PHARMACEUTICAL DRUGS INDUSTRY IN MALAYSIA: SUSTAINABILITY & COMPETITIVE MARKET

WAN LIZA MD AMIN[1], MAWADDAH MUNIRAH ZULFAKAR[2]

I BACKGROUND

In June 2022, the Malaysian Health Ministry (MOH) announces that preventive and correction is required to addresses medicine shortages in Malaysia. To date, the industry is heavily regulated with the major players in the pharmaceutical market in Malaysia i.e.Novartis, GlaxoSmithKline (GSK), Pfizer, Y.S.P. Southeast Asia (Y.S.P SAH), and Kotra Pharma. Pharmaceutical industry is a highly concentrated market. The Malaysia Medical Association (MMA) call upon the authorities to address shortage of medicine supply in the local pharmaceutical industry fast.The Covid - 19 experience warrant a upstream structure of oligopolistic structure which embodies the endogenous conditions with high barrier of regulatory , incumbent strategic behaviour and sunk cost problems. These barriers resulted into prevalent disruptions in drugs supplies in the upstream and downstream market . The disruption causes trickling effects on the consumers and other stakeholders in Malaysia market. The market is further burden with low to non -competition process in the upstream and downstream market This paper examine on how the sequencing of competition can be introduced in the present pharmaceutical market

[1] The author is Professor (associate) Dr. presently deputy director of nexus research University Technologi Mara, head of the Competition law and Policy, former Malaysia Competition appeal tribunal, received her SJD from University Wisconsin , Madison. USA. She is a faculty member of the law school at University Technology Mara, Shah Alam, Selangor Malaysia. Advocate & solicitors High Malaya (1996).

[2] The author is a PhD Candidate of Competition Law from the Institute of Post Graduate Studies, University Teknologi MARA, Malaysia. The author is also a former Law Lecturer from Multimedia University Melaka, Malaysia and a Legal and Intellectual Property Executive of Boon Siew Honda Sdn. Bhd.

structure. A competitive market structure that promotes allocative, productive and dynamic efficiency in the supply chain . The competition framework structure should address collusion, abuse of dominant position exclusive dealings practices which have the cause- effect of prices hikes, shortages, cartel. This efficiency will translate to low barriers among incumbent and new market players, greater choices of drugs cheaper medicine prices. Documentary examination shows, to date, present pharmaceutical market structure divided between Levels 1, 2 and 3 that represent monopolistic and oligopolistic structural framework. To enhance competitiveness and creating a sustainable sector, deregulation and restructuring competition in the market's segments in the pharmaceutical sector. This article adopts thematic and qualitative analysis to generate data on the transition from oligopolistic to a competitive market structure. The competition process data revealed that competition in the market would address present impediments. This study employs a qualitative method from literature analysis and distribution of online questionnaires. Comparative method examination from other jurisdiction such as United States and European Union experiences and lessons also form part of the parameters of this article. The findings in our study proposes stakeholders mutual benefits and relevant with the Malaysia National Medicine Policy 2017-2021 , Healthcare White paper system and the Malaysia Digital economy blueprint 2030. This study concludes our findings with our competitive market structure framework and harmonization of competition policy tool and patents rights.

II INTRODUCTION

On Monday 15th of august Health minister Mr Khairy called upon a collective country of intent asking for "A whole government", "A whole society " mindset. The Health Minister said that the Covid 19 pandemic had brought into sharp focus the need for healthcare reforms, where never

before had the interdependence of health, finance and the social fabric been so visible and the demand for healthcare reforms been more apparent for the health and social needs of the people (The star, 15/8). Recent report also discloses local pharmaceutical barriers, current drugs supply market abuses and its consequentially effects on the consumers welfare. This article presents an analysis on how a competition law and policy tools complements Malaysia Healthcare system, Malaysia Medicine policy (2017-2021) and other emerging policies such as the Malaysia Digital Economy Blueperint 2030. It is widely accepted that competition law and policy are fundamental for ensuring a well-functioning economy (OECD report, 2022). However, the competitive policy delivers the desired effects, in the form of lower prices, increased input and dynamic innovations, only if they are effectively implemented and enforced. Hence, this article's will discuss the constraints, necessary competition endogenous conditions i.e. deregulation process of level 1 -3 of the supply chain, harmonisation of the patent rights and competition law and policy, and last but not least commitments that be imposed or accepted and aims to focus on a workable competitive model to generate the desired results.

The consideration on competition measures have to inline with the the pharmaceutical industry heavily regulated nature. The deregulation to include competition processs in its market structure takes into consideration all aspect of the life -cycle of new drugs. The life cycle of new drugs are regulated, from patent application, to marketing approval, commercial exploitation, patent expiration and competition with generics. All the important actors in the pharmaceutical industry – the manufacturers, wholesalers, retailers, and prescribing physicians are also subject to regulatory controls. These regulatory controls pursue three primary objectives: (a) preserving the incentives for research and development and the flow of new innovative drugs; (b) ensuring the safety of drugs consumed by the public; and (c) controlling the quantity and

quality of drug expenditures. Thus, in this study, deregulation includes both the structural and harmonization of intellectual property rights i.e. patent rights .

