

International Seminar on Pharmaceutical Science and Technology

Faculty of Pharmacy Universitas Padjadjaran Jl. Raya Jatinangor, KM21 Jatinangor, Jawa Barat, Indonesia

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Bandung, 28 February 2014

No : 10/ISPST-FFUP/II/2014

Subject: Invitation as Speaker in the Forthcoming ISPST 2014

Dr.rer.nat. I Made Agus Gelgel Wirasuta

Head of Department of Pharmacy Faculty of Pharmacy Universitas Udayana

Dear Dr.rer.nat. I Made Agus Gelgel Wirasuta

On behalf of the Committee of International Seminar Pharmaceutical Science and Technology (ISPST 2014), we cordially invite you to attend ISPST 2014, which will be held on September 18th and 19th 2014 in Jatinangor, a city is close to Bandung, West Java, Indonesia.

We would welcome a special topic from you, especially about **Forensic Analysis** which we believe is in your area of expertise.

Due to our limited budget we could not support any travel fares, however, in recognition to your contribution, we shall waive the conference fee and provide full hospitality during the seminar, including local transportation and hotel.

We will be waiting for the abstract of your talk soon.

Please do not hesitate to contact us for any additional information.

Thank you very much and looking forward to see you in Jatinangor. With kindest regards,

Dr. Jutti Levita

Chairman of ISPST 2014

ISPST 2014 Secretariate

Faculty of Pharmacy, Universitas Padjadjaran

Telephone: +62 22 7796200, Fax: +62 22 7796200, E-mail: ispst@unpad.ac.id

The Understanding of Forensic Pharmacy For A legalistic and safety Practical Pharmacist

Dr.rer.nat. I Made Agus Gelgel Wirasuta, M.Si. Apt.

Pharmacy Department of Faculty Mathematic and Basic Sciences Udayana University.

Abstract

The Indonesian pharmaceutical practice Act "PP 51 (2009)" is a basic law for pharmacist to do their practice in four mains field units, such as: supplying, production, distribution and caring. The pharmaceutical job desks on every field units are strictly regulated with other pharmaceutical regulations. The objectives of Indonesian pharmaceutical laws are to protect patients or society safety concerting to the pharmaceutical products and caring, to maintain and enhancing the quality of the pharmaceutical products and caring, and to insurance the pharmacist and society on law enforce. Just the registered pharmacists are allowed to do the pharmaceutical practice in Indonesia. This register (STRA) should be renewed on very five years. One articles of regulation for renewing STRA says that, the registration will be postponed or not allowed if the pharmacist proven to breach the Indonesian pharmaceutical laws. Better understanding of pharmaceutical job desk according to the regulation could be guaranty for better and safety practical pharmacist. The forensic pharmacy introduces an application of the pharmaceutical sciences on the regulation and governs the pharmacist to better and safety practice. Forensic pharmacists also engage in professional work relating to litigation, the regulatory process, or the criminal justice system.



The Understanding of Forensic Pharmacy is for A legal and safe **Pharmacy-Practice**

Dr.rer.nat. I Made Agus Gelgel Wirasuta, M.Si. Apt. Pharmacy Department of Faculty Mathematic and Basic Sciences Udayana University



Forensic Pharmacy

- · Application of pharmaceutical sciences into the legal issues
- Pharmaceutical Sciences
 - Drugs Sciences
 - Drug production
 - Cosmetic production
 - Drug distribution
 - Medication Sciences
 - Drug delivery system
 - · Pharmaceutical Care

TIONAL SEMINAR PHARMACEUTICAL SCIENCES AND OGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014



THEORETICAL ASPECT: PHARMACIST PARTICIPATION



Legal aspect of pharmacy practice

- Definition of pharmaceutical practice on
 - manufacture of pharmaceutical products including quality control /assurance and safety on supplying, storage and distribution, medication management, pharmacy services, servicing over prescription, drug information services, as well as development of drug, their substance and ingredient, and traditional medicine (PP 51 th 2009)

Pharmaceutical Regulation / Jurisprudence

- Every Regulation, which related and regulated of drug, medication and practical Pharmacist
 - Describe the job desk and legal responsibilities of **Pharmacist**

