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An overview of Brexit and its impact of the Indian pharmaceutical industry

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Abstract:
European Union is an international organization comprising of 28 member states and governing common economic, social and security policies. United kingdom, one of the European member states, has been panning to leave because of their economic and financial factors within march29.2019. This process of British leaving the European Union is called as Brexit. The consequences faced by the EU and UK government and the impact of Brexit on Indian pharmaceutical industries are discussed in this review.
Key Words: Brexit, British, Europe union, impact, India, pharma industry

1. Introduction:

Brexit is defined as the Britain exit from the European Union. United Kingdom decided to leave from the EU on June 23, 2016[referendum]. Britain Prime minister, David Cameron, resigned after the referendum. Home secretary Theresa may replace his position as a conservative party and as a Prime Minister. Due to the referendum, Britain would face the "hard Brexit", but the prime minister wants the "soft Brexit".
The UK is planning to leave the EU on March 29,2019. After the agreement, May's negotiation with the EU was rejected by 230 votes in the house of commons. she survived a no-confidence vote and has been meeting with EU leaders to renegotiate the terms and conditions. The crisis on the Brexit is Northern Ireland, which is the part of the united kingdom and the Republic of Ireland is the part of the European Union.

Fig: 1.1

Article 50

The process of leaving the EU formally began on March 29, 2017, when May triggered Article 50 of the Lisbon Treaty. The U.K. has two years from that date to negotiate a new relationship with the EU. Talks began on June 19, 2017

History of the European Union

After the Second World War, Europe was in a troubled state. Two bloody wars had been fought on the continent. European countries were making war against one another since the Middle Ages. The relations between the countries were poor. After two catastrophic world wars, the European leaders decided that the only way of preventing war in Europe was to start to cooperate. This cooperation began in trade and economy. Germany, France, Italy, Belgium, the Netherlands and Luxembourg settled their biggest disagreements and started cooperating in the production of coal and steel. Later this cooperation was extended to other areas of life.

Fig: 1.2

The **European Economic Community** (EEC) and other joint institutions were founded. A common administration, the **European Community** (EC), was created in 1967. The European Community had a Council and Commission common to all members.

Establishment of the European Union

For the first time, the citizens could elect members to the European Community Parliament by direct popular vote in 1972.
Finland has been a member of the European Union since 1995. In 1992 the Community members agreed on even closer cooperation. The European Community was renamed the **European Union** (EU).
As the agreement was signed in the City of Maastricht, the treaty establishing the EU came to be known as the **Maastricht Treaty**.
Finland joined the European Union in 1995. Before that, since 1973 Finland had had a Free Trade Agreement (EEC Agreement) with Europe. The Free Trade Agreement made

it possible to trade across the borders in Europe without any customs duties.

2. The Referendum:

"Leave" won the June 2016 referendum with 51.9% or 17.4 million votes; "Remain" received 48.1%, or 16.1 million. Turnout was 72.2%.

The results were tallied on a U.K.-wide basis, but the overall figures conceal stark regional differences: 53.4% of English voters supported Brexit, compared to just 38.0% of Scottish voters.

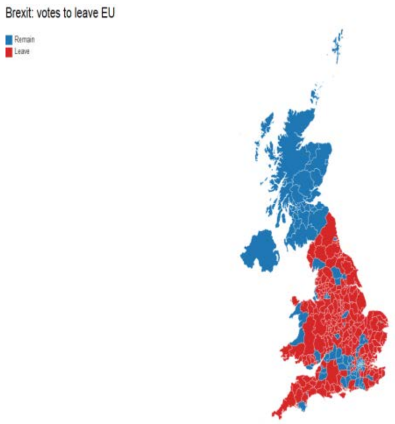

Figure no:1.3 describes the referendum of Brexit.

3. Possibilities of Brexit :

In order to discuss on Brexit, we need to know the possibility of Brexit endings, they are hard Brexit, soft Brexit, no deal Brexit and chequers deal Brexit.

3.1. Hard Brexit:

In a hard Brexit, the UK leaves both the EU government as well as the single market and customs union. In this case, the UK would secure free trade deals with the EU, covering both goods and services. The UK politicians like Jacob rees mog(a member of parliament of the united kingdom) prefers to the hard Brexit, because Britain is free from the European single market, customs union and court of justice.