Healthcare sector comprises of firms from various industries such as pharmaceuticals, medical devices, patient care, facilities, distribution, equipment, and biotechnology (Anthody Ladeesma et al, 2015). The COVID-19 lessons brought about an increased awareness and the required strategic and workable regulatory measures to secure fair competition process in existing market. Malaysian pharmaceutical market structure is identified as oligopolistic (Chong Hooi Ying, Chan Tze Haw, 2014). Oligopolistic pharmaceutical market consists of few dominant firms, interdependence between firms, collusive market and have a high entry and exit barriers. These characteristics carries the risk of fostering anti-competitive coordination between market players (OECD, 1999) which can affect consumer welfare. This study observes sector-based solution that can secure the transition from oligopolistic to competitive pharmaceutical market.

The medicine supply issue in 2022 are due to global pandemic. Malaysia preparedness against the supply shortage is not sufficient. This is because of Malaysia's reliant to imports. It requires the corrective and preventive action from the government (Amrahi Buang, 2022). A heavy reliant to the supply from foreign firms carries the risk of disruption due to global instability. Furthermore, the global situation was affecting the imports of both the finished products as well as raw materials of pharmaceutical products. Thus, the supply and demand situation must be corrected soon (Dr Koh Kar Chai, 2022).

Pharmaceutical is a highly regulated sector (Shweta Handoo et al, 2012). The supply chain is divided into three levels (MyCC, 2017). Pharmaceutical is a highly regulated sector (Shweta Handoo et al, 2012).

The supply chain is divided into three levels (MyCC, 2017) and each of the levels are under the watchful eyes of different ministries and regulatory bodies (collectively known as the 'authorities') for example Malaysia Competition Commission (MyCC), Malaysian Intellectual Property Commission (MyIPO), Ministry of Health (MOH), National Pharmaceutical Regulatory Agency (NPRA) and Ministry of Domestic Trade and Consumer Affairs (MDTCA).

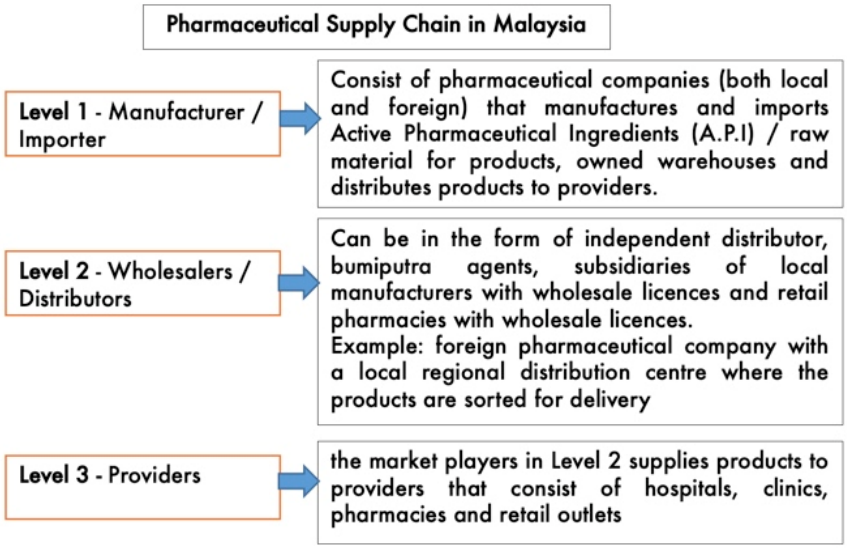


Diagram 1: The diagram showed the structure of Pharmaceutical Supply Chain in Malaysia.

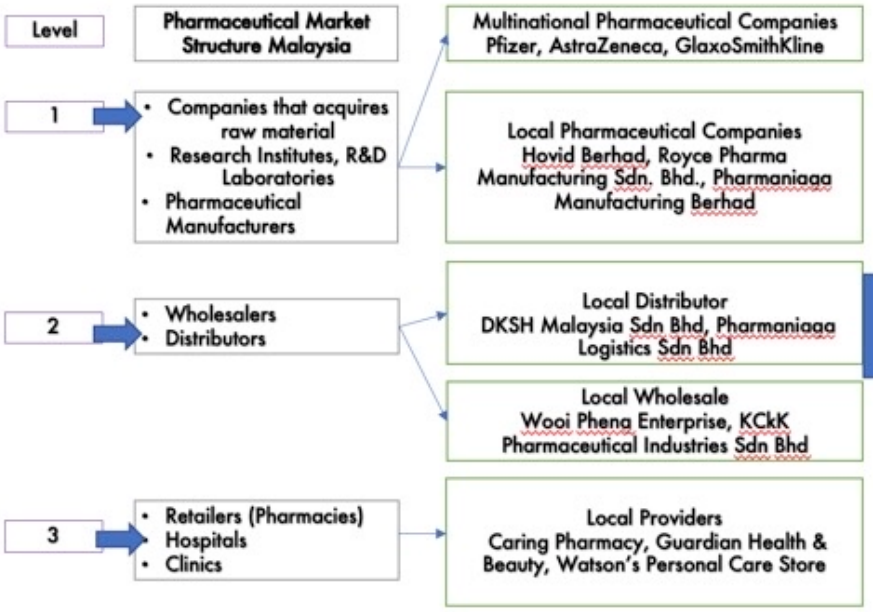


Diagram 2: The diagram showed the example of pharmaceutical firms involved in each level of the supply chain (NPRA, 2022), (MyCC, 2017).

