Survey Form

Title of survey : **CURRENT REGULATORY SYSTEM IN OIC MEMBER STATES**

Objective of survey : This survey is carried out to assess the level of regulatory control on pharmaceuticals and vaccines in each country to better understand the country's regulatory system in order to facilitate the convergence of relevant standards among OIC Member States

Instructions : This survey is divided into six(6) sections as listed below :

Section A : Background information on the National Regulatory Authority (NRA)
Section B : Regulatory System
Section C : Marketing Authorisation and Licensing
Section D : Laboratory Access
Section E : Regulatory Inspections
Section F : Post-marketing Activities

Each section consists of a set of questions relating to a certain topic. Please tick (√) if the description fits the current regulatory control practiced in your country.

D = applicable only to review of drug regulatory capacity
V = applicable only to review of vaccine regulatory capacity
D+V = common to drug and vaccine review
N/A = not applicable

This survey form is also available on the National Pharmaceutical Control Bureau's website : www.bpfk.gov.my

Footnote:
This survey form is adapted from the WHO Questionnaire; in which its use is with permission by WHO.

SECTION A : BACKGROUND INFORMATION ON THE NATIONAL REGULATORY AUTHORITY (NRA)			
COUNTRY			
DATE OF REVIEW			
REVIEW PERFORMED BY			
NAME OF NRA			
NRA FOCAL POINT			
ADDRESS OF NRA			
TELEPHONE NO. NRA			
FAX OF NRA			
EMAIL OF NRA			
POSITION OF NRA			
NRA	**Explain (for each part of NRA if applicable) whether part of Ministry of Health, autonomous administration, etc.**		
	Ministry of Health	**Autonomous**	**Others (please specify)**
Marketing authorisation			
Licensing			
Inspectorate (GMP/GDP)			
Quality Control			
Pharmacovigilance			

SECTION B : REGULATORY SYSTEM						
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES [please tick (√) if available]**	**Area**			
		D	**V**	**D+V**	**N/A**
1. Statutory basis for establishment of regulatory system and enforcement power	○ Legislations exist and cover all medical products for human use				
	○ NRA established and empowered in law				
	○ QC lab or testing function established and empowered in law				
	○ Inspectorate empowered to access facilities and documentation, and to collect samples				
	○ Legal provisions (if applicable) for : ○ marketing authorisations				
	○ appropriate standards (e.g. pharmacopoeias)				
	○ control of importation				
	○ control of exportation				
	○ control of manufacturing				
	○ control of distribution (wholesale and retail)				
	○ monitoring safety of marketed products				
	○ monitoring quantity of marketed products				
	○ control of promotion and advertising				
	○ control of clinical trials				
	○ identifying and sanctioning illegal products and activities				
	○ Regulations based on legislation have been issued for all areas, and kept up to date.				
2. Quality system(s) for all NRA functions	○ Quality system in place for **<u>selected</u>** functions ○ ISO 9000 Certification; please specify : _____				
	○ ISO 17025 Accreditation; please specify : _____				
	○ Others : _____				

SECTION B : REGULATORY SYSTEM						
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES [please tick (√) if available]**		**Area**			
			D	**V**	**D+V**	**N/A**
	○	Quality system in place for **all** functions ○ ISO 9000 Certification				
		○ ISO 17025 Accreditation				
		○ Others : _____				
3. Independence of the regulatory authority in decision making	○	Lines of authority reflecting independence of regulatory system from manufacturer and/or supply system				
	○	If same QC lab serves lab manufacturer and NRA there are mechanism ensuring independence testing and decision-making				
	○	Inspectorate never uses experts from one manufacturer to inspect other manufacturer's facilities				
	○	NRA management or evaluation activities (at any level/stage) never include manufacturers' representatives				
4. Recall system with mechanism to ensure the proper disposition of affected lots	○	Legal/official provision and instruction for recall including destruction				
	○	System based on documented communication to appropriate level of the distribution system with feedback mechanism				
	○	Mechanism to confirm that appropriate action (including destruction when necessary) has been taken				
5. Appropriate expertise/qualification of staff	○	All staff has appropriate qualification to conduct regulatory activities				
	○	Mechanism in place to ensure that staff have sufficient expertise in specialized areas, e.g. immunobiologicals (including vaccines)				

