities pins blame on Bial and Biotrial for fatal drug trial
(24/05/2016) (PharmaFile)
Bial and Biotrial, share blame for many adverse events; Biotrial failed to immediately stop administering the drug after the first hospitalisation or to confirm patient consent before running the trial.

France tightens rules in wake of fatal clinical trial
(23/05/2016) (Science)
After tragic trial, the French government is taking measures to lower the health risks for volunteers and Biotrial, must within a month provide a “plan of action” explaining how it will avoid a repeat.

Outcomes

How to buy more health
(24/05/2016) (Science|Business)
Harvard economist Michael Porter argues that, to improve performance, healthcare systems need to measure not what goes in, but what comes out.

Counterfeiting

Zap a Tomato to See If It’s Good, a Drug to See If It’s Real
(23/05/2016) (Bloomberg)
A startup in Israel called Consumer Physics has developed a keychain-size device called the SCiO, which can spot watered-down fuel at the pump and even tell counterfeit drugs from real ones.

Companies

Sanofi Announces Changes to Executive Committee Aligned to its Strategic Roadmap 2020
(23/05/2016) (FirstWord Pharma)
Sanofi Chief Executive Officer Olivier Brandicourt, MD, announces a number of changes to the company's Executive Committee, supporting Sanofi's recently announced 2020 Strategic Roadmap.

Astellas, Daiichi Sankyo and Takeda to study biomarkers
(23/05/2016) (Pharma Market Live)
Japanese pharmaceutical firms Astellas, Daiichi Sankyo and Takeda have joined forces to create a comprehensive database of biomarkers from healthy adults.
**Brexit**

**UK medicines regulator warns of Brexit hit**
(23/05/2016) (Financial Times)
The UK medicines regulator would struggle to cope with a vastly increased workload and reduced income if the UK leaves the EU, its chair said on Monday; innovative drugs will take longer to reach patients.

**Brexit could lead to longer waiting times for new medicines, warn experts**
(23/05/2016) (The Guardian)
The UK’s influence over regulation could be reduced and waiting times for new drugs and medical devices to become available increased, warn scientists.

**IP**

**India’s new patent policy spurs debate over implications for pharma**
(23/05/2016) (STAT)
Amid an ongoing rift with the US, India issues a new IP policy, but opinions are divided over whether the move will appease pharma, which has been pushing the government to strengthen patent protection.

**Animal Testing**

**Biotech firm fined $3.5 million for animal mistreatment**
(23/05/2016) (PharmaFile)
US-based biotech, Santa Cruz Biotechnology, one of the world’s largest providers of antibodies, has been fined $3.5 million by the US Department of Agriculture mistreating animals.

**Policy**

**India Deliberates Orphan Rules**
(23/05/2016) (Scrip Intelligence)
India is deliberating a string of initiatives to ensure that drugs for rare diseases reach patients faster and are available at "reasonable" prices in the country.