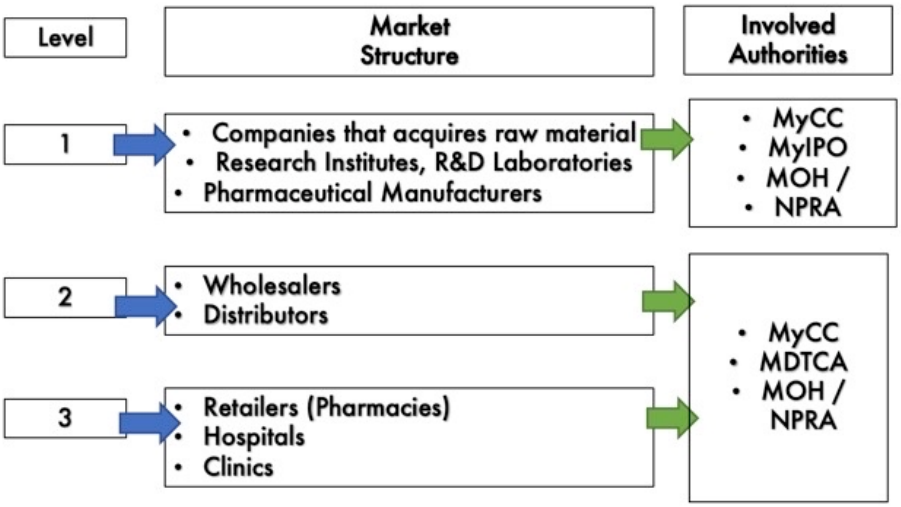


Diagram 3 : The diagram showed the involved authorities in the different level supply chain of the Malaysia pharmaceutical market structure.

Each authorities have defined regulatory, and administrative regulations relating to safety, efficacy and information for the production of a high

quality product (Pierre-Louise Lezotre, 2014). From the discovery of raw materials to production, and distribution, each level is subjected to several quality assurance and certification procedure, patent and product registration, clinical trials, to ensure that products are safely created and delivered to patients (David Taylor, 2015). The complex process somehow becomes a barrier to entry of new market players together with the anti-competitive conduct of incumbent firms. The constraints affect dynamic, innovative, and allocative efficiencies in a pharmaceutical sector (Marina Papalexi et al, 2020).

Due to many layers of the market, product price is marked up at every level (Lim Chee Han and the Penang Institute, 2019). The high price is also contributed by the fact that some pharmaceutical products are patent protected, which the firms are taking advantage of patient's needs. As a result, pharmaceuticals become inaccessible to patients especially lower income group on out-of-pocket expenses (S. M. Mohamed Idris, 2017). The common justification given by the firms is to recoup investments spent for each product.

The conduct of incumbent firms can also influence the market structure of a specific sector. In the United States, Food and Drugs Administration (FDA) controls the market entry for innovators, generics, and follow-on inventions. Incumbent firms producing innovator product contain the financial incentives have the potential to influence regulation and requirements that can complicate future entry of new firms. (Fiona Scott Morton, Lysle T. Boller, 2017). In this situation, regulation has become a barrier to competition. Only few dominant firms can sustain their business and utilised their market power to the disadvantaged of downstream market players. For example, strategies from incumbent firms to delay the entry of generic and follow-on inventions from the act of manipulating the patent system to unfairly extend market exclusivity (Gupta, H. 2010).

These inefficiencies subsequently affect pharmaceutical research and development to be to be unsustainable (James Mittra *et al*, 2011).

The inefficiencies also les to the pharmaceutical drug discovery and development model to be unsustainable (James Mittra *et al*, 2011). Pharmaceutical sector depended on innovation to sustain and accommodate the health needs of the consumers. The primary goal in innovation is to enhance efficiency, shorten the drug development process time, and reduce costs (Yong Chan Kim et al, 2022). The proposal to deregulate the pharmaceutical sector trough eliminating restrictions to the law (OECD, 1997) is expected to enhance dynamic and innovative efficiencies from the availability of multiple substitutes from suppliers (Lim Chee Han and the Penang Institute, 2019).

The structure of this paper is Part 1 of this paper will discuss on the position of competition law, and existing constraints in the pharmaceutical sector in Malaysia. Part 2 explains on deregulation and competitive market. Part 3 puts forward the recommendation for the stakeholders. The documentary analysis reiterates, the implications and effects towards market conduct and relevant agencies.

III METHODOLOGY

The present study applies qualitative methods to answer on competitive market structure through 3 levels deregulation. Secondary data are obtained from literature analysis on Malaysian and comparative analysis with United States and European Union. Primary data are collected through online questionnaire survey that was distributed to the respondents via google form. The response from the questionnaires is analysis through SPSS statistics. This research has collected 106 responses.

Primary data are collected through online questionnaire survey (Virginia Braun *et al*, 2021) that was distributed to the respondents via google form.

The 106 responses from the questionnaires is analysed through SPSS statistics. The demographics of respondents are as per below.

Gender

Male	49.1%
Female	58.1&

Marital Status

Single	63.8%
Married	32.4&
With Dependence	3.8%

Education

High School	2.9%
A-Level & Matriculation	14.3%
First Degree and above	82.9&

Occupation

Government Employee	14.2%
Private Sector Employee	30.2%
Self-Employed	2.8%
Student	51.9%

Retiree	0.9%

IV MATERIAL AND RESULTS

Part 1: Competition Law and Policies, and constraints in pharmaceutical sector

Malaysia dual health care system comprises of public and private sector. Based on the Market Review (MyCC, 2017), the pharmaceutical market reveals that 75% of the local pharmaceutical products are imported innovator and generics manufactured from India, China, US, Australia, France, Germany, and the UK. The 75% percentage illustrates only 25% of the drugs in the market are from local firms. (UNCTAD, 2016). The heavy reliance on imports is twofold (1) foreign MNC produces innovator produces and Malaysia, abiding by the patent protection, to procure only innovator product and (2) procures cheaper alternatives of generics from other countries. In this sector, competition law and policies play a role ensuring competitive process between firms producing both innovator and generic product.

