Vol. 05 No. 02, Agustus 2007

ISSN1693-3591

PHARMACY

JURNAL FARMASI INDONESIA
Pharmaceutical Journal of Indonesia

ISSN 1693-3591 Volume 05 No. 02 2007

Mitra Bestari:

Prof. Dr. Djoko Wahyono, S.U., Apt.

Dr. Tjiptasurasa, S.U., Apt.

Dr. Sabikis, Apt.

Dewan Penyunting:

Dr. Asmiyenti Djaliasrin Djalil, M.Si. (Ketua)

Dr. Nunuk Aries Nurulita., M.Si., Apt.

Suparman, M.Sc., Apt. B

inar Asrining Dhiani, M.Sc., Apt.

Githa Fungie Galistiani, M.Sc., Apt.

DAFTAR ISI

POTENSI KETOKSIKAN DERMAL AKUT PRODUK KOSMETIK	
YANG MENGANDUNG 2% BENZOFENON-3 PADA KELINCI PUTIH	
JANTAN	63-73
Nenik Kusuma Dewi	
GLOBAL PHARMACEUTICAL INDUSTRIES, DRUGS EPLORATION	
AND PATENTING: IMPACT ON DEVELOPING COUNTRIES	74-83
Ari Satia Nugraha	
AKTIVITAS ANTIOKSIDAN EKSTRAK DAUN Garcinia celebica	
Linn (KANDIS) 84-89	
Madyawati Latief, Supriyatna Soetardjo, Husein H. Bahti	
dan Dachriyanus	
PENGARUH KUALITAS PELAYANAN INFORMASI OBAT	
TERHADAP KEPUASAN PESERTA AKSES RAWAT JALAN DI	
RUMAH SAKIT UMUM DAERAH (RSUD) PURBALINGGA	90-99
Indri Hapsari, Iskandar Sudriman, Kristy Yulina Vita	
PENGARUH LAMA PENYIMPANAN TERHADAP PENURUANAN	
KANDUNGAN VITAMIN C PADA JAMBU BIJI (<i>Psidium guajava</i>	
Linn)	100-105
Yeni Uami Dewi, Sumantri dan Pri Iswati Utami	
KOMPONEN UTAMA FRAKSI AKTIF ANTIBAKTERI DARI KULIT	
BATANG KANDIS GAJAH (<i>Garcinia griffithii</i> T. Anders)	
TERHADAP BAKTERI UJI PENYEBAB DIARE Escherichia coli DAN	
Shigella dysentriae	106-112
Elfita, Supriyatna, Husen H. Bahti dan Dachriyanus	
VALIDITAS PENETAPAN KADAR TEMBAGA DALAM SEDIAAN	
TABLET MULTIVITAMIN DENGAN METODE	
SPEKTROFOTOMETRI UV-Vis	113-119
Wiranti Sri Rahayu, Asmiyenti Djaliasrin Djalil, Devi	
Ratnawati	
PENGARUH PEMBERIAN VITAMIN C TERHADAP KADAR	
KOLESTEROL TOTAL SERUM TIKUS JANTAN HIPERLIPIDEMIA	
SETELAH PERLAKUAN JUS LIDAH BUAYA (Aloe vera Linn)	120-130
Endang Sri Sunarih dan Slamet Pamuji	

GLOBAL PHARMACEUTICAL INDUSTRIES, DRUGS EXPLORATION AND PATENTING: IMPACT ON DEVELOPING COUNTRIES

Ari Satia Nugraha¹

¹Corresponding author (email: arisatia@yahoo.com)
School of Pharmacy the University of Jember
Jl. Kalimantan I/2 Jember Jawa Timur 68121

Abstract

Globalization has contributed to the development of pharmaceutical industries in terms of medical exploration and trade among countries around the world. A number of pharmaceutical companies have been established throughout the world and become international businesses. Nowadays, pharmaceutical businesses in developed countries are more likely to embrace global agreement on intellectual properties and trade designed to keep competition fair. Multinational Pharmaceutical Companies (most of them are from developed countries) play a large role in both drug development and supply. According to ABPI in 2004, more than 60% of the world's drugs consumption is supplied by only 20 big pharmaceutical corporations. Can it be argued that multinational pharmaceutical companies give benefit for pharmaceutical companies and people in developing countries around the world? This article will focus on several negative impacts occurred on developing countries.

