Reducing Unnecessary Regulatory Burdens (RURB) in Pharmaceutical Industry

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Adalah dengan ini diperakukan perkhidmatan seperti berikut:-

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Objectives

1. To develop a short list of priority areas for removing or reducing regulatory burdens which impact mainly on the sector under review and have the potential to deliver the greatest productivity gains to the economy

2. To identify regulatory and non-regulatory options which might alleviate the regulatory burdens,- including those which will enhance regulatory consistency across jurisdictions

3. To reduce duplication and overlap in regulation or in the role of regulatory bodies - and, where appropriate, recommend which options are the most suitable

Scope

The pharmaceutical industry in the Malaysia Standard Industrial Classification 2008 (MSIC 2008) are classified under Division 21.

Group 210: Manufacture of pharmaceuticals, medicinal chemical and botanical products

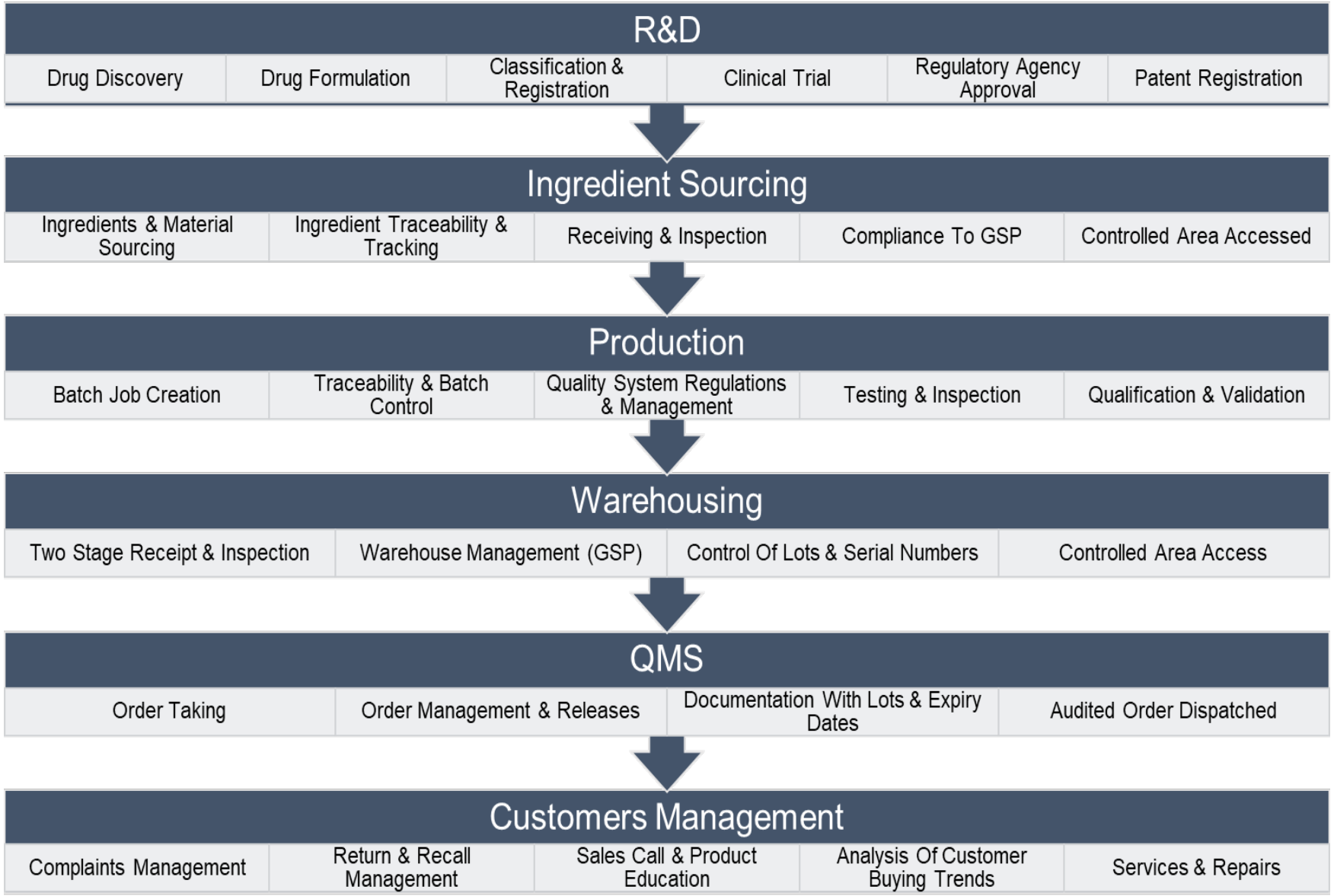
Regulations/Acts in Pharmaceutical Industry

