Guidelines and conditions for NADP Vouchers applications

For more information about the NADP Vouchers, please contact vouchers@nadp.nl.

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1. Background

One of the important objectives of the NADP is to increase the productivity of research and development for new antibiotics and alternatives. The NADP aims to achieve this goal by encouraging cooperation between public and private parties and by identifying new 'leads' for the development of new antibiotics or alternative therapeutics in an early phase. To promote the accelerated development of promising 'leads', the NADP has developed a financing instrument specifically for this purpose: the NADP Vouchers. The vouchers can be utilised in various phases of the drug development process to obtain advice and intensive supervision of (research) projects by independent consultants[1] or consultancy organisations[1] that have specific knowledge and expertise pertinent to the pharmaceutical development process and clinical applications. The options vary from lead identification and optimisation, patent applications, and market analysis to pre-clinical drug development.

2. Application procedure

2.1 Who is eligible to apply?

Employees appointed at one of the following Dutch organisations are eligible to apply for a voucher:

- universities
- university medical centres
- universities of applied sciences (hogescholen)
- small and medium-sized enterprises (SMEs)
- KNAW and NWO institutes
- other scientific institutes, for instance TNO, Wageningen Bioveterinary Research, Intravacc.

2.2 What can be applied for?

The NADP Voucher application must pertain to a lead product that may result in a new antibiotic or alternative therapeutic, as described in the NADP Research and Development Agenda (RDA). The NADP Voucher is a grant that can be used to finance advice and intensive supervision of (research) projects by independent consultants[1] or consultancy organisations[1] that have specific knowledge and expertise pertinent to the

[1] *An independent consultant or consultancy organisation is an organisation, which is not a knowledge institution, possesses expertise in the field of the activities to be funded by means of the voucher, and conducts consultancy and/or contract research assignments as a business activity.*

pharmaceutical development process and clinical applications. Three different vouchers are available via the NADP Voucher financing instrument: Intellectual Property Vouchers, Value Proposition Vouchers, and Lead Development Vouchers. Each applicant can be awarded a maximum of one Intellectual Property Voucher, one Value Proposition Voucher, and/or one Lead Development Voucher.

Intellectual Property Vouchers

These vouchers can be used for independent advice on the patentability of a new lead.

An **Intellectual Property Voucher** can entail:

- a freedom-to-operate analysis;
- drawing up a patent application;
- 1st submission of a patent application;
- drawing up the licence contract between companies and knowledge institutions strategic partners;
- drawing up subsidy contracts with IP clauses, or the company contributing IP to the project;
- consulting on the best strategy to exploit IP, including related protection options, such as a supplementary protection certificate, orphan drug exclusivity, and data exclusivity.

The compensation for the advice and project assistance is up to 75% of the total project costs, with a maximum of 5,000 euro.

Value Proposition Vouchers

These vouchers can be used for independent advice on the valorisation options for a new lead.

A **Value Proposition Voucher** can entail:

- drawing up a business case / business plan;
- market analysis;
- drawing up a product development plan;
- drawing up a target product profile (TPP).

The compensation for the advice and project assistance is up to 75% of the total project costs, with a maximum of 15,000 euro.

Lead Development Vouchers

For independent advice on, guidance of, and execution of a project to select and/or validate a lead compound with specific characteristics that fall within the minimum entry thresholds for enrolment (specified in Appendix 1).

A **Lead Development Voucher** can entail:

- lead selection;
- lead optimisation;
- lead formulation;
- ADME / DMPK studies;
- toxicology studies.

The compensation for the advice and project assistance is up to 75% of the total project costs, with a maximum of 50,000 euro.

Eligable costs considered for the NADP Vouchers (what may be applied for):
Only costs directly related to the project will be considered for the funding. These are divided into the following categories:

- Costs for staff. NADP stipulates a predetermined, fixed maximum rate for all employees of the independent service supplier, i.e. 125 euro per hour excl. VAT;
- Costs for patent application (up to 1st submission);
- Costs for materials, reagents etc. to execute a project aimed at the selection and/or validation of a lead compound.

Costs that are not considered include:

- General operating costs (such as start-up, notarial, accountant costs, administrative costs, etc.);
- Investments in equipment and instruments;
- Costs for patent protection during the conduct of the activities, unless these are covered by an application for an NADP Intellectual Property Voucher;
- Travel and accommodation expenses;
- Study expenses.

