WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Daklinza[1]

International Nonproprietary Name (INN):
Daclatasvir (as dihydrochloride) 30mg tablets

Abstract

The "Procedure for prequalification of pharmaceutical products"[2] defines different evaluation mechanisms for innovator products and multisource (generic) products. In relation to this the "WHOPAR Guidance for Applicants (Manufactures) on the compilation of the WHO Public Assessment Report, v 2.5"[3] defines that for an innovator product that was approved by a medicines regulatory authority in one of the ICH regions and for which a public assessment report was published by the approving authority, the WHOPAR will for parts 1, 3, 4, 5, 6 and 8 refer to this public assessment report.

Daklinza 30 mg film coated tablet, manufactured at Bristol Myers Squibb Pharma EEIG, was submitted to be considered for prequalification in 2016 when the product was licensed / registered in at least one of the ICH regions and subsequently accepted for the WHO list of prequalified medicinal products for the treatment of chronic hepatitis C infections on 14 Oct 2016.

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme.
However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant.

WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

Do not store above 30°C.
The shelf life at this storage condition is 30 months.

Based on the above, the WHOPAR for Daklinza refers for parts 1, 3, 4, 5, 6 and 8 to the previously issued public assessment report as follows:

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

[2] http://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex10.pdf
[3] http://apps.who.int/prequal/WHOPAR/WHOPARGUIDE/WHOPAR_Guid_Appl_v2-5.pdf

WHOPAR part		**Reference[4, 5]**
Part 1	Summary for the Public	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/003768/WC500172850.pdf
Part 3	Package Leaflets	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003768/WC500172848.pdf
Part 4	Summaries Product Characteristics	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003768/WC500172848.pdf
Part 5	Labelling	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003768/WC500172848.pdf
Part 6	Discussion	http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinio_Initial_authorisation/human/003768/WC500169345.pdf
Part 8	Steps taken following Authorization	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/human768/WC500177143.pdf

Parts 2a/b and 7 of Daklinza are included here.

Summary of Prequalification Status for Daklinza:

	Initial Acceptance			
	Date	Outcome	Date	Outcome
Status on PQ list, i.e. date of listing	14 Oct 2016	Listed		
Dossier Evaluation	19 Sept.2016	MR		

MR: meets requirements

The table represents the status of relevant completed activities only.

[4] http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d125

[5] http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003768/human_med_001792.jsp&mid=WC0b01ac058001d124