No.	The Governing Acts	Subsidiary legislations
1	Sales of Drugs Act, 1952 [Act 368] ("SoDA 1952")	• Sale of Drugs (Certificate of Analysis) Regulations, 1997; • Sale of Food and Drugs (Cosmetics) Regulations, 1977; • Control of Drugs & Cosmetics Regulations, 1984, Sale of Food and Drugs (Clioquinol) Regulations, 1982; and • Sale of Food and Drugs (Margosa Oil) Regulations, 1985.
2	Dangerous Drugs Act, 1952 [Act 234] ("DDA 1952")	• Dangerous Drugs Regulations, 1952.
3	Registration of Pharmacists Act, 1951 [Act 371] ("RPA 1951")	• Registration of Pharmacists Regulations, 2004.
4	Poisons Act, 1952 [Act 366] ("PA 1952")	• Poisons Regulations 1952 • Poisons (Psychotropic Substances) Regulations, 1989. • Poisons (Sodium Hydroxide) Regulations 1962 • Poisons (Fees) Regulations 1983
5	Medicines (Advertisement and Sales) Act, 1956 [Act 290] ("MA 1956")	• Medicines Advertisements Board Regulations, 1976.

Government Agencies in Pharmaceutical Industry

No.	The Governing Body	Duties
1	Drug Control Authority ("DCA")	The DCA is responsible for pharmaceutical regulatory control in Malaysia and to ensure the safety, quality and efficacy of pharmaceuticals, health and personal care products that are marketed in Malaysia.
2	Pharmacy Board	Pharmacy Board is responsible to regulate the pharmacy profession which includes the evaluation and recognition of pharmacy degrees in Malaysia.
3	National Pharmaceutical Regulatory Agency ("NPRA")	NPRA is responsible: • to develop and implements the regulations concerning the quality, safety and efficacy of drugs; and • to implement quality control on pharmaceutical products. Hence, the infrastructure and facilities were designed to meet the requirements for testing and quality control activities.
4	Medicine Advertisement Board ("MAB")	MAB has the authority to regulate/enforce the MA 1956. MAB is responsible in respect of the advertisement which relates to medical products or healthcare facilities and services by executing the following roles: • to issue approval for an application for advertisement; • to review, revise its policies and guidelines with regards to such advertisement; and • to cancel / withdraw any approval granted.
5	Poisons Board	• Classification of new chemicals as Poison • The amendment of the classification of poison in the Poisons List • Removal of poison from the Poisons List • The amendment of the list of psychotropic substances in the Third Schedule