Key words: globalization, pharmaceutical industries, developing countries

INTRODUCTION

Globalization has been defined from different perspectives. Fundamentally, Held et al (cited in Guillen, 2001) argue that globalization is the process and

products of transfer in terms of goods, services, money, people, information, and culture. On the other hand, Cox specifies globalization as production and labor migration from north to south countries (Cox, cited in Healey, 2001). This brings Kanter (cited in Healey, 2001) to emphasize the fact that globalization has made the world a single market of commodities and ideas. There is no exact starting point for globalization. Many experts claim it was started when European countries explored the world, driven by economic reasons such as natural resources exploration and trade. However, this economic progress was not integrated globally until the 19th century (Dollar, 2005). Global progress was not steady, since there was an interruption caused by the "First World War and the bout of anti free trade protectionism" that led to the Great Depression in 1930" (Globalization Guide, n.d.). The effect of this depression was to reduce the progress of globalization. However, economic expansion continued again after end of the Second World War. This can be seen from the great movement of capitalism and multinational companies that produced and sold their products across the world (Globalization Guide, n.d.). Advanced technology has supported international businesses and made it possible to establish businesses on a global scale. These business include pharmaceutical industries, which started from around 1920 and have developed world wide since the 1960s. The first important global agreement on drugs development was the Declaration of Helsinki issued by the World Medical Association in 1964. This declaration was concerned with standardization of clinical experiments" (Wikipedia-Pharmaceutical company, n.d.).

One great phenomenon in global business, including the pharmaceutical industries, is agreement on intellectual properties acknowledgement and trade. This was established around 1990 in the form of the Trade Related to Intellectual Properties (TRIPs) agreement. Another development was

multinational companies, especially in pharmaceutical business. These companies have contributed to drug development and supply for global needs. However, multinational pharmaceutical companies and drug explorations that lead to patenting have been criticized as having adverse effect on small pharmaceutical industries and health services in developing countries.

DISCUSSION

Global pharmaceuticals industries

Taking account with multinational pharmaceutical companies contribution in developing countries, these companies realize that establishing their branches (direct manufacturing or joint venture) in other countries is an effective way to address cost, especially cost of research and development (R&D) (Pore, Yu Pu & Cooney, 2006). Because of this, many developing countries may have opportunities to develop their pharmaceutical industries by promoting foreign investment. Take an example from Jordan, where multinational pharmaceutical companies have grown in number (Ryan & Shanebrook, 2004). Other (developing) countries may follow this, since multinational pharmaceutical companies investment may give benefits such as employment for local people as well as technology transfers to local pharmaceutical industries.

However, Kumar (cited in Lalitha, 2004) has suggested that there are many reasons why foreigners want to invest, namely host country policies, availability of human resources, infrastructure, and market size. It seems developing countries have to fulfill those requirements, especially market size, before multinational pharmaceutical companies want to establish a branch. Unfortunately, most developing countries are facing problems related to poverty. Moreover, according to Brundtland (cited in Walt, 2000),

20 % of the world's population have a very low standard of living and almost half of the world's population have an income of less than US \$ 2 per day. Barton (2004) finds that developing countries cannot produce much profit for developing new products since they only have very small markets. For this reason, many multinational pharmaceutical companies feel reluctant to set up their branches in developing countries. This can be seen from the fact that multinational pharmaceutical companies (from developed countries) have established their R&D department only in developed countries (EFPIA, 2007; also see Wagner, 2005).

