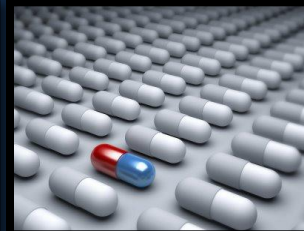




DEVELOPING THE LOCAL PHARMACEUTICAL INDUSTRY THROUGH NKEA HEALTHCARE

6th AUGUST 2015
CHOY LUP BONG
MINISTRY OF HEALTH



CONTENT



Malaysia's Economic Transformation Programme



NKEA Healthcare



NKEA Healthcare 2014 Review



Malaysia's Pharmaceutical Industry



Challenges



Off-Take Agreement



Way Forward



The Malaysian Government has embarked on an Economic Transformation Programme (ETP), an initiative that is aimed at transforming Malaysia into a developed, high-income nation by the year 2020. Under the programme, the healthcare sector has been identified as one of the economic sectors that will contribute to Malaysia becoming a developed and high-income nation. A Healthcare National Key Economic Area (NKEA) has been established to facilitate the development of Malaysia's healthcare sector by identifying and facilitating projects through collaborative efforts between the public and private healthcare providers.

12 NKEAs

**Financial
Services**



Energy



Education



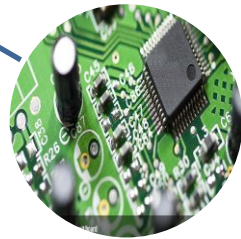
Tourism



**Wholesale
& Retail**



**Electronics
& Electrical**



Healthcare



Palm Oil



Agriculture



**Communications
Contents**



**Business
Services**



**Greater KL/
Klang Valley**



Healthcare industry is more than hospitals.....



NKEA HEALTHCARE: ENTRY POINT PROJECTS (EPP)

- ✓ EPP 1: Mandating Private Insurance For Foreign Workers
- ✓ EPP 2: Clinical Research Malaysia
- ✓ **EPP 3: Malaysian Pharmaceuticals**
- ✓ EPP 4: Healthcare Travel
- ✓ EPP 5: Diagnostic Services Nexus
- ✓ EPP 6: Health Metropolis
- ✓ EPP 7: Upscale Malaysia's In-Vitro Diagnostic (IVD) Industry
- ✓ EPP 8: Build Malaysian Showcase On Next Generation of Core Single Use Device (SUD) Products
- ✓ EPP 9: Become the Hub for High-Value Medical Devices Contract Manufacturing
- ✓ EPP 10: Malaysian Clinical Device Champions
- ✓ EPP 11: Medical Equipment Supply Chain Orchestration
- ✓ EPP 12: High Value Medical Device Manufacturing
- ✓ EPP 13: Build Medical Hardware and Furniture Cluster
- ✓ EPP 14: Renal Products
- ✓ EPP 15: Mobile Healthcare Services
- ✓ EPP 16: Institutional Aged Care
- ✓ EPP 17: Retirement village

HEALTHCARE

BY 2020

RM35.3bil | **181,000**
GNI | NEW JOBS

ETP 1

MANDATING PRIVATE HEALTH INSURANCE FOR FOREIGN WORKERS

Over **1.7 million**

foreign workers have been insured under the Foreign Worker's Health Insurance Protection Scheme (SPIKPA) since 2011



ETP 2

CREATING SUPPORTIVE ECOSYSTEM TO GROW CLINICAL RESEARCH

Luconxia's commencement of the first medical device clinical trial for **automatic peritoneal dialysis devices**

in Malaysia



ETP 3

MALAYSIAN PHARMACEUTICALS

Income generated from pharmaceutical exports

recorded **9%**

growth during the year, surpassing the 5% growth target



EPP 4 REINVIGORATING
HEALTHCARE TRAVEL



The Healthcare Travel sector has grown steadily at an average of

25%

annually since 2010. The number of hospitals registered with the Malaysia Healthcare Travel Council (MHTC) has grown to 74 from the initial 34



EPP 5 CREATING A DIAGNOSTIC
SERVICES NEXUS

The EPP owner,
GE Healthcare
is currently reviewing its
project plan

EPP 6 DEVELOPING A HEALTH METROPOLIS: A WORLD-CLASS
CAMPUS FOR HEALTHCARE AND BIOSCIENCE

**UM Holdings Sdn
Bhd (UMHM)**

is taking further
action to pursue
Planning Approval
for UMHM with
MBPJ and Selangor
State Government



