Summary

The translation of insights from fundamental research to clinical applications is currently referred to as ‘translational research’. In this advisory report, upon the request of the Minister of Education, Culture and Science (*minister van Onderwijs, Cultuur en Wetenschap*; Dutch acronym: OCW), the Advisory Council on Health Research (*Raad voor Gezondheidsonderzoek*; Dutch acronym: RGO) examines several questions about translational research.

Different definitions and descriptions of the term ‘translational research’ are being used. A number of common characteristics emerge when comparing the descriptions. The RGO established the following description on the basis of these characteristics:

The RGO considers translational research as a phase in the knowledge chain. It comprises all steps from the identification of possible leads (in patients or patient material) for diagnostics, prevention or treatment, up and including early application in clinical practice. Research questions may originate from clinical practice as well as from the laboratory.

From an international perspective, the Netherlands has a good position in the field of translational research. The RGO has attempted to specify this general impression of the Netherlands and to outline its knowledge position using existing sources. What emerged from this is that the Netherlands can measure up internationally in practically all areas of medical research. In the Netherlands

much translational research in cancer, cardiovascular diseases and infectious diseases is done, translational research concerning other disease groups also occurs, in particular with gastrointestinal neurological diseases, but the extent of this is not easy to establish. The extent of translational research in a number of other areas, is also difficult to determine, making it impossible to give a detailed and complete description of the Dutch knowledge position. Breakthroughs in many areas of translational research may be expected, but it is practically impossible to predict where exactly they will happen. In practice it is much more important to create optimal conditions for groundbreaking translational research over a broad range than to attempt to stimulate breakthroughs in a number of limited and strictly defined areas.

Comparing the Dutch situation to the developments in other countries, it turns out that our good position in translational research results from several advantageous circumstances. The RGO examines the most important success conditions, grouped in five areas: researchers, infrastructure, funding, commercial activities and legislation/regulatory activities. The strong interaction between medical faculties and academic hospitals, in the form of the university medical centres, is an important factor. The combination of patient care and research in one organization stimulates the collaboration of clinical and non-clinical researchers. The availability and the quality of clinical researchers is also an important factor. With its MD-clinical research trainee programme (*assistent-geneeskundige in opleiding tot klinisch onderzoeker*; Dutch acronym: AGIKO) and clinical fellowships, the Netherlands has proper provisions for educating doctors to become clinical researchers. These provisions should be preserved – the programme for clinical fellowships should even be strengthened. The availability of clinical researchers in the future is a point of concern. Therefore, the RGO recommends establishing secure research time for clinicians and improving the perspectives for a career in clinical research.

In several countries, among which Germany and Canada, developments take place that strongly resemble the formation of university medical centres. In order to maintain the position of translational research in the Netherland compared with other countries, reinforcement of the research infrastructure is recommended. The academic institutions need proper provisions for early clinical trials (phase I and II studies). This could be in the form of an organization that supports multicentre trials with data management, statistics and monitoring. Additionally, cohort-biobanks, which systematically collect body

material and the corresponding clinical data, form an important infrastructure for translational research. The Netherlands has qualitatively good cohort-biobanks. The possibilities for the maintenance of these cohort-biobanks are insufficient, while at the same time, large biobanks are being established in other countries. It is therefore a proper development that the university medical centres establish a large infrastructure for biobanks. This project, entitled *Parelsnoer* (String of pearls), is partially funded by the Economic Structure Enhancing Fund (*Fonds Economische Structuurversterking*; Dutch acronym: FES).

The room for funding translational research by the university medical centres themselves is limited. The Netherlands Organization for Health Research and Development (*de Nederlandse organisatie voor gezondheidsonderzoek en zorginnovatie*; Dutch acronym: ZonMw) and a few charitable funds finance parts of translational research and the training of clinical researchers. The government stimulates translational research to a significant degree by way of interim incentives from the FES. This occurs via the consortiums Top Institute Pharma (*Topinstituut Pharma*; Dutch acronym TIPharma) and the Center for Translational Molecular Medicine (CTMM), among others. However, the incidental character of the FES-money is not optimal for achieving a stable infrastructure. The RGO is in favour of spreading out future funding from the FES for translational research across a substantially longer period.

In the course of translational research, close collaboration among knowledge institutions and commercial parties is often a condition for success. Such public-private collaboration is even institutionalized in initiatives such as TIPharma and the CTMM. Practically all knowledge institutions currently have a 'Knowledge Transfer Office' that supports the interaction between companies and scientists. Agreements about intellectual property rights in public / private partnerships are extremely important. It is desirable that the university medical centres (UMCs) develop similar knowledge transfer policies, for example concerning the distribution of patent proceeds and the participation of employees in a start-up enterprises.

Along with manpower, infrastructure and funding, proper legislation and regulation is also a precondition for translational research. The Netherlands have several laws and rules concerning the use of human body material and animals for research. These contribute to responsible research. The current code of conduct for research on human body material "Towards responsible use" forms a

useful basis for a new bill on this issue. The regulation for the use of genetically modified mice, which is increasingly important for translational research, can be simplified.

The Netherlands has a strong position in the area of translational research, but maintaining that position is not a matter-of-course. The recommendations by the RGO are directed towards strengthening success conditions and eliminating hindering factors where possible.