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PRESCRIPTION

Latest news and updates from the Faculty of Pharmacy, Universiti Teknologi MARA

EMPOWERING ACCESS TO ORPHAN DRUGS AND NON-COMMERCIALLY VIABLE MEDICINES

By: Dr. Nor Khaizan Anuar

Orphan drugs are medicines developed to treat rare diseases. They often receive little attention from major pharmaceutical companies due to their limited market demand and low profitability. In Malaysia, many of these drugs have to be imported or require special approval, resulting in inconsistent supply and issues with accessibility for patients. Yet, despite their small market, orphan medicines play a vital role in advancing medical innovation and safeguarding public health.

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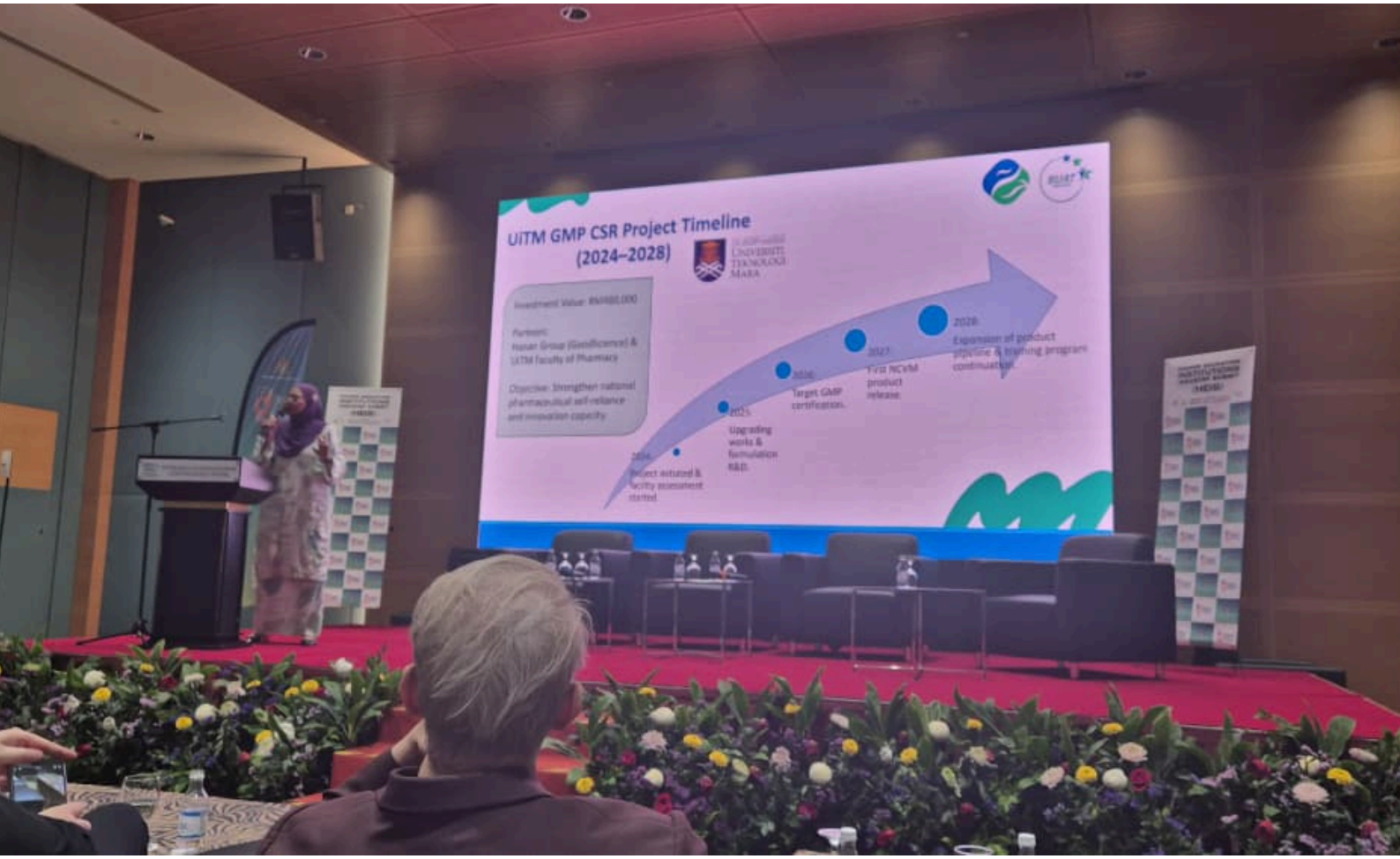

