Benefits of biopharmaca products towards healthy Indonesia

I M Sumarya*, I W Suarda, N L G Sudaryati and I Sitepu
Faculty of Math and Science, Indonesian Hindu University, Denpasar, Indonesia

*sumaryaimade@yahoo.com

Abstract. Biopharmaca is a biological preparation that comes from nature that has properties as a medicine. Biopharmaca products are categorized into three types, namely herbal medicine, standardized herbal medicine (OHT), and phytopharmaca. The research objective is to find out the benefits of biopharmaca products in leading a healthy Indonesia. Qualitative descriptive research with the method of collecting data is observation and recording documents. The results show that the benefits of biopharmaca products can improve health in the community, are more effective, more affordable, and have relatively smaller side effects. The use of biopharmaca products has global competitiveness that is utilized by residents of several countries such as: China (People's Republic of China) reaching 90%, Chile reaching 71%, Colombia reaching 40%, France reaching 49%, Canada reaching 78%, Britain reaching 60%, The United States reached 42%, and Germany reached 73%. In moving towards a healthy Indonesia, biopharmaca products can be utilized. Based on the results of the research that biopharmaca products can be used in formal health services to improve the quality and degree of health in the community towards a healthy Indonesia.

1. Introduction
Indonesia is a country with the second richest biodiversity in the world after Brazil [1]. Therefore, Indonesia has enormous potential as a source and ingredient of natural or herbal medicine. Plants that are most widely used as medicinal ingredients are called medicinal plants (biopharmaca). Indonesia has around 30,000 plant species, around 31.2% are known as medicinal plants and only around 3-4% are used and cultivated commercially as medicinal plants [2].

Traditional / natural medicine or known as biopharmaca products are biological preparations that come from plants that have properties as medicine. According to BPOM RI Head Regulation Number: HK.00.05.41.1384 Traditional medicines are ingredients or ingredients in the form of plant materials, animal ingredients, mineral materials, preparations of sarian (galenik) or mixtures of these ingredients, which have been used for treatment for generations based on experience [3]. The use of natural medicines or biopharmaceutical products has been going on for a long time for generations by the community, especially in developing countries including Indonesia. The development of the use of various sources of biopharmaca (medicinal plants) ranging from plant parts such as leaves, fruit and others, extracts to pure compounds have been developed as natural medicines (biopharmaca products).

Over the past decade the use of natural medicine has expanded globally and reached its popularity. Based on that, WHO with the support of various health authorities in various countries set general guidelines for the research methodology and evaluation of traditional medicines (biopharmaca products) to maintain safety, efficacy and quality control [4]. The use that is very widespread throughout the world and because of the people's desire or back to nature that has globalized [5], WHO recommends the use
of biopharmaca products in health care, prevention and treatment of diseases, especially chronic diseases, degenerative diseases and cancer [6].

The limitations of access to availability and affordability of medicinal raw materials and drug preparations are the main health care problems in Indonesia. Dependence on imports of medicinal raw materials is a major cause of high drug prices [7]. Indonesia is not yet independent in the sector of medicinal raw materials, therefore the development and use of biopharmaca products (drugs derived from nature) need to be done. Biopharmaca products in general are considered safer than modern medicine, because biopharmaca products have relatively smaller side effects. Promotive, preventive, curative and rehabilitative efforts using biopharmaca products are considered more optimal to improve the quality of public health, so that biopharmaca products become a trend and have global competitiveness to realize a healthy and quality Indonesian society.