MEDICAL DEVICES EPPS

EPP 7
UPSCALE MALAYSIA'S IVD INDUSTRY - MEDIVEN & OLIPRO



6 new products

were launched and added to the product portfolio of Dipro Biotechnology. It has also expanded its market to Indonesia and Brunei

EPP 8
BUILD MALAYSIAN SHOWCASE ON NEXT GENERATION OF CORE SINGLE USE DEVICE (SUD) PRODUCTS

Viglenz is now constructing a new infrastructure covering

70,000 square feet

that is four times larger than its current offering and will be ready by 2Q 2015



EPP 9
BECOME THE HUB FOR HIGH-VALUE MEDICAL DEVICES CONTRACT MANUFACTURING



Malaysia will be the sole manufacturer for Smith & Nephew's severe burns wound dressing when Steripack Asia begins operations here in 2015

EPP 13
BUILD MEDICAL HARDWARE AND FURNITURE CLUSTER - LKL

LKL has met the majority of its goals and objectives including to secure projects and sizeable orders to **equip hospitals and medical facilities** within Malaysia as well as in Vietnam, Sri Lanka and the Middle East



EPP 10
MALAYSIAN CLINICAL DEVICE CHAMPIONS - SIMA MEDICAL

Sima Medical will be developing orthopedic clinical devices in Malaysia through its research and development division

The introduction of its activities in Malaysia is expected to draw an investment of **RM7.7 million** with a projected GNI of RM131.81 million by 2020



EPP 12
HIGH-VALUE MEDICAL DEVICES MANUFACTURING

Toshiba has established its manufacturing operations for ultrasound systems, transducers, printed board wired of other medical devices in Malaysia which will be exported.

RM51 million in GNI

RM56 million in new investments

200 new jobs

Toshiba's new facility in Penang, with a total of **7,800m² floor space** commenced production in December 2014



EPP 11
MEDICAL EQUIPMENT SUPPLY CHAIN ORCHESTRATION - UWC GROUP OF COMPANIES

UWC has expanded its product portfolio and transferred its **Advanced Diagnostic Equipment** (cancer diagnostic) from the US to Malaysia



EPP 14
RENAL PRODUCTS - FRESENIUS, LUCENXIA, PROLIGEN

Fresenius Medical Care

a global supplier of renal solutions and a major player in both hemodialysis (HD) and peritoneal dialysis (PD) products, has increased the production output of HD concentrates in its manufacturing facility in Bandar Enstek, Nilai, Negeri Sembilan



SENIORS LIVING EPPS

EPP 15

MOBILE HEALTHCARE SERVICES

The Ministry of Health is also in the midst of amending the current Private Healthcare and Facilities Act to

include mobile healthcare service

which remains unregulated. This measure is therefore necessary to ensure that mobile healthcare service is both regulated and recognised as another way medical services can be provided



EPP 16

INSTITUTIONAL AGED CARE

ECON @ Cheras aims to provide **a unique retirement village-cum-nursing home facility**

The facility will provide its residents with daily conveniences, medical services, nursing care and recreational activities. The project owner has acquired a piece of land with a vacant building with current built-up area of 5,598.00m² in Cheras. Construction of the facility is expected to commence in mid-2015.

EPP 17

RETIREMENT VILLAGES

Eden-on-the-Park Sdn Bhd aims to build a

care residence

in Kuching to make senior living and aged care facilities the preferred choice in Malaysia and establish international standards for aged care in Malaysia

