NHSF Product Accreditation Process - Overview

Premise 1 – the Natural Health Science Foundation (the NHSF or "Foundation" in this document) provides no warranties or review of safety of natural health products, which is the responsibility of the regulatory authorities in each country.

Premise 2 – the Foundation will review trials provided for a specific product for use in an *indication class*, not specific claims. Specific claims made on marketed products are a matter for the regulatory authority in each country.

1.0 Governance Framework for the Product Assessment Process

Oversight – the Expert Advisory Board (EAB) of the Foundation have defined the process and oversee the assessment of products, using the agreed templates for assessment of products. This process will be periodically reviewed and improved where possible**.**

Confidentiality – the Foundation recognizes that the natural medicine industry has special challenges in relation to intellectual property protection and thus at all times will treat any submissions made in the assessment process with the highest confidentiality. Requested documentation will be limited only for the purpose of assessing the product(s) for accreditation, noting that without such documentation a comprehensive review will not be possible. The names of applicants/products submitted for review, identity of assessors and the results of any review will remain strictly confidential. A Confidentiality Agreement among the applicant and the Foundation, the EAB members and the assessor(s) will be executed. The results of a successful review will be governed under a separate Services and Licensing Agreement between the applicant and the Foundation. It will remain confidential that an application has been made, is in process or has been withdrawn or rejected for any reason.

Avoidance of conflicts of interest with Assessors – it is recognized by the Foundation that there may be a limited number of experienced assessors available, and that some might have worked with applicant companies or their competitors. Therefore the EAB will ensure that any assessor appointed to review a submission will have certified that over the past three (3) years they:

a. do not have any interest in; or
b. are not receiving remuneration from

the applicant company or companies with a competitor product to the submitted product. The identity of appointed assessors for a particular product assessment will remain anonymous, although as a group their identities might be published if the Foundation sees fit.

Intellectual property – all intellectual property of an applicant as well as the Foundation will remain the property of the relevant party.

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2.0 Product Assessment Process Overview

Pre-assessment – to avoid review of an incomplete data package, applicants will be required to complete a pre-assessment checklist which will be provided. The Foundation will review the data package against this checklist before triggering the expert review of quality/equivalence and efficacy.

Step 1: Quality & Equivalence Assessment - standard questions on quality will need to be completed satisfactorily. Specific evidence provided on the product in question will be assessed to establish that the evidence is applicable to the product through a Quality & Equivalence Checklist. If there is more than one active ingredient then separate evidence is required for each, and an additional charge is payable. This process will be guided by the Equivalence and Quality Principles standards of the Foundation.

Step 2: Efficacy Assessment – an Efficacy Assessment Checklist will be completed by an applicant and provided to the EAB via the secretariat of the Foundation, together with the clinical trial evidence on the specific product for review. The template will document the assessor's review of the support provided by the evidence submitted for the *indication class* requested by the applicant.

3.0 Expert Assessment - Quality & Equivalence

An external assessment will be conducted, under the oversight of the EAB in accordance with the Foundation's requirements.

Quality Assessor Panel – The EAB will appoint an independent assessor for each product. These assessors will be selected based on expertise in the three herbal medicine quality areas of: sourcing; extraction; and production. If necessary, more than one assessor can be appointed with complementary expertise in the respective quality areas/value chain steps sectors for a joint assessment on a product.

Guidance to quality assessors – one or more invited assessors will be requested to review the completed "NHSF QUALITY AND EQUIVALENCE Assessment Herbal Medicines" [1] and supporting documentation provided by the applicant. Additional active ingredients will require their own submission "NHSF QUALITY AND EQUIVALENCE Additional actives" [2]. This will be reviewed, and a ~250 word report will be written and all reviews will be provided to the EAB for ratification.

Quality assessors – it is a prerequisite that quality assessors are familiar with sourcing of natural raw material and/or manufacture of natural health products.

4.0 Expert Assessment - Efficacy

Efficacy Assessor Panel – the EAB will appoint an assessor for each product, who has research/clinical experience in the indication class of the product. Additional indication classes might require an additional assessor. The EAB may call on other assessors as they deem fit.

Guidance to efficacy assessors – an invited assessor will be requested to review the submitted "NHSF EFFICACY Assessment Natural Medicines" [3] and supporting documentation provided by the applicant and in particular will review the clinical trial evidence provided by the applicant and write a ~250 word report. All reviews will be provided to the EAB for ratification.

Efficacy assessors – the expected profile of an assessor is a researcher/clinician (such as a medically qualified post-doc) active in the conduct of clinical trials, if possible, with familiarity with natural medicines.

5.0 Clinically studied ingredients

Ingredient evidence – the Foundation recognizes that substantial research has been done by ingredient suppliers on their quality/supply chain controls and to provide clinical evidence on their ingredient. The ultimate goal of accreditation is to identify products which are made reliably from batch to batch and which have specific clinical evidence of efficacy on the finished product. If the evidence is limited to an ingredient only, then a different tier of accreditation has been developed to help people identify products that contain natural health ingredients that are reliably made and have been clinically studied.

Finished product equivalence – for an ingredient, a positive Quality & Equivalence assessment will be followed by a review of any specific finished product containing the ingredient. This is to ensure that the finished product contains a therapeutic dose of the ingredient, in an equivalent dosage form and, if it contains any additional ingredients, that they are unlikely to have a negative pharmacodynamic or pharmacokinetic interaction with the assessed ingredient. This is an additional assessment to the Quality & Equivalence and Efficacy Assessments of the ingredient.

6.0 Successfully Accredited Products

Communication rules of the Foundation – results of successful reviews will be published in a standard template, indicating the product brand name(s), identify of the product owner (applicant) and distribution partners by country, claim area supported by specific clinical trial(s) and that the product has successfully been shown to be equivalent to the product used in clinical trials. The communication of a successful review will be governed by a Services and Licensing Agreement between the applicant and the Foundation.

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'Accredited' logo – only the locally allowable claims within the *indication class* / *claim area* approved will be supported by the Foundation. This means that the Foundation will not be supporting any additional claims for a product outside of the claim area that has been assessed. The packaging and point of sale material will need to follow the Foundation's guidelines and accreditation might be revoked if the guidelines are not followed. Databases and education will be built around the clinical evidence of an accredited product, not around other claim areas which might be allowed in any particular countries.

Products with finished product clinical evidence will receive this logo

Products with ingredient clinical evidence, that pass the assessment in 5.0, will receive this logo

1 year renewal – an expedited 1 year review and audit process will allow for continued use of the logo and promotion through the Foundation.

7.0 Accreditation Forms

[1] 2021-12-13 NHSF QUALITY AND EQUIVALENCE Assessment Herbal Medicines
[2] 2021-12-13 NHSF QUALITY AND EQUIVALENCE Additional actives
[3] 2021-12-13 NHSF EFFICACY Assessment Natural Medicines