Developing orphan drugs is far from straightforward. The high research and development costs, coupled with the small patient populations for clinical trials, make it difficult for companies to recover their investments. As a result, these medicines often come with high price tags, making them unaffordable for many patients and healthcare systems. To overcome these barriers, collaboration between the public and private sectors is crucial, bringing together the strengths of government agencies, academia, and the pharmaceutical industry.

To address these challenges, GoodScience Sdn. Bhd. and the Faculty of Pharmacy, Universiti Teknologi MARA (UiTM) have established a strategic partnership to locally produce orphan drugs and non-commercially viable medicines (NCVM). NCVMs refer to medicines that are essential for healthcare but have little or no commercial interest due to low demand or profitability, such as certain paediatric formulations or drugs for rare conditions. Despite their limited market value, these medicines are critical to ensuring equitable access to treatment for all segments of the population.

Under this collaboration, GoodScience brings its pharmaceutical manufacturing expertise and regulatory experience, while UiTM researchers focus on optimising and enhancing product formulations. Together, the partnership aims to strengthen Malaysia's capability to produce high-quality, affordable medicines locally, reducing reliance on imports and shielding the nation from volatile international prices.

This initiative supports the Malaysian National Medicines Policy (MNMP), which emphasises the importance of ensuring the availability of orphan medicines and NCVMs without compromising their quality, safety, or efficacy. By fostering local production and innovation, the project not only enhances access to life-saving treatments but also contributes to Malaysia's long-term medicine security and health system resilience.

Researchers from the Faculty of Pharmacy have successfully secured an industrial matching grant from the Ministry of Higher Education (MOHE) and GoodScience Sdn. Bhd., amounting to RM358,000, to kickstart this initiative at the Faculty's Pilot Plant facility. Extensive preparations are currently underway to obtain Good Manufacturing Practice (GMP) certification, in collaboration with the management of UiTM Cawangan Selangor and the National Pharmaceutical Regulatory Agency (NPRA).

Through this initiative, UiTM and GoodScience are setting a national example of how academia and industry can work hand in hand to deliver impactful healthcare solutions, transforming research into real-world benefits for patients who need them most.

About the Author

Dr. Nor Khaizan Anuar is a Senior Lecturer at the Faculty of Pharmacy, Universiti Teknologi MARA (UiTM) Puncak Alam, specialising in pharmaceutics. She obtained her PhD and MSc in Pharmaceutics from UiTM and a Bachelor's degree in Chemical Engineering (Polymer) from Universiti Teknologi Malaysia (UTM). She has also served twice as the Head of the Department of Pharmaceutical Technology, leading academic and research initiatives within the faculty. Her research interests include formulation development and drug delivery systems. She currently leads an Industry Matching Programme (IMaP) grant valued at RM358,000 for the Development and Manufacturing of Orphan Drugs and Non-Commercially Viable Products to Ensure National Medicine Security.

Quiz questions

01 What are orphan drugs and non-commercially viable medicines (NCVM)?

Answer: Orphan drugs are medicines developed to treat rare diseases that affect a small percentage of the population, while NCVMs are medicines that are essential for healthcare but have little commercial interest.

02 Why do major pharmaceutical companies show limited interest in producing orphan drugs and NCVMs?

Answer: Major pharmaceutical companies show limited interest in producing orphan drugs and NCVMs due to their limited market demand and low profitability.

03 What factors contribute to the high costs of orphan drugs?

Answer: The high cost of orphan drugs is due to substantial research and development costs combined with limited market demand.