This situation made the UK goods and products without any competitions, also the UK have to face border inspections and tariffs. In northern Ireland the physical barrier is not necessary but the EU follow their law accordingly. The abroad citizens law can be protected, they can stay where they are, but after the immigration time, the free movement of people was restricted.

3.2. Soft Brexit:

In a soft Brexit, there is a close relationship to the UK and EU. In a soft Brexit united kingdom would be out of the EU but have a strong economic relationship, free movement of people, make budgetary contributions. The UK can stay within the European single market, a customs union.

So the UK has low tariffs and competition for the goods and products. The UK has the ability to make a new trade agreement with the U.S.A, China and India. The movement of citizens across the border is much easier than the hard Brexit and the northern Ireland borders are not necessary because the trading rules are aligned by the European government. But the people of EU said that this is a betrayal and have no support for the soft Brexit.

3.3. Chequers deal:

Theresa may create this plan named as like as her countryside residence, under this scenario the UK would stay pretty close to Europe under a harmonised way, especially in the trading laws. The UK has traded their goods and services without any tariffs and borders and also the united kingdom has the ability to trade with the countries among the world.

The immigration of people in chequers plan is easy and they can stay with a long time, but the EU government forcefully demanding that it would be taken by the UK's immigration policy and end free movement. the European chief negotiator Micheal Barnier and some of the European politicians criticize this policy.

For more information about the immigration policy, please refer:
https://www.theguardian.com/uk-news/ng-interactive/2017/sep/05/post-brexit-immigration-10-key-points-from-the-home-office-document

3.4. No deal Brexit:

If the agreement isn't reached in time then the Britain crash with EU in economic and financial conditions and ends up with standard international trading rules, EU laws changes from Britain and also lots of tariffs and border taxes will arise. This believed to be lead to an economic crash, shortage of foods and medical supplies.

On the other hand, the hard border between Northern Ireland and the Republic of Ireland is not cleared how exactly looks like and the physical barriers expect to be with police check around the borders and having CCTV surveillance for checking the vehicles crossing the borders.

There are no specific arrangements for the citizens living in abroad. For example, the UK citizens living in the EU and the EU citizens living in the UK are not having any specific arrangements. EU government and the UK made a lot of preparations to avoid this no deal scenario

If the government fail to make the deal before March 29,2019, then it'll end up in the no deal Brexit. To avoid a no deal Brexit the government either delay the Brexit deadline or to call the second referendum

4. The Irish backstop plan:

The backstop plan is essentially a legally binding insurance policy to ensure that there is no hard border between Northern Ireland and the Republic of Ireland. The U.K. and the EU both signed up to the idea of a backstop plan in December 2017.

In the withdrawal agreement the assure that there will be no hard border between these two countries if a Brexit deal is not passed in both U.K. and EU parliaments by the end of the transition period. The EU single market rules describe the insurance policy that keeps Britain in the EU customs union.

Fig: 1.4

The backstop plan is temporary and it will be suspended by a subsequent agreement. This Irish backstop plan can be removed only if both Britain and the EU give their consent.

5. U.K. and EU trade after Brexit:

Theresa May has advocated a "hard" Brexit, meaning that Britain would leave the Eu's single market and customs union, then negotiate a trade deal to govern their future relationship. The Conservatives' poor showing in the June 2017 snap election called popular support for that approach into question, and many in the press speculated that the government could take a softer line.