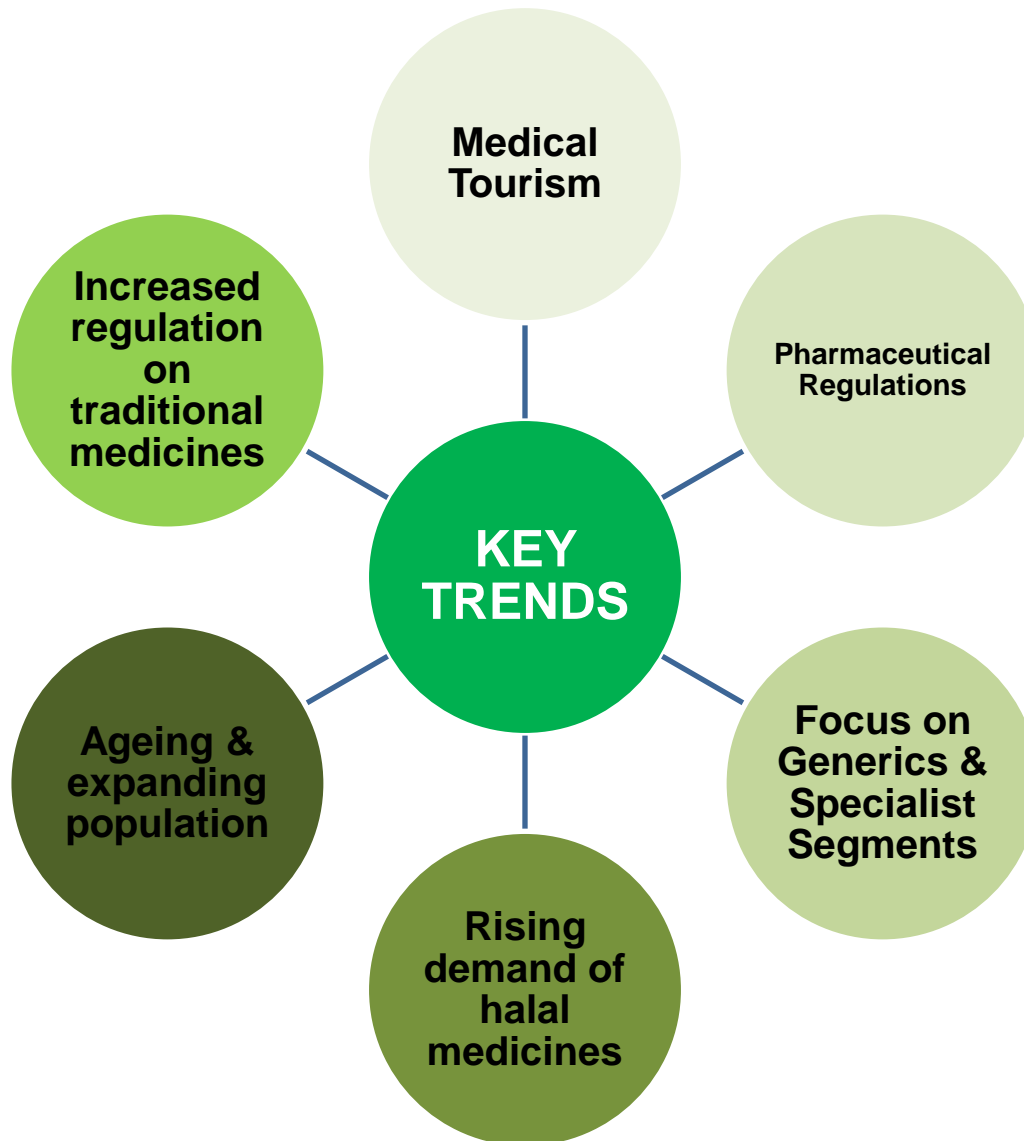


LOCAL PHARMACEUTICAL INDUSTRY



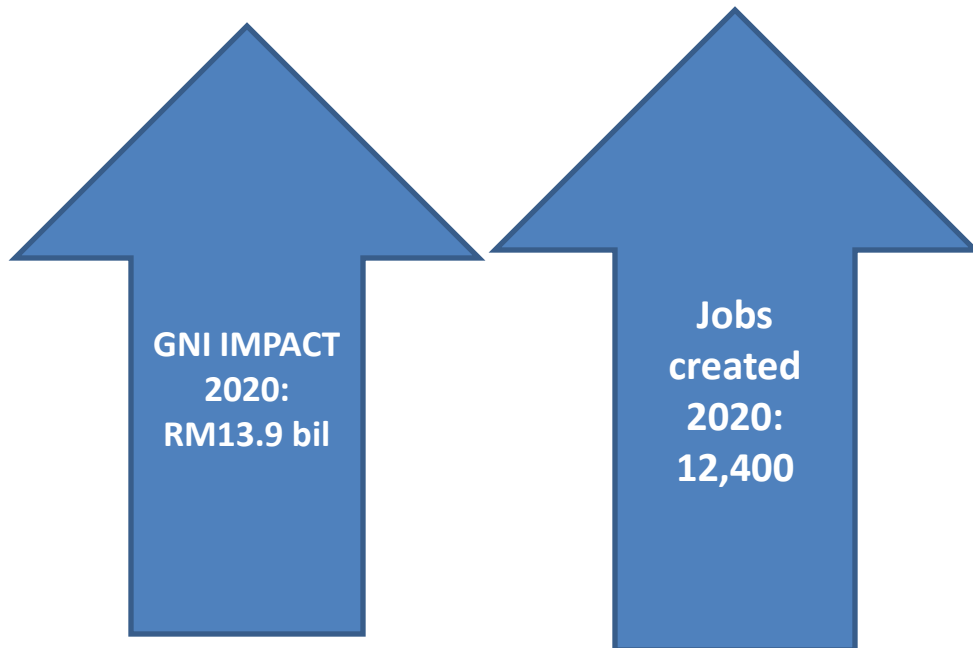
The Malaysian pharmaceuticals industry has the capability to produce almost all dosage forms, including sterile preparation such as eye preparations, injections (both large and small volume), soft gelatine capsules of various sizes and shapes, time release medications and powders for reconstitution.