2. Method
Qualitative descriptive research with the method of collecting data is observation and document recording of documents relating to biopharmaca products or traditional / herbal medicines. Related documents include the Decree of the Minister of Health of the Republic of Indonesia Number: 661 / Menkes / Sk / Vii / 1994 concerning Requirements for Traditional Medicines, Regulation of the Minister of Health of the Republic of Indonesia Number: 006 of 2012 concerning Traditional Medicine Industry and Business, Regulation of the Head of National Agency of Drug and Food Control of the Republic of Indonesia Number: Hk.00.05.41.1384 concerning Criteria and Procedure for Registration of Traditional Medicines, Standardized Herbal Medicines and Phytopharmaca, Decree of the Head of National Agency of Drug and Food Control of the Republic of Indonesia Number Hk. 00.05.4.2411 Regarding Basic Provisions for Grouping and Marking Natural Medicine for Indonesia, WHO / EDM / TRM / 2000.1 concerning General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine. WHO Traditional Medicines Strategy 2002-2005 and references related to traditional medicine / biopharmaca products. The data collected is analyzed qualitatively and described.

3. Results and discussion
3.1. Use of biopharmaca products in improving quality and public health
The problem of national health care is the limited access to the availability and affordability of medicinal raw materials and drug preparations. Therefore, the development of health care in Indonesia needs to be focused on equitable distribution and use of drugs to meet the availability of drugs in a complete type, sufficient quantities, guaranteed quality, efficacy and safety, affordable prices and easily accessible to the public [8]. One way to meet the availability, affordability and ease of access to raw materials for medicines and drug preparations is to use biopharmaca products, so as to improve access to and quality of health services in the community and improve community capacity in health care.

The development of the use of various sources of biopharmaca in various levels ranging from plant parts, extracts, to pure compounds, shows the rapid development of the use of plants as biopharmaca products. This is supported by people's desire and lifestyle to return to nature (WHO and back to nature) and WHO recommendations to use traditional / herbal medicines (biopharmaca products) in health care, prevention and treatment of diseases, especially chronic diseases, degenerative diseases and cancer. WHO also supports efforts in improving the safety and efficacy of traditional / herbal medicines (biopharmaca products) [6].

Regulation of the Minister of Health of the Republic of Indonesia Number 006 of 2012 concerning Traditional Medicine Industry and Business states that traditional medicines are ingredients or ingredients derived from plants, animals, minerals, preparations (galenik), or mixtures of these ingredients which are used for generations treatment in accordance with applicable norms in society [9]. The Regulation of the Head of National Agency of Drug and Food Control of the Republic of Indonesia in 2005 also states that traditional medicines are ingredients or ingredients in the form of plant materials, animal ingredients, mineral materials, sarian (galenik) preparations or mixtures of these materials, which
have been used for generations. Treatment based on experience [10]. So Biopharmaca Products are plant-derived biological species, which have medicinal properties.

Based on the Decree of the Head of National Agency of Drug and Food Control of the Republic of Indonesia Number: HK.00.05.4.2411 concerning Provisions on the Principles of Grouping and Marking Traditional Medicines (Biopharmaca Products) in Indonesia [11], biopharmaca products in Indonesia can be categorized into three categories, namely:

- Jamu (herbal medicine) is an Indonesian traditional medicine that does not require scientific evidence until clinical trials, but it is enough with empirical or hereditary evidence. Herbal medicine must meet the safe criteria in accordance with the stipulated requirements, efficacy claims are proven based on empirical data, and meet applicable quality requirements.

Figure 1. Logo and marking of herbal medicine.

- Standardized Herbal Medicine (OHT) is a drug preparation of natural ingredients that has been proven to be scientifically safe and efficacious with preclinical testing in animals and its raw material has been standardized. Standardized herbal medicine must meet the safe criteria in accordance with the stipulated requirements, efficacy claims are scientifically proven by preclinical testing, and standardization of the raw materials used in finished products has been carried out.

Figure 2. Logo and marking of standardized herbal medicine (OHT).

- Phytopharmaca is a drug preparation of natural ingredients that can be equated with modern medicine because it has been proven safety and efficacy scientifically with preclinical testing in animals and clinical trials in humans, raw materials and finished products have been standardized. Phytopharmaca must meet the safe criteria in accordance with the requirements specified, efficacy claims proven by clinical trials, standardization of the raw materials used in finished products has been carried out.