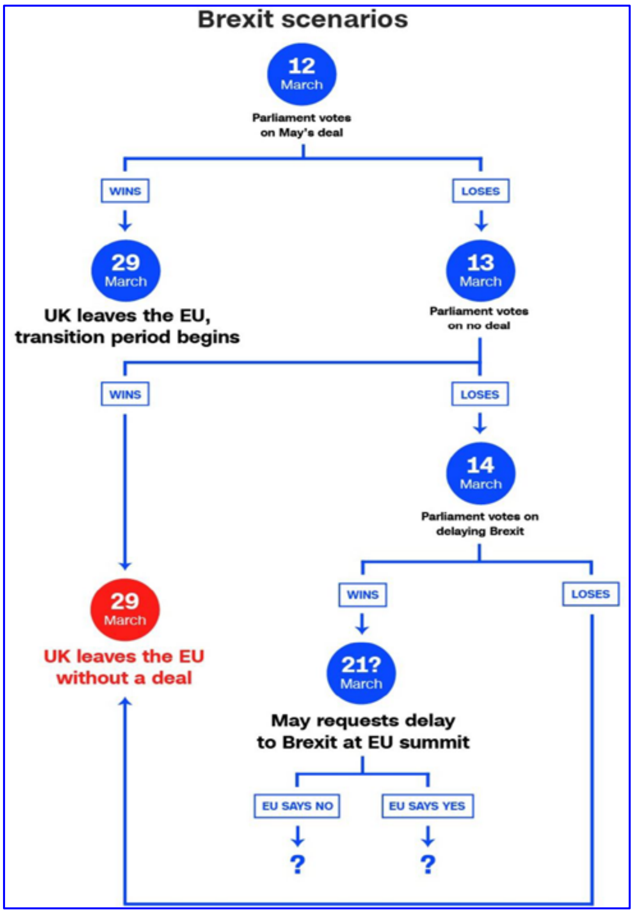

Fig: 1.5- summary of the Brexit scenarios

In her September speech in Florence, May said against her government's hard Brexit opinion, saying "we will no longer be members of it's [the Eu's] single market or its customs union." On the other hand, she proposed a transition period "to adjust to the new arrangements in a smooth and orderly way" of around two years.

In **2015**, the top 10 exports from the U.K. were (in USD):

- Machines, engines, pumps: US$63.9 billion (13.9% of total exports)
- Gems, precious metals: $53 billion (11.5%)
- Vehicles: $50.7 billion (11%)
- **Pharmaceuticals: $36 billion (7.8%)**
- Oil: $33.2 billion (7.2%)
- Electronic equipment: $29 billion (6.3%)
- Aircraft, spacecraft: $18.9 billion (4.1%)
- Medical, technical equipment: $18.4 billion (4%)
- Organic chemicals: $14 billion (3%)
- Plastics: $11.8 billion (2.6%)

6. The Norway model: join the EEA:

The first option would be for the U.K. to join Norway, Iceland and Lichtenstein in the European Economic Area (EEA), which provides access to the EU's single market for most goods and services (agriculture and fisheries are excluded). At the same time, the EEA is outside the customs union, so Britain could enter into trade deals with non-EU countries.

The arrangement is hardly a win-win, however: the U.K. would be bound by some EU laws while losing its ability to influence those laws through it's European Council and European Parliament voting rights. In September, May called this arrangement an unacceptable "loss of democratic control."

7. The Switzerland model: bilateral trade agreements:

Switzerland's relationship to the EU, which is governed by around 20 major bilateral pacts with the bloc, is broadly similar to the EEA arrangement. Along with these three, Switzerland is a member of the European Free Trade Association (EFTA). Switzerland helped set up the EEA, but its people rejected membership in a 1992 referendum.

The country allows free movement of people and is a member of the passport-free Schengen Area. It is subject to many single market rules, without having much say in making them. It is outside the customs union, allowing it to negotiate free trade agreements with third countries; usually, but not always, it has negotiated alongside the EEA countries.

8. The Canada model: a free trade agreement:

A third option is to negotiate a free trade agreement with the EU along with the lines of the Comprehensive Economic and Trade Agreement (CETA), a pact the EU has finalized with Canada but not ratified.

The most obvious problem with this approach is that the U.K. has only two years from the triggering of Article 50 to negotiate such a deal – that is, until the end of March 2019. The EU has refused to discuss a future trading relationship until December at the earliest.

9. Why the Brexit happens?

For a little bit of background. A prevalent issue the European Union has been trying to deal with is the amount of immigration the country has been seeing Right below does not show how many people have been flooding into the continent, but it is tracking the illegal immigration that it has been seeing along its borders.