Each application should include a proposed budget for the activities to be carried out, in any case distinguishing between the three categories of cost items as indicated above (if applicable). Costs are regarded as directly related to the project if: 1) they are direct (research) expenses associated with the purpose described in the application and relevant to the objective(s); 2) such costs are incurred for the duration of the project and not before the date of the Grant Award Decision, unless the NADP Executive Board has explicitly stated otherwise in the Grant Award Decision due to exceptional circumstances associated with the co-funding (or partial co-funding); and 3) the costs are not or will not be funded through other resources.

Please note: All costs incurred from the date on which the implementation contract goes into effect may be declared. Costs incurred prior to this date are not eligible funding and may not be declared. Costs to third parties, including the service provider, must be provided including value-added tax (VAT).

Eligible co-funding considered for the NADP Vouchers:
Co-funding can consist of in-cash and in-kind contributions. In-kind contributions for activities directly related to the project are divided into the following categories:

- Costs for staff. NADP stipulates a predetermined, fixed maximum rate for all employees of the applicant organisation (for all three vouchers), i.e. 125 euro per hour excl. VAT;
- Costs for materials, reagents etc. to execute a project aimed at the selection and/or validation of a lead compound (for Lead Development Vouchers only).

2.3 When can an application be submitted?

- Applications for the Intellectual Property Voucher, Value Proposition Voucher, and Lead Development Voucher may be submitted throughout the year (until 2020, and as long as budget is available) using the application forms available on the NADP website;
- Applications for the Intellectual Property and Value Proposition Vouchers will be collected on 01/09/2018, 01/11/2018, 01/02/2019, 01/04/2019, 01/06/2019, 01/08/2019, and 01/10/2019.
- Applications for the Lead Development Voucher will be collected on 01/09/2018, 01/02/2019, 01/06/2019 and 01/10/2019;
- Applications will be reviewed in order of the date/time of submission (first-come, first-served principle).
- Applicants are allowed to resubmit a revised application.

2.4 How to submit an application?

Applications must be submitted using specific application forms available for download from the NADP website (https://nadp.nl/nadp-vouchers/). Applicants for a Lead Development Voucher must check whether the application meets the entry threshold requirements as described in the entry threshold document, see Appendix 1.

3. Evaluation procedure

3.1 Evaluation procedure for Intellectual Property and Value Proposition Vouchers

After the collection date, eligibility of the IP and VP NADP Voucher applications will be verified by the NADP Support Office on the following criteria:

- The application is complete and fulfils the conditions as stated in the application form and stipulated guidelines;
- The applicant is a Dutch university, university medical centre, small- or medium-sized enterprise (SME)* or a knowledge institution (incl. universities of applied science);
- The application does not exceed the maximum grant budget and meets the co-funding requirement as set for each NADP Voucher.

After the initial eligibility check, the IP Voucher and VP Voucher applications will be reviewed by at least 1 expert from an external independent expert pool appointed by the NADP Executive Board. The expert reviewer will issue a recommendation to the NADP Executive Board whether the application pertains to a promising innovation that may result in a new antibiotic or alternative therapeutic, as described in the NADP Research and Development Agenda, and entails:

in case of an Intellectual Property Voucher:

- freedom-to-operate analysis;
- drawing up a patent application;
- 1st submission of a patent application;
- drawing up the licence contract between companies and knowledge institutions strategic partners;
- drawing up subsidy contracts with IP clauses, or the company contributing IP to the project;
- consulting on the best strategy to exploit IP, including related protection options, such as a supplementary protection certificate, Orphan Drug exclusivity, and Data Exclusivity.

In case of a Value Proposition Voucher:

- drawing up a business case / business plan;
- market research;
- drawing up a product development plan;
- drawing up a target product profile (TPP);

Decision on outcome of the IP Voucher and/or VP Voucher application:
The NADP Executive Board will discuss the applications, including the expert's recommendations, and proceed to award or decline the IP Voucher and/or VP Voucher grant. Applicants will be informed of the board's decision within 6 weeks of the application collection date. Opposition against the decision of the NADP Executive Board is not possible; however, the applicant may resubmit an updated and adapted application.

