National Pharmaceutical Control Bureau (NPCB)
Ministry of Health
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Berita Ubat-ubatan
NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

SEMINAR ON PHARMACOVIGILANCE

Berita Ubat-ubatan November 1998

A seminar conjointly organised by the Ministry of Health, Malaysia and the World Health Organisation was held on 12th and 13 th of October 1998 in Petaling Jaya, Malaysia to discuss issues pertaining to pharmacovigilance. The seminar entitled "Drug Safety & You" was attended by participants comprising of doctors and pharmacists from the government and private sector as well as representatives from the drug regulatory agencies of Indonesia, Singapore, Brunei Darulssalam, Thailand, Philippines, Sri Lanka, Lao P.D.R and Mongolia.

Key Note Address

The keynote address was presented by the Director General of Health, Malaysia, Tan Sri Dato' (Dr) Abu Bakar Suleiman. Health professionals needed to realise the importance of post marketing surveillance and the monitoring of adverse drug reactions (ADR) as a tool for providing safety information. The existing scenario, the shortfalls and aspirations for the ADR programme in Malaysia were discussed. Taking into account the well established immunisation programme ,the regulation of traditional remedies and the usage of tropical medicines, it was felt that Malaysia could contribute much on a global plane towards establishing the safety of these groups of products.

Presentation of Papers

The ten speakers during the paper presentations covered a wide range of topics. Dr Martijn ten Ham began by giving an overview of WHO's role and its achievements thus far in monitoring drug safety globally. Mr Sten Olsson gave an overview of the functions, activities and the collaborative work performed by the Uppsala Monitoring Centre in Sweden and the WHO. Dr Ian Boyd of the Australian ADR Advisory Committee gave an insight into ADR monitoring in Australia, which has been reputed to be one of the best in the world.

Dr Anis Ahmad, our esteemed Director of Pharmaceutical Services, discussed how a multidisciplinary approach involving health professionals, regulators and the industry could be utilised to further improve the quality and rate of ADR reporting. Mr Olsson introduced the audience to the Erice Declaration and the importance of effective communications in the context of pharmacovigilance. The views and expectations of consumers about information on drug safety issues was not forgotten in this seminar and was addressed by Dr K. Balasubramaniam of PAC International.

The topic of dependence related ADRs, which is also an area of concern, was addressed by Mr Tokuo Yoshida of the Psychotropic and Narcotic Drug Division WHO, Geneva.

Datin (Dr) Suraiya Hussein, a consultant dermatologist with the Ministry of Health Malaysia gave an informative description of adverse cutaneous drug reactions encountered with drugs commonly prescribed in Malaysia. The industry's

perspective of ADR reporting and monitoring was aptly presented by Dr Y.M Cheong, who represented the pharmaceutical industry.

Dr M. Ramanathan, a local consultant physician, discussed methods by which ADRs could be identified and recognised. Prof. Dzulkifli Abdul Razak of the National Poisons Centre elaborated on ways by which the Poisons Centre could contribute towards ensuring the safe use of drugs.

Country Reports

The foreign delegates presented several country reports. Ms Chan of Singapore briefly outlined the status of drug registration and the mechanism used for ADR reporting in her country. Ms Wimon of Thailand gave a brief history on the setting up of the Thai National ADR Monitoring Centre and the development of the decentralised centres. Ms Nazarita of Philippines gave an interesting account of the set up in the Philippines and showed the various promotional material which has been used in their ADR training programmes.

Ms Chua of Brunei Darussalam and Dr Fernandopulle of Colombo described the existing systems currently applied for the monitoring of ADRs and the plans, which have been made thus far for setting up National Centres in their respective countries.

Panel Discussion

The panel, chaired by Dr Ramanathan, stimulated a lively discussion with active participation from the floor. Issues that were discussed at great length were the underlying reasons leading to underreporting of ADRs in Malaysia. It was felt that more publicity, especially to prescribers, should be given regarding this programme so that ADR monitoring can be included as a topic for continuing medical education sessions as this subject is not adequately covered in the medical undergraduate programs.

The provision of feedback to reporters on the outcome of ADR reports submitted was identified as being a very important and effective method to stimulate continuation of reporting. Gaining the confidence of the reporters was also deemed to be very important because reporters, at times feared that there may be a breach of confidentiality and were therefore apprehensive to submit reports.

Questions were raised as to the justification in giving free reporting forms with pre paid envelopes. The panellist concurred that the actual cost of the blue card is minimal in comparison to the gains derived from the reports received.

It was heartening to note from the discussion that through this seminar, there was a realisation that ADR reporting contributes towards increasing knowledge about a drug and its safety profile and that it was just as important to report well established ADRs as well as those based on a mere suspicion.

Launching of the MADRAC Homepage

(www.come.to/madrac OR www.madrac.gov.my/madrac)

The Malaysian Adverse Drug Reactions Advisory Commitee's homepage was launched by the Honourable Minister of Health Malaysia, Dato' Chua Jui Meng. In his speech, the Honourable Minister expressed his concerns for monitoring drug safety especially in view of the fact that approximately 20,000 products have been registered for use in this country. All the players involved in the utilisation of drugs needed to realise their roles and responsibilities in the field of pharmacovigilance. It was hoped that this interactive homepage would function as an effective and efficient tool for communicating information on drug safety issues and that prescribers, consumers, industry and regulators would utilise it fully.

The organising committee would like to take this opportunity to thank the speakers, the foreign delegates, local participants and the Malaysian Airlines for their contributions in making this seminar a success.

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