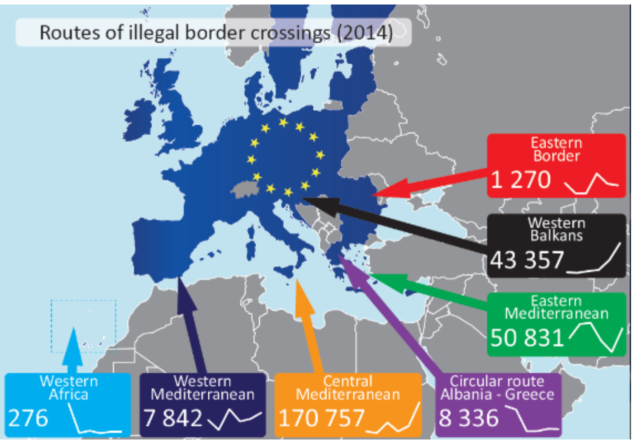

Fig:1.6

The Eastern Mediterranean route has the highest number of illegal immigrants. the top three nationalities are Afghanistan, Syria, and Bangladesh. The people in Britain felt they should not be required to pay for refugees that they did not vote to take in.

10. Brexit- a term for the potential or hypothetical departure of the United Kingdom from the European Union.

- People who were pro-Brexit wanted to leave the European Union to protect the nation's culture and independence.
- These people also had issues with the amount of immigration the European Union was allowing and did not want to take on that burden as well.
- Despite unemployment, some people still believed the right choice was to stay in the union. The people who wanted to stay argued that it would be better for the British economy. It seemed like a more stable choice and less risk was involved with staying in the EU.
- Another reason this occurred is because of the rise of nationalism across the world. And people are having more and more mistrust in multinational organizations.

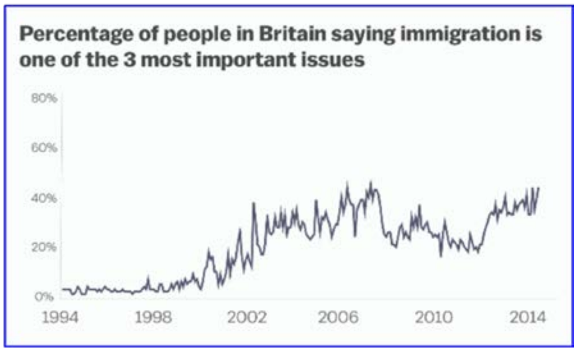

Fig:1.7

11. Who will be the next?

In May 2016, global research firm IPSOS released a report showing that a majority of respondents in Italy and France believe their country should hold a referendum on EU membership.

12. UK lawmakers vote to reject a no-deal Brexit:

U.K. lawmakers have rejected the idea of leaving the European Union without a Brexit deal in place, setting up another vote on Thursday whether its official departure date should be extended. A no-deal exit was widely expected to be defeated as most MP's (Members of Parliament) want to avoid the economic uncertainty and trade disruptions that it could cause. This important change led to May's government ordering its own MP's to vote against its own motion. But the amended motion still passed by 321 votes to 278. The vote was non-binding but it showed the strength of feeling among lawmakers and will hold political weight in future debates. The pound was up about 2 per cent against the dollar as investors become more optimistic that a hard Brexit would be ruled out.

12 people who brought about Brexit:

- ✓ Boris Johnson(British politician, journalist and popular historian),
- ✓ Nigel Farage (British politician, broadcaster , campaigner, political analyst)
- ✓ David Cameron (British politician, prime minister of UK from 2010 to 2016),
- ✓ Jeremy Corbyn(British politician, leader of the labour party),
- ✓ Angela Merkel(German politician, chancellor of Germany),
- ✓ Paul Dacre(journalist of British newspaper-The Daily Mail),
- ✓ George Osborne(British conservative party politician),
- ✓ Matthew Elliott(British political strategist and lobbyist),
- ✓ Will Straw(British politician, CBE in labour party politician)
- ✓ Roland Rudd (founder and chairman of Finsbury, The public relations firm),
- ✓ Daniel Hannah (British writer, journalist, politician conservative member of EU parliament)

13. Is Brexit a positive for the UK's pharma sector?

The UK is a global centre of academic pharmaceuticals research

Pharmaceuticals companies depend on high-quality research facilities to develop the drugs and treatments on which their future sales will depend. The UK is an international hub for such facilities, boasting three of the 17 most important clusters of life sciences research facilities in Europe.