Figure 3. The logo and marking of phytopharmaca.
Decree of the Minister of Health of the Republic of Indonesia Number: 661 / Menkes / SK / VII / 1994 concerning the Requirements for Traditional Medicine states that there are dosage forms of traditional / herbal medicines (biopharmaca products) [12], including:

- **Rajangan** is a natural drug preparation (biopharmaca) in the form of simplicia pieces, a mixture of simplicia, or a mixture of simplicia with galenic preparations, which are used by boiling or brewing with hot water.

- **Pills** are natural medicinal preparations (biopharmaca) in the form of a round mass, the raw materials are simplicia powder, galenic preparations, or mixtures thereof.

- **Dodol or Jenang** is a medicinal preparation of natural ingredients (biopharmaca) whose raw materials are simplicia powder, galenic preparations or mixtures thereof.

- **Pastiles** are medicinal preparations of natural ingredients (biopharmaca) in the form of flat slabs generally in the form of a rectangle, the raw material is a mixture of simplicia powder, galenic preparation, or a mixture of both.

- **Capsules** are natural medicinal preparations (biopharmaca) wrapped in hard or soft shells, the raw materials are made of galenic preparations with or without additives.

- **Tablets** are compact preparations of natural ingredients (biopharmaca) made in press, in the form of flat, cylindrical or other shapes, both surfaces are flat or convex, and made of galenic preparations with or without additives.

- **Drug liquid (syrup)** is a natural drug preparation (biopharmaca) in the form of an emulsion or suspension solution in water, the raw material comes from simplicia powder or galenic preparations and is used as an internal medicine.

- **Sari jamu** is a natural ingredient (biopharmaca) drug preparation in internal medicine with the specific purpose of being allowed to contain ethanol. The ethanol level is not more than 1% v / v at a temperature of 20º C and the methanol level is not more than 0.1% calculated against ethanol levels.

- **Parem, Pilis, and Tapel** are natural medicinal preparations (biopharmaca), solid preparations of traditional medicines, raw materials in the form of simplicia powder, galenic preparations, or mixtures and used as external medicine.

- **Koyo** is a natural drug preparation (biopharmaca) in the form of a suitable and waterproof cloth tape coated with simplicia powder and or galenic preparation, used as an external medicine and the wearer is placed on the skin.

- **External drug liquid** is a natural ingredient drug preparation (biopharmaca) in the form of a suspension solution or emulsion, the raw material is in the form of simplicia, galenic preparation and used as an external medicine.

- **Ointment or cream** is a natural drug preparation (biopharmaca) in the form of a semi-solid preparation that is easily applied, the raw material is a soluble galenic preparation or homogeneously dispersed in a suitable ointment or cream base and used as an external medicine.

Utilization of biopharmaceutical products (traditional / herbal medicine) has guaranteed quality, and efficacy in its use, based on scientific studies that have been carried out, among others:

- Research conducted by Irawan Wijaya Kusuma et al about the antimicrobial and antioxidant properties of medicinal plants used by Bentian tribes from Indonesia. The results stated that some medicinal plants were used potentially as antimicrobials, natural antioxidants and as anti-inflammatory agents [13].

- Likewise, a study conducted by Nemanja Stankovi´et al on the antibacterial and antioxidant activity of traditional medicinal plants from the Balkan Peninsula which results show that the extract has antibacterial activity with MICs ranging from 6.3 - 100 mg mL-1, and MBC ranges from 12, .5-100 mg mL-1 and its antioxidant activity correlates with the total content of its polyphenols and flavonoid [14].

- The results of Simanjuntak et al showed that the results of phytochemical layers of the crown god plant contained alkaloid compounds, flavonoids, saponins and polyphenols. The old fruit
extract has strong antioxidant power, to cure itching, sore, flu, liver, kidney, gout, diabetes and cancer [15].

- Research by Sumarya, I M. et al regarding the antihyperuricemia effect of betel leaf extract reduces oxidative stress by reducing MDA and increasing blood SOD in rat hyperuricemia [16].
- DerManderosian in the formulary book of Indonesian traditional medicine concoctions, BPOM 2011, also states that Celery Extract has an anti-hypertensive effect on rabbits and dogs. Besides that with clinical trials showing celery juice can reduce blood pressure in patients with hypertension [17].