TTERNATIONAL SEMINAR PHARMACEUTICAL SCIENCES AND ECHNOLOGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014

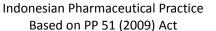




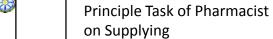
LEGAL ASPECT OF PHARMACY PRACTICE

- The aims
 - provide protection to patients and the society in obtaining and / or determine the pharmaceutical products and pharmacy services
 - maintaining and improving the quality of pharmacy practice according to the upgrading science and technology as well as their regulations
 - provide role of law for patients, society as well as pharmacists and pharmacy technicians

RNATIONAL SEMINAR PHARMACEUTICAL SCIENCES AND HNOLOGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014



- Field of practice (section 2(1), 5)
 - Supplying of pharmaceutical unit
 - Manufacture/Production of pharmaceutical unit
 - Distribution of pharmaceutical unit
 - Pharmaceutical services unit



Ensure the safety, quality and efficacy

- Pharmaceutical Industry
 - Ensure the availability of raw materials or packaging materials of medicine production
- Distribution Unit
- Service Unit
 - Maintain supply of essential medicine



Indonesian Pharmaceutical Practice Based on PP 51 (2009) Act

- Apothecaries as professional and legal responsibilities on
 - Pharmaceutical manufacture
 - Pharmaceutical distribution
 - Pharmaceutical services
- Pharmaceutical practices based on National Act or Role
 - How to do and
 - Negligence of role/Act → Forensic Pharmacy

TIONAL SEMINAR PHARMACEUTICAL SCIENCES AND OGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014



Principle Task of Pharmacist on Production

- Manufacture/Production of pharmaceutical unit:
 - Manufacture of medicinal product
 - Manufacture of herbal remedies / traditional medicine
 - Manufacture of cosmetic product
- Apothecary as professional and legal responsibilities (section 9, PP 51 (2009))
- Forensic issue
 - Under Standard Medicinal Products
 - Fraud and White Collar Crime
 - · Adding medicine compound into traditional medicine
 - Adding non-allowed chemical substance into cosmetic product
 - Pricing of medicinal Goods (fee marketing for physician) - Neglecting responsibilities

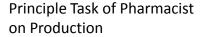
ATTONAL SEMINAR PHARWACEUTICAL SCIENCES AND DLOGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014



Rule of Forensic Pharmacy

- Pharmacy Practice lawful
 - Introduce how to elaborate the principal task and legal responsibilities of Pharmacist from regulation
 - Seek and find out
 - How to do the task properly according to pharmaceutical sciences
 - · How to implementing the pharmaceutical sciences to
 - Avoid to break the regulation

TTERNATIONAL SEMINAR PHARMACEUTICAL SCIENCES AND ECHNOLOGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014

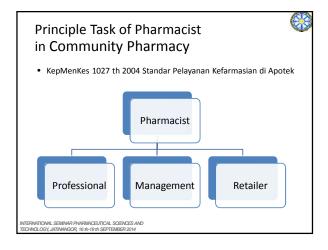




- Ensure on implementing
 - GMP (drug, herbal remedies, cosmetic)
 - GLP (QC/QA)
 - ISO
- Ensure the safety, quality and efficacy

Principle Task on Pharmaceutical Distribution

- Sale of medicinal Products or Medicinal Compound do by 'Pedangan Besar Farmasi (PBF)
 - Wholesale
 - Retail to Pharmacy (Apotek), Drugstore, Hospital
- Apothecary as professional and legal responsibilities (section 14 (2))
 - Good Distribution Practice "GDP" (Section 15)
 - SK KaBPOM No : HK 00.05.3.2522 Th 2003 Ect.
- Forensic issue
 - Illegal distribution (on line shop)
 - Entering illicit medicinal into licit distribution
 - Drug dispensing by not professional pharmacist
 - Neglecting responsibilities



Principle Task of Pharmacist in Pharmaceutical services



- Pharmacy (apotek)
- Hospital pharmacy
- Puskesmas (government Clinic)
- Private clinic
- Drugstore
- Apothecary
 - Pharmaceutical care (section 21, 22, 24)
 - Clinical Pharmacy & Pharmacy Community
 - Drug dispensing (Section 21 (1), 24 (c))
 - Auditing of Rational use of drug and Pharmacoeconomy (section 24, 31)

RNATIONAL SEMINAR PHARMACEUTICAL SCIENCES AND HNOLOGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014



Principle Task of Pharmacist in Community Pharmacy

KepMenKes 1027 th 2004 PharmCare in Community Pharmacy

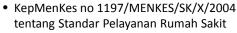
- 1) Screening of Prescription.

