

▪

<p>1.</p> <p> 1.1</p> <p> 1.2</p> <p> 1.3</p> <p>2. -</p>	<p>2.1</p> <p>2.2 가</p> <p>3.</p> <p>4.</p> <p>5.</p>
--	---

1. 가 가가 .

가

가

가

- 가
- 가
- 가

가 가

가 가

(primary 가), 가 (1

metabolites,)

(secondary metabolites,

)

, , , ,

Chemistry);

and developmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction-
가, ()

4가

가

가

가 가

가

가 가

1.3

가

가

Merk 가

(tropic rain forest)

(Inbio program)

가

가

가

가

가

- (Rio Declaration on Environment and Development); 1992

U.N. " 가 가 ,

27

(principles)

2

- (CITES, the Convention on International Trade in Endangered Species of Wild Fauna and Flora); 1975

145

3

(appendices)가

1

- States have, in accordance

. 2

with the Charter of the United Nations

and the principles of international law,

3

the sovereign right to exploit their own

resources pursuant to their own environmental

가 (W.H.O. Guide-line on Traditional Medicine); 20 가 (, 가)

Authorities) 1990 가 가 (MRA, Mutual Recognition Agreement) 가

(Western Pacific Region)

가가 ICH가 가

가 (,)

MRA 가

가

ICH

가

ICH

가

가

가

2. -

가 가

(traditional Oriental medicine) traditional Chinese medicine

(ICH, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use); (European Committee, European Union) (ICDRA, International Conference of Drug Regulatory

(acupuncture and moxibustion) (herbal therapy) 16-17

- Gonzales regimen for pancreatic cancer

21 가 “ (Health and Quality of Life)”

가 (complementary and alternative medicine)

가 1990

)

가

(

가

가

traditional Chinese medicine

가

1992

(National Institute of Health)

1992

가

1998

- 1992- 1997 (5):

5

가

25

“herbal therapy”

- 1998 “Herbal Therapy”

가

가

- St. John's wort for moderately severe depression

2.1

- Glucosamine and Chondroitin sulfate for osteoarthritis

- Ginko biloba to prevent cognitive decline

- Shark cartilage for solid tumors

FDA가

, wall street

, HMO

가 1999 260 () .

10

1999

Office of Natural Health Products

label

FDA

treat

(), diagnose(), cure(), prevent ()

FDA disclaim - This statement has not evaluated by the FDA. This product is not intended to treat, diagnose, cure or prevent disease-

2.1.1 DSHEA (Dietary Supplements Human Education Act)

1994

, herbs

가

가

label

가

DSHEA FDA

FDA

. FDA

, "helps maintain cardiovascular health" "support the immune system"

(natural

OTC-over-the-counter),

"protect against cancer", "treat hot flash", "reduce nausea associated with chemotherapy"

aloe (), cascara (), peppermint oil (), Plantago (), red pepper (), Senna (), witch hazel ()

Food and Drug Cosmetic Act

• IND (Investigational New Drugs)

FDA center for drug evaluation and research 50

가

(上藥) 가 가

2.1.2 : INA
(Institute for Nutraceutical Advance-
ment)

가 plantation

1998 가 INA 30

2.2 가

2.2.1 (European Union)

가 , ,

Ginko

EU

2.1.3 (American
Ginseng Cultivation and Chinese
Herbal Market)

American
ginseng (*Panax ginseng quincofolia*)
1800 1

EU 가 EMA
(The European Agency for the Evaluation of
Medicinal Products) . EMA

2

Guidance

Guideline Regulation

가

EMA guidance 가

ESCOP (The European
Scientific Co-operative on Phytotherapy)
AESGP (European Proprietary Medicine Manu-

facturers Association)

가 가 3

가 (上藥): (中

藥): 가) (下

2.2.2

藥):)

() 2/3가

(single formula)

(poly-

1) 가 (State Commission of Science and Technology) pharmacy, combination of multiple herbs)

(formula)

100,000

3-5 가 2/3 가

(Academy of Traditional Chinese Medicine)

(信息)

1000

가 ()

(decoction), (powder), (- ointment, -fluid extract), (pills), (tablets) (dosage forms)

(Materia Medica (IMPLAD)

Beijing),

(Academy of Sinica)

(union catalog) 12,000

2)

가 가 가 가

95%

80 (

160).

() (verification of effectiveness) (animal and clinical experiments)

3.

(tablets),

가 가 가

가

가

GMP

6.

1) ;

가

p231-282, (

)(1996)

2)

가

가

가 가

가

CITES, Bio-diversity

GMP

GMP

GMP

HMO

- Rio Declaration on Environment and Development; www.igc.apc.org
- CITES; <http://international.fws.gov/global/citesnew.html>
- W.H.O.; www.who.int/
- W.H.O. Western Pacific Region; www.who.org.ph
- ICH; www.ifpma.org/ich8.html
- EMA (The European Agency for the Evaluation of Medicinal Products; www.eudra.org/emea.html)
- ESCOP; www.escop.msstate.edu/
- AESGP; www.aesgp.be
- Pharmaceutical Research & Manufacturers of America; www.phrma.org.
- IFPMA (International Federation of Pharmaceutical Manufacturers Association); www.ifpma.org.
- Nonprescription Drug Manufacturers Association; www.ndmainfo.org.
- Association of the British Pharmaceutical Industry; www.abpi.org.uk
- Verband Forschender Arzneimittelher-

steller E.V. (VFA); www.vfa.de

- Food & Drug Law Institute; www.fdi.org
- DIA (Drug Information Association); www.diahome.org
- US Pharmacopoeia; www.usp.org
- NIH (National Institute of Health); www.nih.gov
- National Center for Complementary and Alternative Medicine; <http://nccam.nih.gov>
- NIH Office of Dietary Supplements; <http://odp.od.nih.gov>
- FDA; www.fda.gov
- The State Sanitary and Epidemiological Inspection of the Ministry of Health of

the Russian Federation;

www.depart.drugreg.ru

- Phtonet; www.exeter.ac.uk
- Healthwell exchange; <http://exchange.healthwell.com>
- Herb World News Online; www.herbs.org
- Herbnnet; www.herbnnet.com
- TradiMed (Traditional Oriental Medicines Database); www.tradimed.co.kr
- The British Herbal Medical Association; www.ex.ac.uk
- Natural Products Industry Center; www.npicenter.com