SECTION B : REGULATORY SYSTEM					
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES [please tick (√) if available]**	**Area**			
		D	**V**	**D+V**	**N/A**
Comments / remarks for Section B : Regulatory System					

SECTION C : MARKETING AUTHORISATION (MA) AND LICENSING					
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES [please tick (√) if available]**	**Area**			
		D	**V**	**D+V**	**N/A**
1. MA system established and operational	○ MA required for all medical products				
	○ No exemptions to MA requirement				
	○ Specific provision for specialized areas, e.g. immunobiologicals (including vaccines), please specify: _____				
2. Guidelines for submission of MA applications	○ Administrative instructions				
	○ Detailed instructions on format and content of dossier				
3. Assessment of MA application	○ Written guidelines for assessment based on specific requirements of specific classes of products				
	○ Assessment of quality, safety & efficacy (QS&E)				
	○ Recognition based on established list of authorities or written criteria to accept/rely upon selected documentation				
	○ Formal mutual recognition agreement (MRA) Please specify : _____				
4. Appropriate assessment expertise	○ Written procedures for experts on Quality, Safety and Efficacy (e.g. need for expert advice, selection of experts, working procedures, frequency of meetings, publicity of proceedings, binding advice, etc.)				
5. Criteria/standards for evaluation of imported and domestic products	○ Same criteria and standards				
6. GMP assessment in MA process	○ Written criteria for assessment of manufacturers				
	○ GMP inspections carried out for domestic manufacturers				

SECTION C : MARKETING AUTHORISATION (MA) AND LICENSING					
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES [please tick (√) if available]**	**Area**			
		D	**V**	**D+V**	**N/A**
	○ GMP inspections carried out abroad				
	○ Agreement with other NRA for exchange of inspection reports/certificates				
	○ List of reference countries whose certificates and decisions are accepted				
7. Variations to MA	○ Written guidelines for applicants with definition of types and scopes of variations				
8. Waiver of assessment steps/ requirements (e.g. orphan drugs)	○ Written procedures for waivers				
9. Decision making and modification of decisions (e.g. appeal)	○ Written procedures for decision making				
	○ Appeal mechanism in place				
10. Availability of information on authorized products	○ List of all approved products published and regularly updated (e.g. on the website)				
11. Licensing of manufacturing sites required	○ Licensing required on the basis of inspection and regularly enforced for any pharmaceutical manufacturing				
	○ Same licensing procedure applied also for manufacturing for export only and government-owned manufacturers				
12. Licensing of importers required	○ Licensing required on the basis of inspection and regularly enforced				
	○ Requirement for availability of data on imported items enabling traceability of products and consumption/utilisation statistics				

SECTION C : MARKETING AUTHORISATION (MA) AND LICENSING					
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES [please tick (√) if available]**	**Area**			
		D	**V**	**D+V**	**N/A**
13. Licensing of wholesalers/ distributors (includes handling of free samples)	○ Licensing required on the basis of inspection and regularly enforced				
	○ Requirement for availability of data on traded items enabling traceability of products and consumption/utilisation statistics				
Comments / remarks for Section C : Marketing Authorisation and Licensing					

SECTION D : LABORATORY ACCESS					
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES [please tick (√) if available]**	**Area**			
		D	**V**	**D+V**	**N/A**
1. QC lab available and functioning or operational agreement to use external laboratory	○ QC lab available in the country				
	○ Reliable system to use external / foreign lab				
	○ Specifications and analytical methods set when approving MA and made available to QC lab				
	○ Lab conducts test on :- ○ Pharmaceuticals (e.g. physico-chemical, microbiological)				
	○ Biological testing (e.g. potency test, etc.)				
2. Laboratory quality system	○ Quality system in place for **selected** functions ○ ISO 9000 Certification; please specify : _____				
	○ ISO 17025 Accreditation; please specify : _____				
	○ Others : _____				
	○ Quality system in place for **all** functions ○ Certification ISO 9000				
	○ Accreditation ISO 17025				
	○ Others : _____				
3. Documentation of procedures and responsibilities in place	○ Document control				
	○ SOPs (test procedures, sample handling, data management)				
4. Equipment documentation in place	○ Records available for commissioning, operation manuals and logs, calibration and maintenance schedules, validation protocols and others				