 - eutic, Clinical aspect Realize Rational use of drug
- 2) Compounding.
- 3) Dispensing
- Drug Education and Information
- 5) Consoling 6) Patient Medication Record
- 7) Monitoring of the medication 8) Home Care

PP 51/2009 obligatory do by pharmacist

IATIONAL SEMINAR PHARMACEUTICAL SCIENCES AND OLOGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014

Principle Task of Pharmacist in Hospital Pharmacy



- Clinical Pharmacy Practice: a responsible and professional approach of *PharmCare* to ensuring the use of drugs and medical devices in accordance with the indications, effective, safe, and affordable.
- Goal of this practice:
 - to prevent drug misuse, drug overuse, drug abuse, and ADR / medication error

TERNATIONAL SEMINAR PHARMACEUTICAL SCIENCES AND ICHNOLOGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014



Principle Task of Pharmacist in Private Clinic

PerMenKesRI NO 028/MENKES/PER/I/2011 Private Clinic

- · Pharmaceutical service
 - PharmCare
 - Clinical Pharmacy

RIVATIONAL SEMINAR PHARIMACEUTICAL SCIENCES AND INOLOGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014



Indonesian Pharmaceutical Practice Based on PP 51 (2009) Act

- Register Pharmacist (Surat Tanda Register Apoteker "STRA") (Section 39 (2))
- License pharmaceutical Practice (section 52 (2))
 - SIK (Surat ijin Kerja) is license for apothecaries, who do their pharmaceutical practice in production and distribution unit
 - SIPA (Surat ijin Praktek Apoteker) is license for apothecaries, who do their pharmaceutical practice in Pharmaceutical service:
 - Community pharmacist
 - · Clinical pharmacist



Rule of Forensic Pharmacy

- Forensic Expert involved in
 - Pharmacy Malpractice
 - Malpractice of Other Health Professionals
 - Effects of Drugs on Defendants
 - Effects of Drugs on Victims
 - Fraud and White Collar Crime
 - Unlabeled uses of medications
 - Death Investigation



Health Minister Regulation According How to get STRA (889/2011)

- · Revoked of License
 - Self Application
 - No longer meet the physical and mentally requirements to run a pharmacy practice
 - Brach of etic and discipline of Pharmacy practice
 - Violation of law in field of Pharmacy

Forensic Pharmacy Job Description and Careers in USA

- Experts in this area, known as Forensic Pharmacists,
 - consulted about a number of issues involving drugs and medications

 - sulfed about a number of issues involving drugs and m medication error prescription forgery policies and procedures for the dispensation of drugs violations of FDA regulations product transpering drug patients, insurance fraud insurance fraud insurance fraud product transpering drug patients, insurance fraud product transpering drug patients, and the product transpering drug patients, and the product transpering drugs product transpering drugs product produc
- Forensic Pharmacists perform
- such general litigation support tasks as analyzing,
- Such general migration support tables as an annimental evaluating cases to helping lawyers to determine the facts of a case, gathering evidence, interviewing witnesses, formulating lists of questions that lawyers would ask witnesses, and so on may assist and educate attorneys by addressing forensic topics.

 may assist and educate attorneys by addressing forensic topics.

 may assist with written reports, depositions, and document reviews

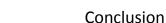
ATIONAL SEMINAR PHARMACEUTICAL SCIENCES AND DLOGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014



Control of Pharmacy Practice

- Cooperation between
 - Government and Indonesian Pharmacist Association (IAI)
- - MEDAI (Majelis Etik dan Disiplin Apoteker Indonesia)

TTERNATIONAL SEMINAR PHARMACEUTICAL SCIENCES AND ECHNOLOGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014



- Better understanding of principal task pharmacy practice
- Forensic pharmacy introduces an application of the pharmaceutical sciences to the regulation and governs the pharmacist to better and safety practice.
- · Forensic pharmacists also engage in professional work relating to litigation, the regulatory process, or the criminal justice system.

