Recommended Comparator Products: treatment of disorders due to use of nicotine

Comparator products should be purchased from a well-regulated market with stringent regulatory authority [*].

Invited medicinal products (refer to EOI for more information e.g. requirements for scoring)	Recommended comparator product (Strength, Manufacturer)
Nicotine chewing gum: 2 mg and 4 mg (as polacrilex).	Nicorette chewing gum (2 and 4 mg (as polacrilex), GlaxoSmithKline)
Nicotine transdermal patch: 5 mg to 30 mg/16 hours	Nicorette transdermal patch (5 – 25 mg/16h, Johnson&Johnson)
7 mg to 21 mg/24 hours	Habitrol transdermal patch (7 - 21 mg/24h, Dr. Reddys Laboratories SA)[1] Nicoderm CQ transdermal patch (7 – 21 mg/24h, Sanofi Consumer Healthcare) Niquitin transdermal patch (7 – 21 mg/24h, Omega Pharma) Nicotinell transdermal patch (7 – 21 mg/24h, Novartis)

[1] The recommended comparator product is approved by USFDA; the comparator product should be obtained from the US market.

[*] A regulatory authority that is:

a) a member of ICH prior to 23 October 2015, namely: the US Food and Drug Administration, the European Commission and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or
b) an ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swissmedic and Health Canada; or
c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein and Norway.

Obtaining Comparator

Comparator products should be purchased from a well-regulated market with stringent regulatory authority. If the recommended comparator cannot be located for purchase from the market of one of the identified countries, the applicant should consult with WHO regarding the sourcing of an acceptable comparator product.

Information Requirements

Within the submitted dossier, the country of origin of the comparator product should be reported together with lot number and expiry date, as well as results of pharmaceutical analysis to prove pharmaceutical equivalence. Further, in order to prove the origin of the comparator product the applicant must present all of the following documents:

1. Copy of the comparator product labelling. The name of the product, name and address of the manufacturer, batch number, and expiry date should be clearly visible on the labelling.
2. Copy of the invoice from the distributor or company from which the comparator product was purchased. The address of the distributor must be clearly visible on the invoice.
3. Documentation verifying the method of shipment and storage conditions of the comparator product from the time of purchase to the time of study initiation.
4. A signed statement certifying the authenticity of the above documents and that the comparator product was purchased from the specified national market. The certification should be signed by the company executive or equivalent responsible for the application to the Prequalification Programme.