From the research that has been done on quality, efficacy and safety, abundant types of medicinal plants and empirical experience from generations of generation, the use of biopharmaceutical products can be used to improve public health more than maximally, the security is relatively more secure because it is believed to have more side effects small compared to modern medicine and cheaper in price [18]. This is also supported by the World Health Organization (WHO) regarding the tendency of the global community to consume traditional / herbal medicines (biopharmaceutical products) so that the demand for traditional / herbal medicines is increasing [6].

The use of biopharmaceutical products is increasingly in demand because it is supported by several factors including: Traditional medicine seems to be considered efficient, safe, cost-effective and affordable; other than that, it can be accessed especially for the poor and for those who live in remote areas, who tend to rely more on traditional and herbal medicines than people who live in urban areas [19]. Extensive use of traditional medicines / biopharmaca products in the health system and economic interests. In Africa up to 80% of the population uses it to help meet their health care needs. In Asia and Latin America, residents continue to use it as a result of historical conditions and cultural beliefs. In China, biopharmaca products contribute around 40% of all health care delivered. Meanwhile, in many developed countries biopharmaca products are becoming increasingly popular. The percentage of residents who have used it is 48% in Australia, 70% in Canada, 42% in the USA, 38% in Belgium and 75% in France [20].

The tradition of using traditional / herbal medicines (biopharmaca products) is strong among the people, there is standardization of raw materials and the support of the General guidelines for methodologies on WHO research and evaluation and the issuance of guidelines for determining basic criteria for evaluating the quality, safety and efficacy of WHO and the Union Europe and the strong policy of some countries regarding regulatory and legal mechanisms to promote and develop quality, safety, efficacy, availability, protection and further development of biopharmaca products can be used as drugs for self-medication and formal health services. The use of biopharmaca products in formal health services is expected because the price is more affordable, the benefits are guaranteed, the side effects are relatively smaller. The composition of drugs in formal health services can be partially replaced with traditional / herbal medicines (biopharmaca products) that have permits and have gone through preclinical and clinical trials.

3.2. Biopharmaca products as a trend and global competitiveness

The use of biopharmaca products by the community in an effort as promotive is to maintain and maintain health, as a preventive means of preventing disease, which is curative for the treatment of diseases and as rehabilitation, namely to restore health [18].

In the current era of globalization, the tendency to use biopharmaca products has spread throughout the world, and is known as a back to nature lifestyle trend [6]. Therefore, its use has the potential to be developed and has global competitiveness because the number of countries that use herbal medicines (biopharmaca products) is very high. According to WHO, up to 65% of the population of developed countries and 80% of the population of developing countries have used drugs derived from natural ingredients (biopharmaca). The driving factors for an increase in the use of herbal medicines in developed and developing countries are: 1) increasing life expectancy when the prevalence of chronic diseases increases, 2) failure to use modern drugs for certain diseases such as cancer, and 3) expanding access to herbal medicine information worldwide [21].
The resolution of Promoting the Role of Traditional Medicine in Health Systems: A strategy for the African Region, adopted by the 50th WHO Regional Committee for the African Region in August 2000, states that around 80% of the population is in WHO member countries (World Health Organization) in Africa using natural medicine for health purposes. Some African countries conduct training in the use of natural ingredients (biopharmaceuticals) to pharmacists, doctors and medical professionals. Similarly, the use of natural ingredients (biopharmaca) in Asia continues to increase despite the availability and circulation of many chemical drugs. In China (People's Republic of China), the use of natural medicine (biopharmaceuticals) reaches 90%, in Japan 60-70% of doctors prescribe natural ingredients (biopharma), known as "kampo" for their patients. TCM in India uses natural ingredients (biopharmaca) to reach 90%. Meanwhile, the WHO Regional Office of the Americas (AMOR / PAHO) reports 71% of the population of Chile and 40% of the population of Colombia use natural ingredients (biopharmaca). In developed countries, the use of natural ingredients (biopharmaca) is very popular. Some sources say the use of natural ingredients (biopharmaca) by the population in France reaches 49%, Canada 78%, Britain 60% and the United States 42% [22].