Another supporting evidence that shows multinational pharmaceutical companies retain their position in developed countries is that pharmaceutical work are still dominated by people from developed countries (Japan, Europe and US), they make up almost 80% of world's total pharmaceutical employment. (Pore, P & Cooney, 2006). According to Lalitha (2004), foreign direct investment in China and India has increased recently, though there is lower patent protection in those countries. In India, however, multinational pharmaceutical companies do not contribute to development of local pharmaceutical industries but exploit the domestic market. Lalitha also refers to a study in India which stated that multinational pharmaceutical companies do not contribute to large-scale technology transfer (Lalitha, 2004). From Lalitha's report it is clear that FDI in India (and maybe in other developing countries) only pursue profit instead of contributing to pharmaceutical industries development in developing countries. Considering these drawbacks of foreign direct investment, developing countries that want to play in the global market have to increase their capability and capacity. A good example is India, which has realized those drawbacks and turned to new strategies by establishing their own R&D agencies in order to increase their independence and competency (Athreye and Kale, 2006) However this

strategy can only be pursued by developing countries which have sufficient resources, for instance, China, Korea, Brazil and India.

Global Patenting

Turning to global patenting, WHO (2001) states that patents have triggered drug research and development. Patenting has been a considerable revenue generator. This may influence developing countries to invest in R&D projects. PRMA staff (2005, p1) determined that setting up an R&D agency should be supported by advanced technology and scientific resources. In contrast, according to Lalitha (2004), few companies in developing countries have sophisticated R&D facilities. Lalitha also found that many R&D (in small pharmaceutical companies) have turned from R&D investment. This means that few pharmaceutical industries in developing countries, such as India and China, are able to compete globally. Another consideration is that patents grant "absolute protection of the product" (Oh, 2007). As a result, though small pharmaceutical companies in developing countries can produce the drugs by themselves, they have to buy a license and of course, pay the royalty; otherwise they will be committing "piracy". Therefore, small pharmaceutical companies experience high production costs. This is worsened since many small pharmaceutical companies in developing countries, according to Oh (2007), have to buy expensive raw materials. This situation may damage developing countries' pharmaceuticals industries and health services in two ways. Firstly, according to Lehman (2003) although developing countries may be involved in drug development, many of them need protection and assistance in order to develop their capacity and capability. This means poor countries have a lag time before entering the real competition, though in fact, even then they will not be able to compete against well-established multinational pharmaceutical companies. Secondly, buying a license leads to increased production costs which makes medicine

more expensive and therefore less affordable. This can decrease the quality of health services in developing countries.

Global drugs exploration

Turning to global drugs exploration, it is noticeable that patenting has become a driving force in developing new drugs (WHO, 2001). On the other hand, investment in drug research and development is very expensive. Therefore, only big companies can afford it; as a result, these companies become leaders in finding potential new drugs as well as in marketing. The top pharmaceutical companies which have invested in R&D are multinational pharmaceutical companies (MedAdNews, 2005 cited in Wikipedia, n.d.; see also ABPI, 2004).

According to WHO's report (cited in Fransworth, 1988) in the late 1980s, 80 % of people in developing countries had used traditional medicine for main health needs. He claims, "Approximately 119 pure chemical substances extracted from higher plants are used in medicine throughout the world". It is a fact that highly valuable pharmaceutical plants are found in developing countries. Unfortunately, since the patenting system has grown, almost all patents have been granted to developed countries and developing countries have lost their chance to develop their traditional medicines or even to use them (UNDP, 1994). Nowadays, this kind of exploitation is known as "biopiracy". An example of biopiracy is that patent on Ancistrocladus korupensis has been granted to the US National Cancer Institute (NCI) though the original sources (plants) are located in the Korup forest of Cameroon and Nigeria (GAIA/GRAIN, 2000). Another example comes from Biolink, a Canadian pharmaceutical company, which has a patent on rurupunine (a contraceptive agent). In fact, this compound was extracted from biribiri plants (Octotea radioei) that were found in the Amazon region (Yazicioglu & Yalciner, n.d.). Biopiracy can cause inequality in sharing the

benefits of traditional plants use between people in developing countries and companies in developing countries. This has become worse since genetic materials, have also been explored and patented by developed countries (UNDP, 2004). This means that people from developing countries, even scientists, will lose their chance to retain, develop or commercialize their knowledge and resources.