RNATIONAL SEMINAR PHARMACEUTICAL SCIENCES AND INOLOGY, JATINANGOR, 16 th-19 th SEPTEMBER 2014

The Understanding of Forensic Pharmacy For A legalistic and safety Practical Pharmacist

by Gelgel Wirasuta

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INTERNATIONAL SEMINAR PHARMACEL/TICAL SCIENCES AND



Forensic Pharmacy

- Application of pharmaceutical sciences into the legal issues
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 - Drugs Sciences
 - Drug production
 - Cosmetic production
 - Drug distribution
 Medication Sciences
 - · Drug delivery system
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ERWITONAL SEMINAR/HAVEMOELTICAL SCIENCES AND

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INTERNATIONAL SEMINAR/HARMOSE/FIGAL SCIENCES AND

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THEORETICAL ASPECT: PHARMACIST PARTICIPATION

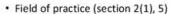
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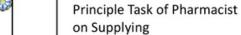
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Indonesian Pharmaceutical Practice Based on PP 51 (2009) Act



- Supplying of pharmaceutical unit
- Manufacture/Production of pharmaceutical unit
- Distribution of pharmaceutical unit
- Pharmaceutical services unit



Ensure the safety, quality and efficacy

- · Pharmaceutical Industry
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 - Maintain supply of essential medicine

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- · Apothecaries as professional and legal responsibilities on
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Principle Task of Pharmacist in Pharmaceutical services

- · Pharmaceutical services unit (Section 19)
 - Pharmacy (apotek)
 - Hospital pharmacy
 - Puskesmas (government Clinic)
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INTERNATIONAL SEMINAR/HARMACEL/TICAL SCENCES AND



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INTERNATIONAL SEMINAR PHARMACILITICAL SCIENCES AND

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Conclusion

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- Forensic pharmacy introduces an application of the pharmaceutical sciences to the regulation and governs the pharmacist to better and safety 2 actice.
- Forensic pharmacists also engage in professional work relating to litigation, the regulatory process, or the criminal justice system.

INTERNATIONAL SERVING PHARMICEUTION, SCIENCES AND TECHNOLOGY, AUTONOSOR, 16 (N-19 In SEPTEMBER 2014



The Understanding of Forensic Pharmacy For A legalistic and safety Practical Pharmacist

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ISPST 2014 International Geminar on

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Organized by: Faculty of Pharmacy Universitas Padjadjaran Bandung, Jatinangor, West Java, Indonesia September 16th-19th, 2014

Abstracts & Programs

In collaboration with:









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Dr. rer.nat | Made Agus Gelgel Wirasuta (Indonesia)

I Made Agus Gelgel Wirasuta studied Pharmacy at Bandung Institute of Technologicontinued his study and achieved his doctoral degree in Clinical Toxicologicon Forensic Analysis at Goerg August University, Germany in 2004. He teaches Pharmacy at Department of Chemistry, Faculty of Mathematics and Natural Surveys Universitas Udayana, Bali, Indonesia.

THE UNDERSTANDING OF FORENSIC PHARMACY FOR A LEGALISTIC AND SAFETY PRACTICAL PHARMACIST

Dr.rer.nat. I Made Agus Gelgel Wirasuta, M.Si. Apt.

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ABSTRACT

The Indonesian pharmaceutical practice Act "PP 51 (2009)" is a basic law for pharmaceutic do their practice in four mains field units, such as: supplying, production, distribution accaring. The pharmaceutical job desks on every field units are strictly regulated with other pharmaceutical regulations. The objectives of Indonesian pharmaceutical laws are protect patients or society safety concerting to the pharmaceutical products and caring, amaintain and enhancing the quality of the pharmaceutical products and caring, and insurance the pharmacist and society on law enforce. Just the registered pharmacists are allowed to do the pharmaceutical practice in Indonesia. This register (STRA) should be renewed on very five years. One articles of regulation for renewing STRA says that, the registration will be postponed or not allowed if the pharmacist proven to breach the Indonesian pharmaceutical laws. Better understanding of pharmaceutical job desk according to the regulation could be guaranty for better and safety practical pharmacist. The forensic pharmacy introduces an application of the pharmaceutical sciences on the regulation and governs the pharmacist to better and safety practice. Forensic pharmacists also engage in professional work relating to litigation, the regulatory process, or the criminal justice system.

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FAGULTY OF PHARMACY UNIVERSITAS PADJADJARAN

ertificate

gus Gelgel Wirasu

Speaker

in International Seminar on Pharmaceutical Science and Technology 2014 entitled:

The Understanding of Forensic Pharmacy for A Legalistic and Safety Practical Pharmacist

Jatinangor, Indonesia, 18-19 September 2014

























SKP: Speaker (7) Moderator (3) Committee (3) Participant (12) Accredited by Indonesian Pharmacist Association No.: 022/SK-SKP/PP.IAI/IV/2014

Dr. Ahmad Muhtadi. MS. Apt.