A The Malaysia Pharmaceutical Current Market Structure Issues

The present 3 structure levels of Malaysia Pharmaceutical Sector are presented in the diagram below.

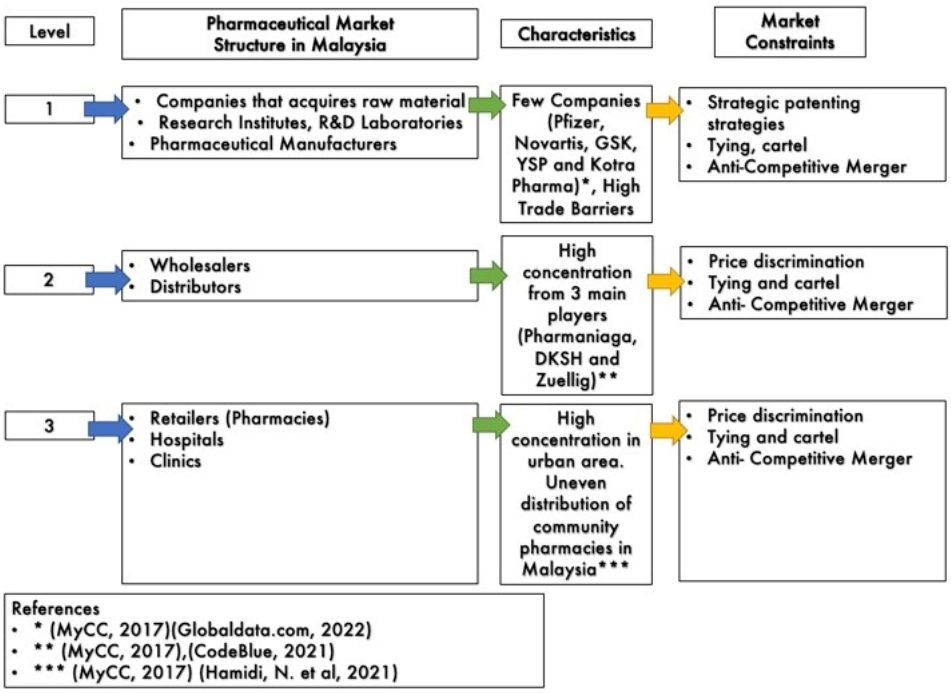


Diagram 4: This diagram showed the characteristics of each level of supply chain and the existing market constraints.

The component of market players in level 1, manufacturing and importers dominated by multinational corporations (MNC) and major dominant local firms (PhAMA, 2018). The firms obtain raw materials, undergo research and development to product either innovator or generic pharmaceutical products. Only a handful of firms possessing the capacity to become manufacturers which indicates the small number of dominant firms exist in the market especially in level 1. The present issue in this level is the complex regulatory requirements that becomes barriers to entry (OECD, 2005). Simultaneously, there exist collusion risk associated with anti-competitive behaviors (strategic patenting strategies, tying, cartel, unfair clauses, and mergers) by the players at this level will have direct impact towards the downstream market. Output restriction and price increase (Hassan Qaqaya, George Lipimile, 2008).

Level 2 saw the manufactured products from manufacturers are obtained by wholesalers and distributors. Similar issue arose in level 2, which is few players. Can comprise of manufacturer's owned subsidiary company or independent company. Four categories of wholesalers and distributors were identified: large independent distributors, Bumiputera agents, wholesalers and distributors that are subsidiaries of manufacturers, and retail pharmacies that also do wholesale. Despite the large number of players, this market is highly concentrated. Dominant firms enjoy oligopolistic power, exercise a high degree of control over prices, reap high profit margins and are disposed to engage in anti-competitive conduct (MyCC, 2017).

Level 3 consist of providers supplies drug to consumers and patients through hospitals, clinics, and pharmacies Procures the supply from wholesaler and distributors. There is some degree of vertical integration, all downstream, among the large pharmaceutical manufacturers. All the manufacturers import active pharmaceutical ingredients and other raw materials. Major firms have their own warehousing and distribution firms and market and sell directly to pharmaceutical providers. The market is highly competitive. Anti-competitive conduct by firms, by selling to different providers at different price (MyCC, 2017). Investigation against several pharmaceutical firms' possible infringement of competition act, lack of evidence (MyCC, 2020).

Collusion by market players brings about double jeopardy for the patient, for example in bid rigging, the conduct lessens competition in the market especially when it involved procurement contracts in both public and private sector. Second, as the participating firms may set up to bid at almost the same price that are higher than the reserve price, it increases the tender costs and thus affects the overall expenditure to acquire the supply of

products (Antonio Miño López, 2019) . Furthermore, the practice would make it difficult for new firms to enter a certain market which are controlled by a cartel, and further from the act of refusal to supply to non-cartel members.

firms that want to manufacture, distribute the product, or import pharmaceuticals, are required to obtain approvals relevant agencies through licenses, and certifications. Each application is required to be accompanied by proper documentations, licensing, and renewal fees (NPRA,2020) including patent registration in Malaysia and overseas (MyIPO). The complexities contribute to barriers that complicates the entry of new players. Furthermore, the anti-competitive interaction between market players reflects a form of abuse of dominant position. Collusive action by certain players makes the level becomes concentrated which fulfills the characteristic of oligopolistic market. The long-term effect of this market structure will contribute towards an unsustainable pharmaceutical sector.