3.2 Evaluation procedure for Lead Development Vouchers

After the collection date, eligibility of the Lead Development NADP Voucher application will be verified by the NADP Support Office for the following criteria:

- The application is complete and fulfils the conditions as stated in the application form;
- The applicant is a Dutch university, university medical centre, small- or medium-sized enterprise (SME)* or a knowledge institution (incl. universities of applied science);
- The application does not exceed the maximum grant budget and meets the co-funding requirement as set for Lead Development Vouchers;
- The application pertains to an innovation that may result in a new antibiotic or alternative therapeutic, as described in the NADP Research and Development Agenda, and concerns a lead that falls within the minimum entry thresholds, as defined in Appendix 1.

The Lead Development Voucher applications will then be reviewed by at least 3 independent experts from an external expert pool. The experts will issue a recommendation to the NADP Executive Board to approve/reject the application. The

following evaluation criteria in which a weighting factor of 2:2:1:1 will be used for criteria 1 to 4:

1. Knowledge foundation and innovativeness
    - Knowledge that serves as the foundation for the lead (according to minimal thresholds);
    - Innovative elements of the lead compared to existing antibiotics.

2. Quality of the project plan description
    - Practical and economic approach;
    - Activity plan;
    - Project budget, itemised by project activity;
    - Availability of other (financial) resources for this project.

3. Commercial potential
    - Possible applications and added value;
    - Societal impact and commercial opportunity.

4. Quality of the applicant(s)
    - Scientific expertise;
    - Entrepreneurial and commercial skills;
    - Level of motivation and ambition.

The NADP Executive Board will discuss the application considering the experts' recommendations. The Board may invite applicants for an interview and/or a presentation on the proposed Lead Development project. Based on the experts' evaluation and, if applicable, the interview/presentation, the NADP Executive Board will then also consult with the NADP Commissioners Board, before awarding the grant to the applicant. Applicants will be informed about the board's decision within 10 weeks of the collection date. Opposition against the decision of the NADP Executive Board is not possible; however, the applicant may resubmit an updated and adapted application.

4. Awarding

The project must begin within 2 months after awarding of the NADP Voucher. The project must be completed no later than 1 year after the start date. A final report must be submitted to NADP within 6 weeks of the completion of the advice and/or supervision project. This final report must correspond to the report format and guidelines provided by the NADP.

4.1 Transfer of the grant to the applicant

The grant of the awarded NADP Voucher will be transferred to the applicant in two stages. 80% of the awarded grant will be transferred upfront the start of the project. The final 20% of the grant will be transferred to the applicant after completion of the project and after approval of the final report by the NADP Executive Board.

5. Publication

By accepting an awarded NADP voucher, the applicant confirms he or she will mention the NADP when publishing results from projects that are partly or fully funded with a NADP voucher.

Appendix 1

Key requirements and entry thresholds for a lead compound to enrol in the NADP Lead Development Voucher financing instrument

- The lead compound must concern a novel antibiotic or alternative therapeutic for the treatment of bacterial infections, as described in the NADP Research and Development Agenda. Preventatives, diagnostic tools, (medication) delivery devices, new formulations of existing therapeutics, and enabling technologies will not be considered.
- The lead must target at least one pathogen from the WHO priority pathogens list for R&D of new antibiotics (http://www.who.int/mediacentre/news/releases/2017/bacteria-antibiotics-needed/en/). Additional pathogens considered here include *Clostridium difficile, Streptococcus pneumonia*, and *Mycobacterium tuberculosis*.
- The lead development stage must lie between "having a validated hit ready to enter lead selection" and "the end of pre-clinical testing".
- A minimum of 4 of the following characteristics should be available about the antibiotic or alternative therapeutic lead involved, where more characteristics provide a higher chance of awarding:
    1. *Demonstrated understanding of the mode of action;*
    2. *Minimal inhibitory concentration (MIC) ≤ 32 µg/ml for Gram-negative pathogens or MIC ≤16 µg/ml for Gram-positive pathogens (or proven in vitro activity if MIC values cannot be measured);*
    3. *In vitro minimal bacterial killing dose for alternative therapeutic leads (i.e. 10 phages/bacterium);*
    4. *Demonstrated chemical or biological structure;*
    5. *Reasonable route of synthesis (or availability of product if natural-product derived);*
    6. *Activity against relevant resistant strains, if targeting a known mechanism;*
    7. *First data on stability, solubility, selectivity, and bioavailability;*
    8. *First data on haemolytic, cytotoxic, and/or immunogenicity data of alternative therapeutic lead;*
    9. *Enough starting material should be available upfront the study to complete proposed project.*