These facilities have an impressive track record of collaboration with pharma companies

These life sciences clusters have a long and impressive track record of working with commercial businesses to develop drugs that make it to market. Examples include

Humira, co-developed in Cambridge, and now the best-selling drug worldwide.

R&D spending on pharma in the UK remains strong

R&D spending is the lifeblood of the pharma sector and is a top business spend in the UK. Almost half (47%) of all R&D spending in the UK is in the pharmaceutical sector, with charitable endeavours supplementing the R&D firepower of commercial businesses. The Wellcome Trust awarded £600 million of new research grants in the UK last year alone.

Brexit will cement the UK’s global leadership on pharma regulation

The UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) is among the world’s most highly-respected and authoritative regulators, second only to the Food and Drug Administration (FDA) of the US.

Currently, however, its focus has been on operating as part of the EU, where the European Medicines Agency is the primary regulator.

The MHRA currently undertakes more cross-border authorisation work in Europe than any other country-based institution and will flourish outside of the EMA system.

Post-Brexit, the UK will be better placed to target the world’s most lucrative pharma markets

Supremacy for the MHRA will be a major boost for the UK as it seeks to develop individual trade agreements and authorization arrangements with the US -the biggest market for pharmaceutical companies and the highest spender - and the Middle East and Asia — where the market is growing most rapidly.

Regulatory harmonization is key to trade agreements in the pharmaceutical industry and this will be simpler and quicker to agree on a one-to-one basis.

Some of the mid-market CEO's featured in the current Catalyst Pharma Fast 50 view this as the key to success.

Chris Watt, CEO of the winning company Qualasept Pharmaxo said: "The key to success post-Brexit will be the speed at which the MHRA can achieve the fullest regulatory harmonization, supported by the government agreeing on trade agreements with other territories.

This will provide an exciting opportunity for UK pharma which has a comparative advantage globally.”

The EU in any case, be anxious to agree on a mutual authorization deal for UK pharma

Given the strong track record of UK companies in developing life-saving and improving drugs and treatments - as well as the attractiveness of the UK marketplace and the need to prioritize patient safety - the EU is likely to prioritize a mutual authorization deal with the UK post-Brexit. This would mean UK companies do not lose out on sales to the EU.

The UK’s tax regime is especially favourable to the pharmaceuticals sector

The UK government has promised to reduce corporation tax to 17% by 2020, one of the lowest rates in any Western economy. Moreover, through tax efficient schemes such as the patent box and R&D credits, many UK pharmaceutical companies will pay an effective rate of between 11% and 13%

14. **Impact on Pharmaceuticals**

- The impact may be minimal for most pharma firms as the US is their bigger market, not Europe, after which comes to India.
- Apart from the currency volatility that will have a bearing on company financial, trade agreements between countries and whether the UK would now have a set of separate regulatory approvals, even if EU approvals are in place, have given rise to uncertainties.
- Pharmaceutical United States is India’s biggest market for Pharmaceutical exports, while EU accounts for 10-13% of India’s total ph exports. The share of UK in India’s pharma exports is about 3-4%.
- The pharma companies do not really expect a big hit following the Brexit and have indicated a limited impact of Pound depreciation. The pharma companies reported having hedged their exposure to the Euro.
- Further, the companies pointed out that the rules, regulations and product registrations are already different for the UK and EU and hence any adverse impact on the sector can be ruled out.

15. How can Indian Pharmaceutical Companies deal with Brexit?

- ➢ The UK has traditionally been among India's closest friends in Europe among the western countries and has been a traditional jumping pad for Indian companies entering Europe.
- ➢ Alongside, the UK's exit from the EU could trigger the need for a fresh regulatory policy between India, UK and EU regarding the Marketing authorization for Medicinal Product in the UK and EU.
- ➢ It will concern Products already marketed in the EU but also the new product development. India has been negotiating an FTA with the EU since 2007. Brexit will give Britain the freedom to manage its own affairs.
- ➢ people of Britain has been given the power of decision making of their country but Britain trade rules are bounded by European law. After Brexit Britain can negotiate the terms and condition of the trade with different countries.
- ➢ Britain imports more than it exports. Britain is a big economy and has low resources, hence it is depended on Europe, China and India for its imports. Europe has been providing free trade area to Britain until now.