Pharmaceutical Industry Value Chain

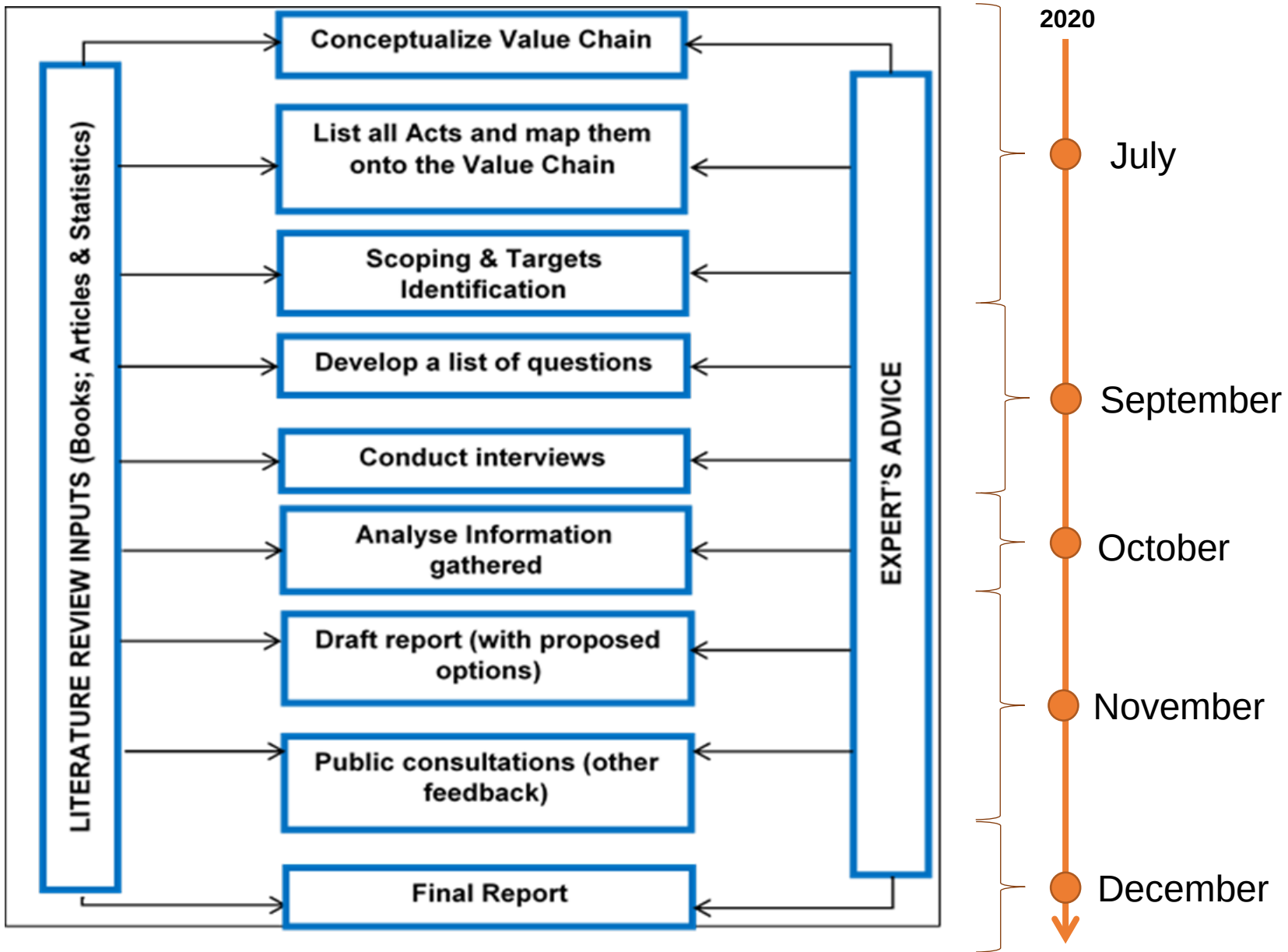


Unnecessary Regulatory Burden

Unnecessary regulatory burdens can typically be categorised under three broad headings:

1. Problems with regulations themselves
2. Poor enforcement and administration
3. Unnecessary duplication and inconsistency

Summary of RURB Process & Timeline



Issues highlighted by Industry

No	Activities	Acts/Regulations	Regulators/ Government Bodies	Remark
Ingredient Sourcing / Procurement				
1	Import Gelatin - Requirement to have Import Permit from Malaysian Quarantine and Inspection Services Department (MAQIS)	Malaysian Quarantine and Inspection Services Act 2011	Malaysian Quarantine and Inspection Services Department (MAQIS)	Gelatin is a finished product and used as raw material for production. Suggest to remove requirement for import permit.
Production / Operations				
2	Change of design for exhaust chimney	Environmental Quality (Clean Air) Regulations 2014	Department of Environment	New regulation requires to change the design of our chimney. Not necessary for us since our discharge doesn't contain harmful gases.
3	Medical Surveillance Monitoring	The Occupational Safety and Health (Use and Standards of Exposure of Chemicals Hazardous to Health) Regulations 2000	Department of Occupational Safety and Health	Our lab employee's exposure to hazardous chemicals is very minimal and we suggest to conduct risk-based assessment to determine whether necessary for medical check-up, instead of sending all employees for medical check-up.
4	*Sistem Pengawasan Kebakaran Automatik (SPKA)* replaces the existing Computerised Fire Alarm Monitoring and Communication System (CMS)	Fire Services Act	Fire and Rescue Department of Malaysia (BOMBA)	Cost of implementing SPKA is very high and in the same time not efficient compared to previous system (CMS).
5	Professional Visit Pass (PVP) permit for visiting experts	Immigration Act and Regulations 1959/63	Immigration Department	We suggest to introduce 'Special PVP' for foreign experts with visits less than 1 month, coming for installation and commissioning, machine qualification and unplanned machine breakdown. Current tedious process and long processing time disrupts our planning as well as opportunity to bring in the foreign experts for machine maintenance and repair. By the time we get the approval, the foreign expert will be busy with other projects at different parts of the world.
R&D				
6	Registration for Medical Device-Drug (combined product)	a) Medical Device Act 2012 b) Poisons Act 1952 c) Drug Regulatory Guidance Document	Medical Device Authority (MDA) National Pharmaceutical Regulatory Agency (NPRA)	Have to register with both NPRA and MDA. Time consuming. We suggest to register only with NPRA.