The process of drug discovery and development involves several steps and it usually takes about 10 - 15 years before a new drug is available to patients (PRMA, 2005). These stages include research into the disease itself, drug discovery (compound), pre-clinical testing, clinical testing and drug registration-which means that a drugs can be sold legally. In the early stages of the process, scientific breakthroughs such as genomics, proteomics and computational power are very helpful in developing a comprehensive understanding. Good scientific minds, highly sophisticated technologies and good management influence the success of drug discovery and development. As a result of this, many safe drugs have been discovered which have brought hope to millions of people suffering (PRMA staff, 2005). This has led to improving the quality of health service considerably.

These facts have attracted many developing countries to conduct research in developing new drugs. According to Shamoo (2005), since there were less cost and fewer restrictions in developing countries, clinical experiments conducted both developed and developing countries have grown considerably. This is followed by rapid growth of research using humans as subjects which brings up a moral issue, since regulation are inadequate to protect the subjects. Shamoo (2005) shows that many countries have established rules of "protection for human subject", but these are only strictly enforced in developed countries such as the United States. He also shows that this moral issue has become more contentious since the people in

developing countries often used becoming a clinical subject as a way to earn money (Shamoo, 2005).

CONCLUSION AND SUGGESTION

Conclusion

In conclusion, it is clear that multinational companies have not played significant roles in the development of global pharmaceutical industries yet, even though they have set up partnerships programs. They tend to over exploit drug markets and even exploit people (as experiment subjects) from developing countries that caused developing countries losing over all. Global agreements in pharmaceuticals, such as patents, have made developing countries facing a dilemma of whether obeying or breaking the agreement (to protect their health services). The World Health Organization, therefore, facilitated the Doha Declaration that considered to public health protection, especially in developing countries (WHO, 2006).

Suggestion

In the future, a good partnership among developed and developing countries may be useful for eliminating problems of pharmaceutical industries and health services around the world.

REFERENCES

- ABPI (The Association of the British Pharmaceutical Industry) (2004), *Facts & statistic from the pharmaceutical industry*, p. 1, viewed 3 march 2007
- < http://www.abpi.org.uk/statistics/section.asp?sect=1>
- Athreye, S. & Kale, D., (2006), Experimentation with strategy in the Indian pharmaceutical sector, *IKD Working Paper*, No. 16, November.
- Barton, J.H. (2004), TRIPS and the global pharmaceutical market, *HEALTH AFFAIRS*, Vol. 23, No. 3, pp. 147, viewed 17 February 2007
- < http://content.healthaffairs.org/cgi/reprint/23/3/146>
- Dollar, D. (2005), Globalization, poverty and inequality since 1980, *The World Bank Research Observer*, Vol. 20, No. 2, Fall, p. 148.