16. Brexit implication on startups

The impact will be minimal on early-stage investments. Overall Indian start-up will not get hit from Brexit due to 100 per cent FDI in India. The rate of success that start-ups get after getting into the European market through Britain will be slowed down

Fig: 1.8 (show the relationship between Britain and India)

16.1. Impact of Brexit

- The UK has always been accessing point for business for Indian companies, being able to do business in the UK also provide access to the European companies. After Brexit, this window will get close.
- India exports to Britain at 17.66 per cent of the total exports, which includes textiles, clothing, machinery, jewellery etc, this export rate might decrease after Brexit.
- Indian companies that have exposure to the UK may get temporary hit because of Brexit
- The government of India has allowed 100 per cent FDI in India, this step can help India to become a major global finance market

Brexit coming into force the following may be the consequences:

- Rupee may depreciate because of the double effect of foreign fund outflow and dollar rise.
- Cheaper rupee will make Indian exports competitive
- Deloitte in May said India is the third largest source of FDI to the UK in terms of numbers of projects, with 122 projects encompassing inward investment in the last financial year, an increase of 65 per cent from the previous year, which leads to the creation of 7,730 jobs and protection of 1,620 jobs. According to the consultancy firm, key sectors attracting Indian investment include health-care, food, and drink.
- "There are an estimated 800 Indian owned businesses in the UK, including companies like Tata Motors, with more than 110,000 employees. Further, the UK is also India's largest G20 investor," it said.
- Brexit could force Indian companies to take note of the unwise decisions they've made. For historical and cultural reasons, India Inc. has had a bias toward investing in the U.K. India is now the third-largest source of foreign investment in the U.K.
- In fact, Indian companies invest more in the U.K. than in the rest of the European Union combined, despite the fact that Britain's economy is just 17.5 per cent of the whole EU.

From the Prime Minister of India

Narendra Modi said so himself in 2015, too often Indian companies have replaced a European strategy with a Britain-focused one. Brexit might force them to look harder at opportunities in the rest of Europe. Brexit might improve the conditions under which India trades with the U.K.

Annexure: India-UK Trade and Investment relations

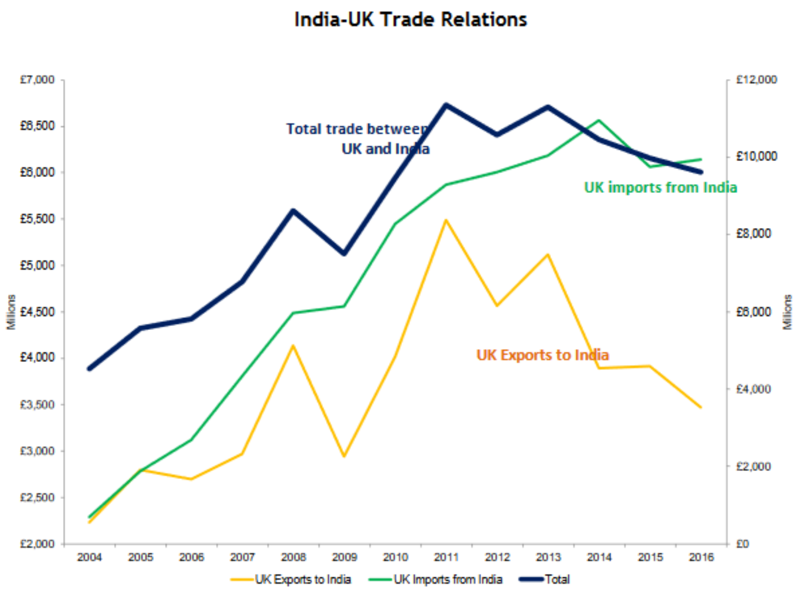

Fig:1.9. Trading relationship between India and The UK has described

CONCLUSION

The UK and the EU are losing trading partners in this process. So both will be looking for replacements. Here, India can play a crucial role. Moreover, Indian may get more attention with regard to investments made by the UK to take part in the Indian growth story.

Generic pharmaceuticals continue to face higher compliance costs. This is no longer seen as a defensive industry. India does seem to be able to expand its presence in chemicals substantially.

Be used in another and this is something very difficult to achieve and can provide Indian industry with a great advantage. Good governance will be the need of the hour to face the situation over the next few years.

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