Germany is also a developed country in Europe that gives considerable attention to the development and use of herbal medicines. The results of the 2010 Allensbach Institute study show that in Germany patients have access to herbal medicine (HM) through doctors, non-medical practitioner’s complementary alternative medicine (CAM) and on their own initiative. As a result, health care professionals, especially doctors, nurses, pharmacists, and non-medical practitioners of CAM are involved in HM. In Germany, HM is known as one of the elements of classical naturopathic play (phyotherapy, hydrotherapy, exercise therapy, diet therapy, and "lifestyle" therapy) also known as Kneipp therapy. The overall percentage of the German population using HM increased from 52% in 1970 to 70% in 2010 [23]. In 2011, around one billion euros was spent on herbal medicine which is equivalent to around 20% of total expenditure on OTC drugs in Germany. In addition, herbal medicines are sold at drug stores, via the internet, and so on. About 20% of the herbs are sold on prescription basis and around 80% are sold at the counter [24].

Based on this, the use of biopharmaca products is a trend in society and is globally competitive. WHO also supports efforts in improving the safety and efficacy of herbal medicines (biopharmaca products) [6]. WHO claims 80% of the population in developing countries uses biopharmaca products. Based on this, it is expected that Indonesia will begin to exploit the potential of abundant biological resources to produce quality, safe biopharmaca products that are useful to be used to improve public health.

The development of the herbal medicine industry (biopharmaca products) in Indonesia needs to be increased and always monitored by bpom so that access to medicines in the community becomes evenly distributed, quality, safety and efficacy that are guaranteed to reach the public. Drugs in formal health services can be dominated by natural medicine (biopharma) such as countries that have implemented policies on the use of natural ingredients (biopharmaca products) are more encouraged than drugs derived from synthetic chemicals.

4. Conclusion
Based on the results of the study, it can be concluded that biopharmaceutical products can be used to improve the quality and degree of health of the people towards healthy Indonesia. The use of biopharmaceutical products is a trend for the global community.

References
[1] Hernani H 2011 Pengembangan Biofarmaka Sebagai Obat Herbal Untuk Kesehatan Buletin Teknologi Pascapanen Pertanian 71 pp 20-29
[2] LPPM UNUD 2014 Tanaman Obat : Sembuhkan Penyakit Untuk Sehat (Universitas Udayana, Denpasar)
[3] BPOM 2005 Peraturan Kepala Badan Pengawas Obat Dan Makanan Republik Indonesia Nomor : Hk.00.05.41.1384 Tentang Kriteria Dan Tata Laksana Pendaftaran Obat Tradisional, Obat
Herbal Terstandar Dan Fitofarmaka

[4] WHO 2000 General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine (Document WHO/EDM/TRM/2000.1) Geneva

[5] Salim Z and Munadi E 2007 Info Komoditi Tanaman Obat (Badan Pengkajian dan Pengembangan Perdagangan Kementerian Perdagangan Republik Indonesia)

[6] WHO 2016 Traditional Medicine [Online] Retrieved from: http://www.searo.who.int/entity/medicines/topics/traditional_medicine/en/ Accessed on: 2018 Pebruari 1

[7] Saragih B M A 2016 Kebijakan Pemerintah dalam Rangka Menciptakan Obat Murah dan Berkualitas (Instruksi Presiden Nomor 6 Tahun 2016)

[8] Balitbangkes 2015 Balai Besar Penelitian dan Pengembangan Tanaman Obat dan Obat Tradisional Laporan Nasional Eksporlerasi Pengetahuan Lokal Enomadesin dan Tumbuhan Obat Berbasis Komunitas di Indonesia (Riset Tumbuhan Obat dan Jamu 2015) Jakarta