B *Competition Law and Policies*

Competition law and policy applies regulatory measures or standard to ensure competitive conduct by market players (OECD, 1999). Malaysia Competition Law 2010, United States Sherman Act & Clayton Act, and European Union's Treaty of Functioning of the European Union, has the symmetrical impact of upholding the competition process between firms by prohibiting anti-competitive conduct. Sections 4 and 10 of Competition Act oversees on any possible infringement from horizontal and vertical agreements and abuse of dominant position.

Specialized Commission are in place for investigation which are MyCC for Malaysia, the Federal Trade Commission for the United States and National Competition Authority (NCA) together with European Commission. in Malaysia appeal can be made to the Competition Appeal Tribunal (CAT). The level playing field encourages firms to be efficient, creates a wider choice for consumers and helps reduces prices and improve quality. The generated efficiency from a competitive market ensures low prices for all, better quality of product, and greater choice for consumers. This is the result of innovative efficiencies and efficient allocation of resources. Benefits not only towards consumers but also stakeholders (European Commission).

In the United States pharmaceutical sector, generic and biosimilar products (categorized as follow-on inventions) pose a threat to the patent holder or innovator product. Existing firms with financial incentives have the capacity to influence regulation to make entry of new pharmaceutical firms harder and difficult. Subsequently, regulations become a barrier to entry (Fiona Scott Morton, Lysle T. Boller, 2017). In European Union, inconsistencies between international and national regulatory requirements, posed a form of trade barrier. From an identified barrier with China, the European Commission stated that "*There is a need for further alignment of the pharmaceutical regulatory system with international standards and practices. Current main concerns relate to new pharmaceuticals approval process; pricing and reimbursement policies*." (European Commission, 2019).

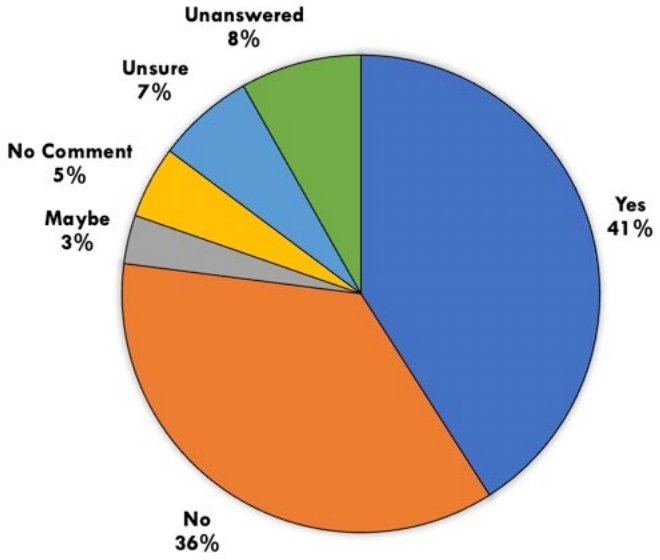
Intellectual Property (IP), especially patent, are largely involved in the pharmaceutical sector from the aspect of patent ownership on the active ingredients, the involved processes, and formulations. Furthermore, the patent can be in the form of primary patent for first novel inventions and

secondary patent for incremental innovations (Olga Gurgula, 2020). By allowing the patent grant for slight modification from the primary patent, there has been an increase of patent application for secondary patent. Strategies to delay the entry of new players and unduly the market exclusivity of the primary patent, for example the active ingredient ((Gupta, H. 2010). IP limits competition from the monopoly rights and consumers are at a disadvantage for having to pay high cost to use the invention. On the other hand, competition law removes impediments that restricts fair competition that may affect consumer welfare. Both laws are complementary in promoting innovation and efficiency in effective market operation for economic and consumer welfare. The exercise of rights under both IP and Competition Law should be towards maximising consumer welfare by increasing accessibility of the inventions. This can be achieved by expanding the access of health care to low-income populations (M. Deen Islam *et al*, 2019). Implementation of regulation and policies should encourage competition between market players to produce affordable alternatives without jeopardising innovation (Outterson, K., 2005). The dynamic allocation of resources would benefit the consumers by the ability to obtain necessary products at a lower price (OECD, 1998).

United Nations Conference on Trade and Developmen through a session Intergovernmental Group of Experts on Competition Law and Policy in July 2022, puts forward the discussion on "rethinking competition law enforcement lessons learned from the pandemic, particularly in socially important markets – challenges and opportunities for an effective response during the pandemic and economic recovery in the post-pandemic period" (UNCTAD, 2022). The competition authorities have introduced changes in administration and law enforcement to respond to the implications of the pandemic especially on essential supplies of PPEs and essential medicines. Government is pushed to protect the competition process

through necessary regulatory measures (UNCTAD, 2022). The discussion also highlighted the need of countries to prepare for supply disruptions in the future that can affect essential needs of the people. Balance has to be introduced between public and private interest to ensure sustainability of the pharmaceutical sector.