KEY TRENDS IN THE MALAYSIAN PHARMACEUTICAL INDUSTRY



NKEA HEALTHCARE: EPP 3 - Malaysian Pharmaceuticals

Leverage patent expiry cliff by pursuing generic opportunities



MADE IN MALAYSIA

EPP 3: MALAYSIA PHARMACEUTICALS

Malaysia will execute a strategy to transform Malaysia into a major force in the export of generic pharmaceutical.

Strategies:

- ✓ To produce enabling environment for Malaysian pharmaceutical industry.
- ✓ To facilitate generics export opportunities and transform the industry by creating export platform, localisation and upgrading, as well as collaboration between MNCs and local manufacturers.
- ✓ To create greater market access.

CHALLENGES

Market Access

- Non Tariff Barriers.
- Internationalisation.

Regulatory

- Multiple authorities locally.
- Non Tariff Barriers overseas.

Talents

- Limited talent pool locally.
- Sourcing of expatriates.

Eco-System

- Costly regulatory requirements.
- Support from financial institutions.

PHARMACEUTICAL COMPANIES WITH EPP STATUS

A|F|T *pharmaceuticals*

BioCare



CCM PHARMACEUTICALS DIVISION


**IMPIAN EKSEKUTIF
SENDIRIAN BERHAD**

RANBAXY


AJBiologics


Biocon

hovid
Continuous Innovation & Quality


**KOTRA
PHARMA**


SERVIER

Servier Malaysia Sdn. Bhd.

OFF-TAKE AGREEMENT



The Off-Take Agreement (OTA) is one of the Government's initiatives to facilitate local manufacturers in developing a vibrant pharmaceutical industry in Malaysia. The rationale behind OTA is to provide an additional incentive for the local manufacturing of new pharmaceutical products for exports as well as to encourage new investments in the pharmaceutical industry in Malaysia.

PHARMACEUTICAL OFF-TAKE AGREEMENT



Pharmaceuticals Off-Take Agreement will be the catalyst for our local pharmaceutical industry to grow.



Objective - To encourage and develop the pharmaceutical industry in Malaysia.



Malaysian Pharmaceuticals is the most important EPP in Healthcare NKEA with 40% of Healthcare NKEA GNI impact.



Government procurement of local manufactured pharmaceuticals will be a very important incentive for existing and new pharmaceutical plants to expand or invest in Malaysia.

GENERAL PRINCIPLES FOR THE OFF-TAKE AGREEMENT

1

- **Entry Point Project under ETP.**

2

- **Registered with Ministry of Finance.**

3

- **For new investments and for products not manufactured in Malaysia.**

4

- **For finished products produced in Malaysia.**

GENERAL PRINCIPLES FOR THE OFF-TAKE AGREEMENT

5

- Agreement for 3 years and renewable for another 2 years upon submission of proof of registration and sales of products abroad.

6

- Items under existing Government tenders or any other procurement arrangements not included.

7

- The awarding of OTA is subjected to MOH's need and requirements based on SOP approved by Ministry of Finance and upon successful negotiations (product, specification, price offered) with MOH.

WAY FORWARD...

MOH is working on:



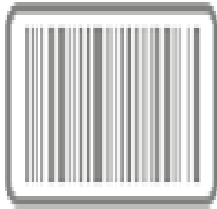
Establishing government to government agreements – giving Malaysia market access and mutual recognition of product registration with selected countries.

- ASEAN harmonization but still non-tariff barriers exists.
- E.g.: Lengthy product registration process, labeling requirements, mandatory local testing of product.





MOH is working with Ministry of Domestic Trade, Co-Operatives and Consumerism to review the Patent Act.



Establishing and implementing the national drug registration system besides regulating the pharmaceutical industry.



Fast Track Registration; The registration period was cut from 18 months to 60 working days for all EPP status companies.

THANK YOU.