- EFPIA (The European Federation of Pharmaceutical Industries and Association) (2004), *The Pharmaceutical Industry in Figures*, pp.9-10, viewed 28 February 2007
- http://www.efpia.org/Objects/2/Files/infigure2004KeyFirgures.pdf
- Farnsworth, N. R., 1988, 'Screening plants for new medicines' in E.O. Wilson (ed) *Biodiversity*, ed. Washington, D.C., National Academy Press.
- GAIA/GRAIN (2000), Biodiversity for sale: Dismantling the hype about benefit sharing, Issue No.4, April, pp. 10, viewed 16 February 2007
- < http://www.grain.org/briefings_files/benefitsharing.pdf>
- Globalization Guide.org (n.d.), *When did globalization begin?*, p.2, viewed 20 February 2007 http:globalisationguide.org/01, html>
- Guillen, M.F. (2001), 'What is globalization?', *Annual Review of sociology*, Vol. 27, viewed 31 January 2007
- http://knowledge.wharton.upenn.edu/papers/938.pdf
- Healey, J. (2001), Issues in Societies: globalization, The Spinney Press, Australia.
- Lalitha, N. (2004), *Trips and pharmaceutical industry : issues and propspect*, Gujarat Institue of Development research, Ahmedabad, pp. 7-9, 12-13, viewed 28 February 2007
- http://www.iprsonline.org/ictsd/docs/ResourcesHealthArticleLalitha.doc
- Lehman, B. (2003), the pharmaceutical industry and the patent system, International Intellectual Property Institute, pp.3, viewed 28 February 2007
- <www.earthinstitute.columbia.edu/cgsd/documents/lehman.pdf>
- Oh, C. (2007), *Patents and monopoly prices*, pp. 1, viewed 2 February 2007 http://www.twinside.org.sg/title/twr131b.htm
- PRMA (Pharmaceutical Research and Manufacturers of America) (2005), *Inside innovation: the drug discovery process*, viewed 22 February 2007
- http://innovation.org/index.cfm/InsideDrugDiscovery/Inside_Drug_discovery
- Pore, M., Yu Pu, Cooney, C. (2006), Off shoring un the pharmaceutical industry in workshop on the offshoring of engineering: facts, myths, unknowns and implication, October 24-25, 2006, Washington DC, pp. 2-3, viewed 28 February 2007
- <www.nae.edu/nae/engecocom.nsf/weblinks/PGIS-6W8TJZ/\$file/Cooney% 20Paper% 2010-24-06.pdf>
- Ryan, M.P., Shanebrook, J. (2004), Establishing globally competitive pharmaceutical and bio-medical technology industries in Jordan: assessment of business strategies and the enabling environment, viewed 26 February 2007

- <www.iipi.org/reports/Jordan_Report.pdf>
- Shamoo, A.E. (2005), Addressing the health needs of host nations while guarding against subject exploitation and other pitfalls, pp.1-2, viewed 13 February 2007
- http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=165484
- UNDP (The United Nations Development Programme) (1994), *Bio-piracy* cheats developing countries and their indigenous people \$5.4 billion a year plant and knowledge royalties, says study conducted for *UNDP*, p.1, viewed 15 February 2007 http://twm.co.nz/Biopircay.html
- Wagner, C.K. (1993), Startegy first in international joint ventures, *The journal of technology transfer*, Vol. 18, No. 1-2, December, Springer Netherlands, pp. 39-48, viewed 24 February 2007
- http://.springerlink.com/content/u0867whn4462662g/?print=true
- WHO (The World Health Organisation) (2006), 'Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action', *Fifty-ninth World Health Assembly: Agenda item 11.11*, 27 May, p.2, viewed 20 February 2007 www.who.int/gb/ebwha/pdf files/WHA 59/A59 R24-en.pdf>
- WHO (The World Health Organization) (2001), Information on technical and financial cooperation programmes carried out by the World Health Organization and that are relevant to TRIPS implementation and access to drugs, *WHO submission to TRPS Council*, p. 1, viewed 12 February 2007 http://www.cptech.org/ip/wto/who-trips.html
- Walt, G. (200)0, 'Globalization and health', *People's Health Assembly*, 13 May, p.3, viewed 23 February 2007
- http://phmovement.org/pubs/issuepapers/walt.html
- Wikipedia (n.d.), *Pharmaceutical Companies*, p.2, viewed 3 March 2007,
- http://en.wikipedia/wiki/List_of_pahrmaceutical_companies>
- Wikipedia (n.d.), *Pharmaceutical Company*, p. 2, viewed 13 February 2007 http://en.wikipedia.org/wiki/Pharmaceutical_company
- Yazicioglu, M., Yalciner, U. (n.d.), Intellectual property right & implementations: "BIOPIRACY: another method of making profit over underdeveloped countries, p. 5, viewed 15 February 2007
- <www.metu.edu.tr/~mengu/biopiracy_mengu_odev.pdf>