On of the question from the online questionnaire is "Do you think that the current pharmaceutical market structure is fair and provide equal opportunities to all market players to succeed?". The response received are 41% agrees to this while 36% responded 'No'. Fair opportunities for all market players to succeed is pertinent to indicate the level playing field from that sector and to ensure that there is no abuse of dominant position by firms.



C *Anti-Competitive Behaviors by Firms*

In Malaysia, the Commission Competition investigated seven local pharmaceutical firms in 2016 over allegations of discriminatory conduct of the firms in favor of general practitioners (MyCC, 2017). The then CEO of MyCC stated that the wholesalers are charging different prices of medicines to suppliers that becomes the main problem (Bernama, 2016). Based on the statement by MyCC, the investigation on abuse of dominant position requires the assessment on the dominant position based on Anatomical Therapeutic Classification (ATC) the dosage form, routes of administration and side effects of the drugs. The investigation however was discontinued due to insufficient evidence (MyCC, 2020).

Effects of patentee's behaviour infringements of competition law is best explained by the UK Competition and Markets Authority (CMA) published statement; after case reassessment, the CMA has provisionally found that Pfizer and Flynn has abused their dominant positions by overcharging the National Health Service (NHS) for vital anti-epilepsy drugs. The CMA Chief Executive said:

> "*Thousands of patients depend on this drug to prevent life-threatening seizures as a result of their epilepsy. As the CAT recognised, this is a matter that is important for government, for the public as patients and taxpayers, and for the pharmaceutical industry itself. Protecting these patients, the NHS and the taxpayers who fund it, is our priority*."

The 5th August 2021 reports, having gathered further evidence and after carefully assessing the facts, the Competition and Markets Authority (CMA) has reached a provisional view – known as a Statement of Objections – that Pfizer and Flynn broke competition law by charging unfairly high prices for phenytoin sodium capsules. The CMA has provisionally found that the firms exploited a loophole by de-branding the

drug – known as Epanutin prior to September 2012 – with the effect that the drug was not subject to price regulation in the way branded drugs are. As Pfizer and Flynn were the dominant suppliers of the drug in the UK, the NHS had no choice but to pay unfairly high prices for this vital medicine.

Following the overnight price increases by the firms, NHS spending on phenytoin sodium capsules rose from around £2 million a year in 2012 to about £50 million in 2013. For over 4 years, Pfizer's prices were between 780% and 1,600% higher than it had previously charged. Pfizer then supplied the drug to Flynn, which sold it to wholesalers and pharmacies at prices between 2,300% and 2,600% higher than those they had paid previously. In December 2016, following an in-depth investigation, Pfizer and Flynn were both fined by CMA for infringing competition law by charging unfairly high prices for phenytoin sodium capsules.

The case illustrates two patentee firms Pfizer and Flynn anti – competitive behaviour, Philip Marsden, Chairman of the Case Decision Group for the CMA's investigation, said:

1. The firms deliberately exploited the opportunity offered by de-branding to hike up the price for a drug which is relied upon by many thousands of patients. These extraordinary price rises have cost the NHS and the taxpayer tens of millions of pounds.

2. Businesses are generally free to set prices as they see fit but those holding a dominant position should not abuse this situation and set prices that are excessive and unfair. There is no justification for such rises when phenytoin sodium capsules are a very old drug for which there has been no recent innovation or significant investment.

3. This is the highest fine the CMA has imposed and it sends out a clear message to the sector that we are determined to crack down on such behaviour and to protect customers, including the NHS, and taxpayers from being exploited.

4. Although Pfizer has claimed that Epanutin was loss-making before it was de-branded, the CMA has calculated that, according to Pfizer's figures, all such losses would have been recovered within 2 months of the price rises.

5. In order to ensure that there should be no risk to the ongoing supply of phenytoin sodium capsules to those patients who rely on it, the CMA has given Pfizer and Flynn between 30 working days and 4 months to reduce their respective prices. Both firms will continue to be able to charge prices which are profitable, but their prices must not be excessive and unfair.

6. CMA has imposed a record £84.2 million fine on the pharmaceutical manufacturer Pfizer, and a £5.2 million fine on the distributor Flynn Pharma after finding that each broke competition law by charging excessive and unfair prices in the UK for phenytoin sodium capsules, an anti-epilepsy drug. The CMA has also ordered the firms to reduce their prices.

7. The fines follow prices increasing by up to 2,600% overnight after the drug was deliberately de-branded in September 2012. For example, the amount the NHS was charged for 100mg packs of the drug rocketed from £2.83 to £67.50, before reducing to £54.00 from May 2014. As a result of the price increases, NHS expenditure on phenytoin sodium capsules increased from about £2 million a year in 2012 to about £50 million in 2013. The prices of the drug in the UK have also been many times higher than Pfizer's prices for the same drug in any other European country.

"Phenytoin sodium *capsules are used in the treatment of epilepsy to prevent and control seizures, and are an important drug for an estimated 48,000 patients in the UK. Epilepsy patients who are already taking phenytoin sodium capsules should not usually be switched to other products, including another manufacturer's version of the product, due to the risk of loss of seizure control which can have serious health consequences. As a result, the NHS had no alternative to paying the increased prices for the drug".*

Prior to September 2012, Pfizer manufactured and sold phenytoin sodium capsules to UK wholesalers and pharmacies under the brand name Epanutin and the prices of the drug were regulated. In September 2012, Pfizer sold the UK distribution rights for Epanutin to Flynn Pharma, which de-branded (or 'genericised') the drug, meaning that it was no longer subject to price regulation. Since September 2012, Pfizer has continued to manufacture phenytoin sodium capsules and has supplied them to Flynn Pharma at prices that were significantly higher than those at which it previously sold Epanutin in the UK – between 780% and 1,600% higher than Pfizer's previous prices. Flynn Pharma then sells on the products to UK wholesalers and pharmacies charging them prices which have been between 2,300% and 2,600% higher than those they had previously paid for the drug.