[9] Menteri Kesehatan R I 2012 Permenkes No 006 Tahun 2012 Tentang Industri dan Usaha Obat Tradisional

[10] Badan POM 2005 Peraturan Kepala Badan Pengawas Obat Dan Makanan Republik Indonesia Nomor : Hk.00.05.41.1384 Tentang Kriteria Dan Tata Laksana Pendaftaran Obat Tradisional, Obat Herbal Terstandar Dan Fitofarmaka

[11] Badan POM 2004 Keputusan Kepala Badan Pengawas Obat dan Makanan RI No. HK.00.05.4.2411 tentang Ketentuan Pokok Pengelompokan dan Penandaan Obat Bahan Alam (Biofarmaka) Indonesia

[12] Menteri Kesehatan RI 1994 Keputusan Menteri Kesehatan Indonesia: 661/Menkes/SK/VII/1994 Tentang Persyaratan Obat Tradisional

[13] Kusuma W, Murdiyanto, Arung E T, Syafiriza and Kim Y 2014 Antimicrobial and antioxidant properties of medicinal plants used by theBentian tribe from Indonesia Food Science and Human Wellness 3 pp 191–196

[14] Stankovi´ N, Mihajilov-Krstevb T, Zlatkovi´ B, Stankov-Jovanovi´ V, Miti´ V, Jovi´ J, Comi´ L, Koci´ B and Bernstein N 2016 Antibacterial and Antioxidant Activity of Traditional Medicinal Plantsfrom the Balkan Peninsula NJAS - Wageningen Journal of Life Sciences 78 pp 21–28

[15] Simanjuntak P, Bustanussalam, Srikandace Y, Hapsari Y, Soeksmanto A and Citroreksoko P 2006 Analisis Antioksidan dan Profil Senyawa Kimia dalam Buah Mahkota Dewa (Phaleria macrocarpa L.) (Pusat Penelitian Bioteknologi-LIPI)

[16] Sumarya I M, Adiputra N, Sukrama I D M and Putra-Manuaba I B 2016 Betel Leaf Extract (Piper betle L.) Antihyperuricemia Effect Decreases Oxidative Stress by Reducing the Level of MDA and increase Blood SOD Level of Hyperuricemia Wistar Rats (Rattus norvegicus)

[17] DerMaderosian A 2008 The Review Of Natural Product 5th edition Wolter Kluwer health Inc. Missouri p 280-282

[18] Katno and Pramono S 2008 Tingkat Manfaat Dan Keamanan Tanaman Obat Dan Obat Tradisional. Farmasi Bahan Alam UGM [Online] Retrieved from: https://fbaugm.wordpress.com/ 2008/08/10/tingkat-manfaat-dan-keamanan-tanaman-obat-dan-obat-tradisional/

[19] WHO 2017 Trips, CBD and Traditional Medicines: Concepts and Questions. Report of an ASEAN Workshop on the TRIPS Agreement and Traditional Medicine, Jakarta, February 2001 [Online] Retrieved from: http://apps.who.int/-medicinedocs/en/d/Jh2996e/6.2.html Accessed on: 2018 September 8

[20] Heather McLeod 2011 ENZCAM Brief for Health Professionals : WHO Policy on TM/CAM (University of Canterbury. New Zealand)

[21] Sukandar E Y 2015 Tren Dan Paradigma Dunia Farmasi Industri- Klinik-Teknologi Kesehatan (Departemen Farmasi, FMIPA, Institut Teknologi Bandung, Bandung)

[22] WHO 2002 WHO Traditional Medicine Strategy 2002- 2005. Geneva: World Health Organization [Online] Retrieved from: http://www.who.int/medicines/publications/traditional-policy/en/index.html
[23] Allensbach Institute for Opinion Research, *Naturheilmittel 2010* [Online] Retrieved from: http://www.ifd-allensbach.de.

[24] Association of German Pharmaceutical Manufacturers [Online] Retrieved from: http://www.bahn-bonn.de/index.php?id=177