MODAFINIL 100 MG AND 200 MG TABLETS
PL 30684/0220-1

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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted DAWA Limited Marketing Authorisations (licences) for the medicinal products Modafinil 100 mg and 200 mg Tablets (PL 30684/0220-1) on 19 October 2012. These medicines are only available on prescription from your doctor.

Modafinil 100 mg and 200 mg Tablets contain the active ingredient modafinil. Modafinil 100 mg and 200 mg Tablets can be taken by adults who suffer from narcolepsy to help them to stay awake. Narcolepsy is a condition that causes excessive daytime sleepiness and a tendency to fall asleep suddenly in inappropriate situations (sleep attacks). Modafinil Tablets may improve your narcolepsy and reduce the likelihood that you will have sleep attacks but there may still be other ways that you can improve your condition and your doctor will advise you.

No new or unexpected safety concerns arose from these simple applications and it was, therefore, judged that the benefits of taking Modafinil 100 mg and 200 mg Tablets outweigh the risks and Marketing Authorisations were granted.
MODAFINIL 100 MG AND 200 MG TABLETS
PL 30684/0220-1

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted Marketing Authorisations for the medicinal products Modafinil 100 mg and 200 mg Tablets (PL 30684/0220-1) to DAWA Limited on 19 October 2012. The products are prescription-only medicines (POM) indicated in adults for the treatment of excessive sleepiness associated with narcolepsy with or without cataplexy.

Excessive sleepness is defined as difficulty maintaining wakefulness and an increased likelihood of falling asleep in inappropriate situations.

These applications were submitted as abridged applications according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Modafinil 100 mg and 200 mg Tablets (PL 22805/0028-9; Orchid Europe Limited) which were granted Marketing Authorisations on 22 January 2010 following completion of the Decentralised Procedure NL/H/1278/01-02/DC. Modafinil 100 mg and 200 mg Tablets (PL 22805/0028-9) cross-refer to Provigil 100 mg and 200 mg Tablets (PL 16260/0001-2; Cephalon UK Limited), which were first authorised in the UK on 14 October 1997.

The active ingredient, modafinil, is a centrally acting sympathomimetic drug in the pharmacological class of psychoanaleptics (ATC Code N06BA07). Modafinil promotes wakefulness in a variety of species, including man. The precise mechanism(s) through which modafinil promotes wakefulness is unknown.

No new data were submitted nor were they necessary for these simple applications, because the data packages are identical to those of the previously granted cross-reference products.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 30684/0220-1
PROPRIETARY NAME: Modafinil 100 mg and 200 mg Tablets
ACTIVE(S): Modafinil
COMPANY NAME: DAWA Limited
E.C. ARTICLE: Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS: POM

1. INTRODUCTION
These are abridged applications for Modafinil 100mg and 200 mg Tablets, submitted under Article 10c of Directive 2001/83/EC, as amended.

The applications cross-refer to Modafinil 100 mg and 200 mg Tablets (PL 22805/0028-9) which were granted Marketing Authorisations to Orchid Europe Limited on 22 January 2010. The current applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 Name(s)
The proposed names of the products are Modafinil 100 mg and 200 mg Tablets. The products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Each tablet contains 100 mg or 200 mg of the active ingredient, modafinil. The tablets are for oral use and packaged in polvinylchloride/Aclar or aluminium blisters. These are packed into cardboard cartons with Patient Information Leaflets in pack sizes of 10 and 30 tablets.

Not all pack sizes may be marketed.

The packaging, proposed shelf-life (2 years) and absence of any special storage conditions are consistent with the details registered for the cross-reference products.

2.3 Legal status
On approval, the products will be available as prescription-only medicines (POM).

2.4 Marketing Authorisation Holder/Contact Persons/Company
DAWA Limited, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD, United Kingdom.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference products and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed compositions are consistent with the details registered for the cross-reference products.
2.7 Manufacturing process
The proposed manufacturing processes are consistent with the details registered for the cross-reference products and the maximum batch sizes are stated.

2.8 Finished product/shelf-life specification
The proposed finished product specifications are in line with the details registered for the respective cross-reference products.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference products.

2.10 TSE Compliance
With the exception of lactose monohydrate, none of the excipients contain materials of animal or human origin. The supplier of lactose monohydrate has confirmed that the milk used in the production of lactose monohydrate is sourced from healthy animals under the same conditions as that intended for human consumption. In addition, the supplier has confirmed that no ruminant material other than calf rennet is used during the production of lactose monohydrate. This is consistent with the cross-reference products.