The final decision and fines relate to both the prices that Pfizer has charged to Flynn Pharma and the prices that Flynn Pharma has charged to its customers, since September 2012. The CMA has found that both firms have held a dominant position in their respective markets for the manufacture and supply of phenytoin sodium capsules and each has abused that dominant position by charging excessive and unfair prices. Even though, Pfizer has claimed that Epanutin was loss-making before it was de-branded, the CMA has calculated that, according to Pfizer's figures, all

such losses would have been recovered within 2 months of the price rises. In order to ensure that there should be no risk to the ongoing supply of phenytoin sodium capsules to those patients who rely on it, the CMA has given Pfizer and Flynn between 30 working days and 4 months to reduce their respective prices. Both firms will continue to be able to charge prices which are profitable, but their prices must **not be excessive and unfair** (Gov.UK, 2021).

V DEREGULATION, COMPETITIVE MARKET AND SUSTAINABILITY

WHO has urged countries to provide free or affordable access of essential medicines to the people through amendments of national laws or constitutions as a form of right to health. The biggest stakeholder in the healthcare sector is the consumer, that is the payer for all prescribed pharmaceuticals and healthcare services for personal or household usage (Zeti Zuryani, Rahmah Ismail, 2017). For high income populations, the high cost of health care will not be an issue. However, it will pose a threat to low-income populations as health care expenses are mostly out-of-pocket expenditure especially in the absence of universal healthcare (S. Vinvent Rajkumar, 2020).

As mentioned in Part 1, regulatory complexities led to barriers to entry. Deregulation is seen as an alternative to decrease the limitation and restriction imposed on manufacturing and marketing activities. National and European legislation utilised pharmaceutical deregulation to obtain economic advantages (Marchetti, M., & Minghetti, P.,1989). Deregulation is expected to contribute to a competitive market. In European Commission, the impact of deregulation of community pharmacies saw an increase in access to pharmacies which is attributable to populations with

already good accessibility. It was proposed by the researcher that policymakers must ensure equitable access and sustainable competition in the sector (Sabine Vogler *et al*, 2014). This paper highlights the need of simplifying or eliminating any complex regulatory requirements that are redundant and encourage data sharing between agencies for speedy approval process. For example, increasing the threshold for patent to ensure that only primary and inventions that fulfills the need for novel invention, inventive step and industrially applicable are granted a patent. Inventions with incremental inventions should be scrutinised accordingly. The long-term aim of this proposed reform is for a competitive and sustainable pharmaceutical sector from deregulation.

Evelien Wynendaele *et al* (2021) puts forward 10 sustainability principles in drug discovery and the five principles that is relevant for this paper is on medical needs, root cause of illness, artificial intelligence and big data, cost-effective, and responsible research, and innovation.[3] These five principles co-relate with the aim of innovation in pharmaceuticals. The time spent on development can be reduced by incorporating digital technologies that are different from the existing drug development processes. One example is the development of various vaccines against COVID-19. The recent pandemic shows how collaboration that embed digital technology was significantly improved and activated with COVID-19 (Yong Chan Kim et al, 2022).

The importance of competition law and policies, deregulation to contribute towards innovative efficiencies for a sustainable pharmaceutical sector. Improvement led to competitive market, availability of multiple substitutes

[3] The other five sustainability principles by the author are ecological-environmental impact (benign-by-design), green chemistry, risk and decision-taking models, biomarkers and bioinformatics to support precision medicine, and lastly lean discovery process.

and affordable and accessible pharmaceutical products. At the national level, the harmonisation of functions between competition authorities, enforcement agencies, pharmaceutical market players and policymakers are necessary to prevent possible anti-competitive practices at each level of supply chain for the benefits of consumers from both public and private sector (UNCTAD, 2015). The enforcement efforts by relevant agencies warrants the protection of consumer against the anti – competitive behaviors of market players. A highly competitive market would protect consumer welfare as dominant players has less monopoly over market and products (Noriah Ramli *et al*, 2017). The effect of fair competition would lower the prices of products and services to an acceptable level that can be afforded even by lower income populations. Furthermore, the constant market observation by the enforcement agencies for patent and competition, to prevent anti-competitive behaviors that would jeopardise consumer welfare.

VI CONCLUSION

Part 3: Recapitulations and Recommendation :

Malaysia Sustainable Competitive Pharmaceutical Market

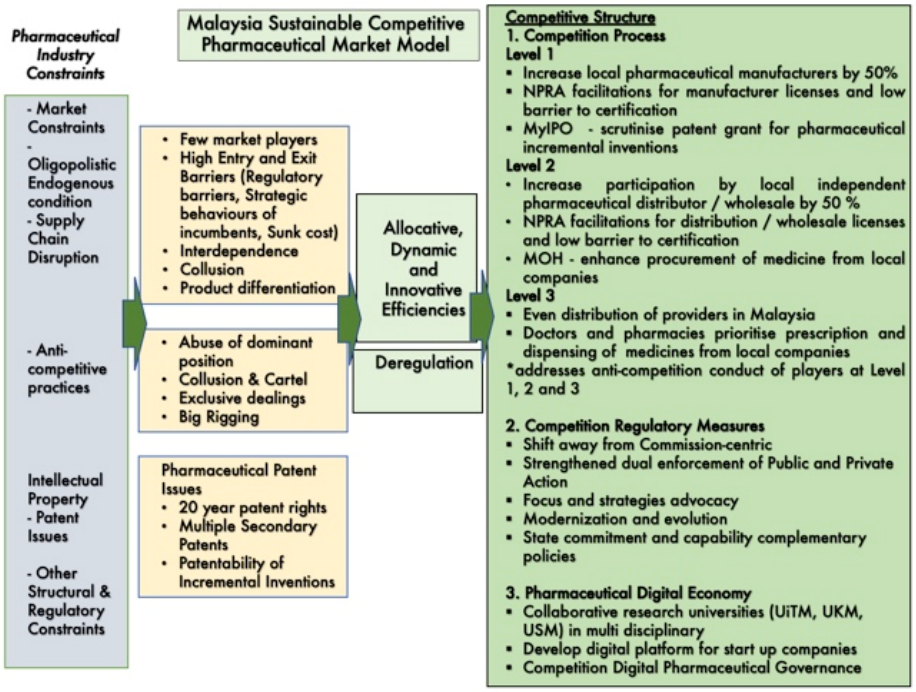


Diagram 5 : This diagram explains the Malaysia Sustainable Competitive Pharmaceutical Market Model

The Competition policy tools provide the structural and enforcement mechanisms to ensure medicine supply, greater drugs innovation and lower prices to the all stakeholders . The deregulated competitive framework is able to address short- and long-term challenges by providing the inclusion elements to present incumbent and potential market players. The new competitive process in each level is protected by the existing regulatory framework i..e. competition act 2010 and competition authorities .This study framework's proposes a regulatory capture with the harmonization of patents rights and competition policy objectives , this framework is not a panacea to all problems in the industry . It is a a novel analysis to achieve sustainability by applying competition law and policy tools. This in turn we hope will generate a resilient pharmaceutical competitive ecosystem mutual benefits to consumers and industry players.

1. Competition framework - Deconstructing level 1, 2 and 3 market structure, increase the number of competitors in level 1 and 2 will provide the much-needed increased competitive ecosystem to generate the three efficiency benefits of competition law. The upstream and downstream market shifts from 'monopoly' of level 1 market players in the upstream high market share in downstream as market player via subsidiaries firms. This competitive market structure in level 1 eliminates and balances market power and results more IPs in non-exclusive license that would generate more biomedicine creations. This also benefits businesses as extension of patent rights in generic use of drugs incentives new entrant. High market barrier entry limits innovation in R&D Level 2 oligopolistic would benefits from more competitors as accessibility will generate high market power in a few existing firms. Oligopolistic constraints create disruption in the supply, choices and price collusion and manipulations. A level playing field in this level will also generate the much-needed efficiency in greater choice and better-quality drugs supplies.
2. Shift away from Commission -centric -The importance of Institutional arrangement that determine state of competition and its jurisdiction. The content of rules, doctrines, or policies are the consequences of choices made by various institutions entrusted with implementing regulatory programs. It is impossible to access the origins of doctrine or evaluate its quality without accounting for the design, capability, and diversity of the relevant implementing institutions, for the quality of institutional arrangements often governs the effectiveness of a regulatory regime. A jurisdiction that is attentive to the role of institutional arrangements in shaping substantive policy will want to redefine the role of its competition

policy and alter the focus of their activities in three basic ways. The first is to adopt a view of competition policy that encompasses the full range of policies and institutions that determine how the acquisitions and exploitation of IPRs affect competition. The second is to expand the capacity of the competition agency, chiefly by enhancing the agency's knowledge of commercial and regulatory phenomena that determine competition in sectors in which intellectual property is significant. The third is to build relationships between the competition agency and other government institutions whose decisions are element of a jurisdiction's competition policy for intellectual property.

i. Building CA institutional capacity
ii. Institutional Cooperation and coordination
iii. Revolutionize dual enforcement private and public better deterrence system.

3. Strengthened dual enforcement: Empowerment of Private Actions enforcements- The CA has embodied dual enforcement system however to date the enforcement is confined to Section 60 administrative remedy. Section 64, private action remedies is yet to be developed. Studies have shown maximization of the dual regime creates broader and stronger enforcement strategies. The private action in follow-on and stand-alone actions provides four interrelated goals. The goals remedy the losses and harm suffers by victims of violation of competition laws. There are vast studies in efficacy of dual or mixed enforcement regulates patents infringement of competition law.
4. Focus and Strategies Advocacy- programs to all stakeholders. Increase awareness programs should be a shares responsibility and customized in accordance to stakeholder's institutional objectives.

5. Modernization and evolution – The eleven years in competitive culture categorizes the nation as one of the emerging authorities. Sequencing strategic economic liberalization, guidelines and regulatory measures would assist stakeholders in anticipates new and potential challenges in this sector.
6. State commitment and capability complementary policies – perhaps the most important ingredient in planning the growth of competition culture and managing, balancing strategic competition market behaviors regulation. As without the policy makers, and government will and commitment, the challenges in this sector are subjects to high risks, the most important value i.e. human life.

VII ACKNOWLEDGEMENT

This research received funding from Geran Khas UiTM. The authors would like to thank the love and support from our loved ones.