SECTION D : LABORATORY ACCESS					
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES [please tick (√) if available]**	**Area**			
		D	**V**	**D+V**	**N/A**
5. Staff training plan developed and implemented	o Identification of skills required				
	o Staff training plan developed and implemented				
6. Existence of an audit and review system	o Comprehensive internal audit and review system in place				
	o Documentation of actions taken as result of audit				
	o Audited by external organisation (e.g. Certification, accreditation)				
7. Validation procedures in place for all tests	o Validation programme only for non-compendial tests				
	o Full validation programme (justifying exemptions)				
8. Existence of a general safety programme	o List of hazardous substances available				
	o Responsible staff designated				
	o Full safety programme				
9. Reference standards and reagents	o Catalogue (list, specifications and sources) for standards and reference materials				
	o System in place to establish national reference standards				
10. Participation in international proficiency schemes and collaborative studies	o Regular participation Please provide data of last participation, scope, product(s), coordinating institution : _____				

SECTION D : LABORATORY ACCESS					
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES** **[please tick (√) if available]**	**Area**			
		D	**V**	**D+V**	**N/A**
Comments / remarks for Section D : Laboratory Access					

SECTION E : REGULATORY INSPECTIONS					
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES [please tick (√) if available]**	**Area**			
		D	**V**	**D+V**	**N/A**
1. GMP requirements	○ Legal basis/ regulation/ order to enforce GMP				
	○ National GMP code exists and is consistent with/based on WHO's				
2. Requirements for distribution channel facilities	○ National codes/requirements exist and cover all activities				
	○ Requirements or guidelines are made available to facilities				
3. Certification of compliance with GMP	○ NRA issues GMP certificates				
	○ NRA participates in WHO Certification Scheme				
4. Enforcement of GMP in domestic/foreign production facilities	○ To conduct GMP inspection in all or selected production facilities				
	○ Requirement for keeping record and full reports of inspection				
5. Inspection procedures	○ Documented procedures (inspection manual and checklist)				
6. Inspections at appropriate intervals	○ Satisfactory plan				
	○ Adequate inspectors and resources to implement plan				
7. Appropriate qualifications for inspectors	○ Trained and experienced inspectors (both GMP and distribution channels)				
	○ Participation in joint GMP inspections (e.g. WHO, PIC/S)				
8. Defined actions following inspection	○ Written procedures for follow-up of deficiencies/violations (including timeframes)				
	○ Evidence that the follow up process is implemented				
9. Assurance of independence of NRA inspectors from manufacturers	○ Conflict of interest provisions for all members of the team				

SECTION E : REGULATORY INSPECTIONS					
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES** **[please tick (√) if available]**	**Area**			
		D	**V**	**D+V**	**N/A**
Comments / remarks for Section E : Regulatory Inspection					

SECTION F : POST-MARKETING ACTIVITIES					
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES [please tick (√) if available]**	**Area**			
		D	**V**	**D+V**	**N/A**
1. Provision for post marketing safety monitoring in the MA process	○ Ad hoc provision related to the MA requiring applicant to actively monitor adverse reactions (give details)				
	○ Requirement for Periodic Safety Update Reports (PSUR) / Periodic Benefit-Risk Evaluation Report (PBRER)				
2. Pharmacovigilance	○ ADR reporting system in place (please choose one): ○ **member** of WHO Drug Monitoring Programme				
	○ **not member** of WHO Drug Monitoring Programme				
	○ Regular access to use of international sources of information on ADR and drug safety information				
3. Capacity to produce/ control drug information	○ Requirements for summary of product characteristics (SPC) in the MA process				
4. Quality monitoring and special programmes	○ Criteria for sample collection based on risk assessment				
	○ Special programme for detecting and combating : ○ counterfeit products				
	○ substandard products				
	○ illegal pharmaceutical trade				
	○ Other special programmes Please specify: _____				

SECTION F : POST-MARKETING ACTIVITIES					
ELEMENTS OF INFORMATION FOR REVIEW OF NATIONAL REGULATORY FUNCTIONS	**GUIDING CRITERIA AND EXAMPLES** **[please tick (√) if available]**	**Area**			
		D	**V**	**D+V**	**N/A**
Comments / remarks for Section F : Post-Marketing Activities					