1. Import Requirements

Issue	Remarks	Suggestion
Customs? Import of gelatine require to have Import Permit from Malaysian Quarantine and Inspection Services Department (MAQIS) in compliance with the Malaysian Quarantine and Inspection Services Act 2011	Gelatin is a finished product and used as raw material for production.	Remove requirement for import permit.

Questions

- How many products/companies involved with the issue?
- Is there any other related products/process?
- Benchmark with other countries' best practices?
- Rationale for suggestion/recommendation?

2. Ambiguous Regulations

Issue	Remarks	Suggestion
Department of Environment (DOE) Require change of design for exhaust chimney to comply with the Environmental Quality (Clean Air) Regulations 2014	New regulation requires to change the design of our chimney.	Not necessary for the industry since the discharge doesn't contain harmful gases.

Questions

- ❑ How many products/companies involved with the issue?
- ❑ Is there any other related products/process?
- ❑ Benchmark with other countries' best practices?
- ❑ Rationale for suggestion/recommendation?

3. Ambiguous Regulations

Issue	Remarks	Suggestion
Department of Occupational Safety and Health (DOSH) The Occupational Safety and Health (Use and Standards of Exposure of Chemicals Hazardous to Health) Regulations 2000 requires Medical Surveillance Monitoring	The lab employees exposure to hazardous chemicals is very minimal.	Conduct risk-based assessment to determine whether necessary for medical check-up, instead of sending all employees for medical check-up.

Questions

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- Rationale for suggestion/recommendation?

4. New Regulatory Impacts

Issue	Remarks	Suggestion
Fire and Rescue Department of Malaysia (BOMBA) Sistem Pengawasan Kebakaran Automatik (SPKA) replaces the existing Computerised Fire Alarm Monitoring and Communication System (CMS) in compliance with the Fire Services Act	Cost of implementing SPKA is very high and at the same time is not as efficient as compared to previous system (CMS). "CMS is better as there is no human intervention between the triggering off of the alarm and the signal reaching the fire station. In the SPKA, there is human intervention and a delay of up to two minutes at least." Issue on monopoly by iScada Net Sdn. Bhd.?	CAP suggested that the mandatory use of SPKA should be suspended and a full investigation be carried out on the questionable open tender.

Questions

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- Rationale for suggestion/recommendation?

5. Foreign Workforce

Issue	Remarks	Suggestion
<u>Immigration Department</u> Professional Visit Pass (PVP) permit for visiting experts in compliance with the Immigration Act and Regulations 1959/63	Current tedious process and long processing time disrupts the planning as well as opportunity to bring in the foreign experts for machine maintenance and repair. By the time it is approved, the foreign expert will be busy with other projects at different parts of the world.	Introduce 'Special PVP' for foreign experts with visits less than 1 month, coming for installation and commissioning, machine qualification and unplanned machine breakdown.

Questions

- ❑ How many products/companies involved with the issue?
- ❑ Is there any other related products/process?
- ❑ Benchmark with other countries' best practices?
- ❑ Rationale for suggestion/recommendation?

6. Multiple Agency Approvals

Issue	Remarks	Suggestion
Medical Device Authority (MDA) & National Pharmaceutical Regulatory Agency (NPRA) Registration for Medical Device-Drug (combined product)	Have to register the finished products with both NPRA and MDA. Time consuming.	Register only with NPRA

Questions

- How many products/companies involved with the issue?
- Is there any other related products/process?
- Benchmark with other countries' best practices?
- Rationale for suggestion/recommendation?

Thank You

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RURB Study on Pharmaceutical Industry: Engagement with Industry

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Scope

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Group 210: Manufacture of pharmaceuticals, medicinal chemical and botanical products

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