2.11 Bioequivalence
No bioequivalence data are required to support these simple abridged applications, as the proposed products are manufactured to the same formulae and utilise the same processes as the reference products Modafinil 100 mg and 200 mg Tablets (PL 22805/0028-9).

3. EXPERT REPORT
The applicant cross-refers to the data for Modafinil 100 mg and 200 mg Tablets (PL 22805/0028-9), to which these applications are claimed to be identical. This is acceptable.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product names. The appearances of the products are identical to the respective cross-reference products.

5. SUMMARIES OF PRODUCT CHARACTERISTICS (SmPCs)
The proposed Summaries of Product Characteristics are consistent with the details registered for the respective cross-reference products.

6. PATIENT INFORMATION LEAFLETS (PILs) AND LABELLING
The Patient Information Leaflets have been prepared in-line with the details registered for the cross-reference products.

Orchid Europe Limited previously submitted results of consultations with target patient groups (‘user testing’), in accordance with Article 59 of Council Directive 2001/83/EC, for the reference products Modafinil 100 mg and 200 mg Tablets (PL 22805/0028-9). The results indicate that the leaflets are well-structured and organised, easy to understand, and written in a comprehensive manner. The tests show that the patients/users are able to act upon the information that the leaflets contains.
As the leaflets for Modafinil 100 mg and 200 mg Tablets (PL 22805/0028-9) and these products are considered the same, no further user testing of the leaflets for these products is necessary.

**Carton and blister**
The proposed artwork is consistent with the artwork registered for the respective cross-reference products and complies with statutory requirements. In line with current legislation, the applicant has also included the names of the products in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

**7. CONCLUSION**
The data submitted with the applications are acceptable. The grant of Marketing Authorisations is recommended.
NON CLINICAL ASSESSMENT

As these are abridged applications submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA). As the applications are for identical versions of already authorised products, it is not expected that environmental exposure will increase following approval of the Marketing Authorisations for the proposed products.

Suitable justification has been provided for non-submission of an Environment Risk Assessment (ERA). This is consistent with the cross-reference products.

The grant of Marketing Authorisations is recommended.
CLINICAL ASSESSMENT

As these are abridged applications submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

The Marketing Authorisation Holder has not submitted a Risk Management Plan (RMP). As the applications are for identical versions of already authorised reference products, for which safety concerns requiring additional risk minimisation have not been identified, a Risk Management Plan is not considered necessary. The reference products have been in use for many years and the safety profile of the active ingredient is well-established.

The grant of Marketing Authorisations is recommended.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
The data for these applications are consistent with those previously assessed for the cross-reference products and as such have been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY
These applications are identical to previously granted applications for Modafinil 100 mg and 200 mg Tablets (PL 22805/0028-9).

SAFETY
No new safety data were supplied or required for these applications. Modafinil has a well-established safety profile. No new or unexpected safety concerns arose from these applications.

PRODUCT LITERATURE
The SmPCs, PIL and labelling are satisfactory, and consistent with those for the cross-reference products.

BENEFIT/RISK ASSESSMENT
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s products are identical to the cross-reference products. Extensive clinical experience with modafinil is considered to have demonstrated the therapeutic value of the products. The benefit/risk balance is, therefore, considered to be positive.
STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Marketing Authorisation applications on 20 June 2012.
2 Following standard checks and communication with the applicant the MHRA considered the applications valid on 06 July 2012.
3 Following assessment of the applications the MHRA requested further information relating to the dossier on 04 August 2012 and 20 September 2012.
4 The applicant responded to the MHRA’s request, providing further information on the 10 September 2012 and 03 October 2012.
5 The applications were granted on 19 October 2012.
SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
PATIENT INFORMATION LEAFLET

In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
LABELLING

Modafinil 100 mg Tablets
Aluminium/Aluminium cartons:

Each tablet contains 100 mg modafinil. Also contains lactose.
For oral use only.
See enclosed leaflet for further information. Read the package leaflet before use.
Keep out of the sight and reach of children.
Each tablet contains 100 mg modafinil. Also contains lactose.

For oral use only.

See enclosed leaflet for further information. Read the package leaflet before use. Keep out of the sight and reach of children.

Modafinil 100 mg tablets

Aluminium/Aluminium blisters:

Modafinil 100 mg tablets

Marketing Authorisation Holder: Dawa Limited, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD - UK

Expiry: MM YYYY

LOT XXXXX
PVC/Aclar cartons:
PVC/Aclar blisters:
Modafinil 200 mg Tablets
Aluminium/Aluminium cartons:
Aluminium/Aluminium blisters:
PVC/Aclar blister: