NFU
NETHERLANDS FEDERATION OF
UNIVERSITY MEDICAL CENTRES

Ten principles for Socially Responsible Licensing

June 2019

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Preface

Most Dutch people will never enter an UMC. But as a society, we want to use the results of the high-quality research conducted by the UMCs. Those results can help us to remain healthy or to get the best treatment if we do become ill.

It is important for the research results of UMCs to be translated as quickly as possible into an application. For that purpose, UMCs sometimes work together with commercial parties and grant licenses to companies for their researchers' discoveries. The NFU has now formulated 10 principles for socially responsible licensing in collaboration with many partners.

As part of their three key tasks of research, education and patient care, the UMCs are responsible for making new scientific insights useful for society (valorisation). Sometimes they can accomplish that themselves, but for example in the case of new drugs, they need partners, like biotech and pharmaceutical companies, so the process runs as efficiently and favourably as possible.

Ultimately, the collaboration must lead to the effective availability of the new drugs. A good balance between the innovative strength of companies on the one hand and keeping medicines affordable and available on the other is extremely important for patients. With these principles the UMCs ensure for the first time that when arranging licensing agreements, the intention is expressed of being socially responsible for arriving at a reasonable price and the availability of medicines.

The NFU is actively involved in this and is willing to shoulder responsibility along with other concerned parties. That is why the NFU took on the task of advising the Minister about licensing. A working group composed of a wide range of collaborators that was established, talked to the important parties in the field and arranged an open, online consultation.

This is the result you are reading. The formulated principles will be elaborated further in the near future in a broad national and international coalition, with the Netherlands playing a pioneering role.

The working group contained representatives of UMCs, universities, ZonMw, Topsector LSH/ Health~Holland, Oncode, the collaborating health funds (SGF) and patient representatives. I want to thank them all for their contribution and I look forward to a continuation of this process with them and other partners.

Prof. Willy Spaan, NFU chair

1. Background

The Netherlands Federation of University Medical Centres (NFU) established a national working group composed of a wide range of collaborators and, with their recommendations and a wide-ranging consultation of the field, has arrived at ten principles. The development of the principles started after consultation with Minister Bruins of Medical Care and Sport to inform him of the possibilities for socially responsible licensing.

The background to the minister's request is formed by the discussion of the high prices of medicines. Expensive medicines are a significant and increasingly larger burden on the Netherlands health care budget. According to the NZA Monitor of January 2019, the expenses in the expensive medicines category (more than € 1,000 per patient per year) in 2017 amounted to € 2 billion, or 9 percent of the total spending on medical specialist care. Some treatments are so expensive that they cannot be immediately reimbursed. In other words: the effective availability of established and new treatments for all patients in the Netherlands can be endangered by the high prices of some medicines. In the initiative memo 'Big Farma: niet gezond!', MPs Dijksma (PvdA), Ellemeet (GroenLinks) and Kooiman (SP) presented their vision of this problem. One of their proposed measures is that academic institutions should set conditions when arranging licensing agreements and transferring their licences to manufacturers to ensure the accessibility of any medicine developed.

The national working group under the leadership of the NFU, with representatives from knowledge transfer organisations (KTOs) of UMCs and other academic institutions, from financiers of research and patients' organisations, took on the challenge to talk with various stakeholders, to formulate principles that do justice to the social responsibility of UMCs and of companies that conclude a licensing agreement. The accompanying principles closely follow on from the debate on medicines, but could also be applicable in other contexts, for example in agriculture or information technology. There is consideration for social responsibility there, too, and it is desirable that the fruits of publicly financed academic research should be effectively gained by society.

A political and international increase in scale is required for these principles to have an impact. In the Netherlands only a small proportion of the available drugs was developed (partly) on the basis of Dutch academic research. An even smaller proportion was based on patents from Dutch academic institutions. To actually contribute to greater transparency and acceptable prices, the principles specified here must be embraced in a broad international context alongside implementation in the Netherlands. It is therefore desirable that the Dutch government and the academic institutions work together to get the principles for socially responsible licensing on the agenda within the EU and worldwide and work towards international agreements in this field. The Netherlands can play a pioneering role in this, comparable to our pioneering role in the area of Open Science. Individual academic institutions could also fulfill such a role, like the University of Maastricht, which is participating in the Universities Allied for Essential Medicines (UAEM) and in the 'Socially Responsible Licensing' initiative.

The principles for socially responsible licensing build on various earlier operational outline documents, like the NFU valorization framework (‘Naar een goede waarde’) from 2009 and the Dutch code of conduct for scientific integrity from 2018. They were formulated in the sequence of the process of knowledge creation and arranging an agreement with a partner (commercial or otherwise). These principles already form part of the standard procedures of the KTOs of UMCs, like the requirement that the licence holder actually undertakes action to develop products or services with the licensed knowledge (‘anti-shelving’). The UMCs must therefore verify even when selecting collaboration partners that the prospective licence holder exercises corporate social responsibility and will develop the academic knowledge into a product or service for the benefit of others.

A new element in these principles is the explicit requirement that transparency and the final price-setting must be discussed when arranging the licensing agreement. This is complex material. It must be prevented from leading to a delay in reaching an agreement. Given the ambition and task of UMCs and other academic institutions to increase the societal impact of research and innovation, a more rapid conclusion of agreements is preferable. In the same context, a balanced and nuanced vision is needed with regard to the various social responsibilities of companies (national and international). These principles for socially responsible innovation are effective when they promote the valorization and thus the impact of research. It is not the intention to damage the climate for innovation in the Netherlands by establishing these principles, or to hinder the translation of academic knowledge into accessible applications in Dutch health care.

In all these considerations, the core objective remains to prevent publicly financed research contributing to an extremely high cost of care and other socially undesirable developments. The NFU wants to initiate a process of concrete change with these principles for socially responsible licensing. It has taken the initiative to form a broader coalition, in which all of the important agents from knowledge organisations, the business community, patients’ organisations and healthcare funds develop broadly supported principles. This requires the next step, in which other academic institutions join this movement through their umbrella organisations, so that administrative embedding occurs. Subsequently, an earlier request from Minister Bruins can be addressed: ‘This process must lead to the operationalisation and then application of principles of socially responsible licensing in medicine development by Dutch academic institutions supported by public funding.’ This will demand action from the NFU together with other academic institutions, the innovative business community, investors (venture capital funds) and other involved parties to develop model agreements based on the accompanying principles. The aim will be to produce a well-filled toolkit with models that can be used in various scenarios, sectors and relationships. The fruitful discussions conducted when preparing these principles can be continued, in which the interests of the different partners (academic institutions, companies, social organisations like healthcare funds, patients’ organisations, etc.) can be made explicit in concrete formulations. If these model agreements are made public, everyone concluding a licensing agreement will be transparent about what these agreements aim to achieve. It is important that industry and financiers are involved, and we hope for their positive contribution. Here, too, the Netherlands can take a pioneering stance given the boundary-crossing nature of knowledge and innovation. Of course, licensing remains customised work, and adjustments may be needed to the model agreement in individual cases.

The joint academic institutions could also determine, for example, the monitoring of compliance with the principles specified here and the model agreements. They would have to strive for optimal transparency, taking into account the interests of the licence holders. Implementation and effective use of the principles can be done, for example, through the annual reports of the academic institutions, which will explain how the principles were applied when arranging licensing agreements. The working group or another appointed agent can monitor this and ensure a centralised reporting. Socially responsible licensing can also be incorporated in internal training courses, like the onboarding of new staff members and young researchers in the field of knowledge transfer.

In short, the NFU considers these principles as a prelude to further discussion with other academic institutions and stakeholders. The UMCs want to make their social responsibility more concrete and invite their partners in the business community to accept their part in it. The Dutch government can encourage this development by propagating this practice and looking for international partners to get the theme on the international agenda. The UMCs are asking all stakeholders to agree to these principles, have them approved by their executive boards and thus contribute to raising awareness, which will lead to socially responsible licensing becoming self-evident.

The Vereniging van Universiteiten (VSNU), Topsector Life Sciences & Health (Health~Holland), Vereniging Samenwerkende Gezondheidsfondsen (SGF), Oncode Institute and ZonMw recognise the importance of these principles and support the social movement that the NFU initiated, after consultation with the relevant parties in the field. The VSNU, Health~Holland, SGF, Oncode Institute and ZonMw want to remain engaged in the further development and application of the principles in practice.

2. Socially responsible licensing

This memo concerns the social responsibilities of publicly financed UMCs and commercial companies when developing products or services based on licensed scientific knowledge. Scientific research within UMCs produces knowledge that can be applied in new drugs or other treatments. Often an intensive and expensive development process is required first, which may lead to new scientific questions.

This thus concerns a complex public-private partnership with potentially huge societal and economic interests, such as, for example, the development of effective and safe treatments of conditions for which there is currently no medical treatment available. The interests of UMCs and companies run parallel here in part, but each has its own tasks and responsibilities. The question is how can the parties best deal with the tension between science, commerce and society, and how can a climate of transparency be promoted. Socially responsible licensing means that account must be taken of the effective availability of the products or services to be developed based on the licensed knowledge.

Origin

At the request of Minister Bruins of Medical Care and Sport, the NFU together with ZonMw surveyed the best way to take the social responsibilities of companies and UMCs into account when these parties conclude agreements for the application of patented knowledge. The NFU established a working group and arrived at a set of ten principles with its recommendations. The result is this memo, in which the principles are laid out to produce a guideline for arranging agreements. The working group (its composition is given on page 15) created these principles in consultation with various parties in the field (see page 15). They were subsequently submitted to a wide-ranging audience of interested parties in an internet consultation. Although there will always be differences in emphasis for a topic like this one, the working group trusts implicitly that these principles will be broadly supported in the research world and in the innovative Dutch business community. As these principles can be applied more widely than just in the context of medicine development, for example in improved agricultural methods or algorithms for better electronic service provision, this memo will also be offered to the Ministries of Education, Culture and Science (OCW) and Economic Affairs and Climate (EZK).

From knowledge to innovation

For UMCs the development and sharing of knowledge are key tasks. They serve the public interest, both in the Netherlands and Europe and globally.
Sometimes a discovery leads directly to innovations, for example in the field of new preventive measures, surgical treatments or conservation methods.
The development process required to transform the scientific discovery into a practical application often takes place within a professional context (involving, for example, social workers in prevention, surgeons, conservationists). The UMCs actively contribute to the distribution of this type of knowledge, through scientific publications and by developing guidelines and educating current and future professionals.

With other discoveries, there can be good reasons for protecting the knowledge with a patent. The exclusiveness provided by such a patent is often a precondition for a financier or commercial partner before investing further in the development of the idea in question (see box).

Patents and innovation

A patent offers its holder the exclusive right to forbid competitors from using the invention described in it for a specific period.
This right is especially needed in cases in which further investment is required to develop the invention. Many inventions, for example new medicines or new methods to protect crops against fungi, cannot be marketed until after careful research into their effectiveness and safety. A company or financier will not invest in it if competitors can also start using the results of the expensive development work.
From the perspective of the UMCs, the great benefit of patents is that they can be published. The relevant knowledge is thus public, and scientific publications can deliberate about it, without the further development into a product being endangered.
Patents are an essential part of our high-tech economy. They do provide a monopoly position for the patent holder, but only for a set period, usually 20 years.
The period of protection starts from the moment of patenting, often long before the final product or service arrives on the market. For example, years are often required for drug development, and it remains uncertain whether the product will ever be marketed. In addition, the patent holder's monopoly is restricted to the knowledge described in the patent; it is conceivable that other patents can lead to comparable products (for example, different drugs for the same disease).
Patents can sometimes form a barrier to innovation and the development of products. This applies especially when many different patents from different patent holders are required for a specific application, and this application is incorporated by many different companies in products or services. The technology behind a CD player or mobile telephone is a typical example of this. It can be useful in those cases to set up 'patent pools'. These are bundles of patents, for which a potential licence holder only has to go to one office to reach an agreement.
An additional benefit is that standards are established. In the life sciences such bundles have not been commonplace so far, but with the new technologies in the field of genetic modification (CRISPR-CAS9), such a 'patent pool' is being considered.

The licensing agreement

Most scientific discoveries have to go through a development process before they are suitable for commercial application in the form of a product or service. Protection with a patent is often the first step. On the basis of the patent, a method is sought to finance and carry out the development process. Therefore, the UMC starts searching for partners in the business community, or a spin-off is set up. In both cases a public-private partnership is established, as part of which the commercial partner is licensed to use the UMC's discovery.

A licensing agreement offers the possibility to secure the interests of both parties and take into account the social responsibilities of the collaborating partners. The best way to achieve this differs from one situation to the next.

Every agreement between parties is individual. Academic institutions have therefore set up knowledge transfer organisations (KTOs) that house extensive expertise in that field. The KTOs of the universities and UMCs developed and agreed on overarching outlines for public-private partnerships in their national consultation. For example, they established that part of the net profit should return to the UMC and the original inventors. The UMCs will use the income from licensed knowledge for financing research, education and other core tasks like patient care.

The principles formulated in this document and assessed during the national consultation of all KTOs, supplement the existing guidelines. They are meant to be a guide to arrive at balanced solutions when arranging agreements and the use of research results by commercial parties, and while taking into account the social responsibilities of the different partners. The KTOs of UMCs will stimulate the application and further shaping of these principles by exchanging knowledge between them, including internationally, for example, via the ASTP, the European professional association of and for professionals in technology and knowledge transfer. The UMCs will also regularly report on how they are bringing these principles into practice. Because of the confidentiality of licensing agreements, these findings will be presented at the aggregated level.

3. Ten principles for socially responsible licensing

The working group formulated ten principles together with the parties in the field. The sequence in which they are presented here runs parallel to the process of knowledge development and licensing, as viewed from the knowledge institution's perspective.

1. Academic institutions strive to ensure that research contributes to societal and/or economic development.

Academic institutions are financed with public funding. The principle is that research must ultimately benefit society's needs, help to answer questions that are important to society and/or solve problems that are important in society and the public. This does not mean that every bit of research must produce knowledge with a clear application. But researchers and academic institutions must be able to point out in the social debate why particular research is done and what the expected benefit for society will be. The associated challenge is to describe for those who are not researchers which new answers, solutions or insights are possible.

2. Academic institutions retain the right to continue using their own results and to let them be used for research and education.

Science is a continuing process, building on earlier results and subjecting them to discussion. The primary task of academic institutions is to contribute to the national and international practice of science with the appropriate openness. They also have an educational task that demands optimal openness. For UMCs there is additionally a responsibility for patients in their own institution and in the region.

In discussion with partners, financiers and other involved parties, the academic institutions will ensure that they retain the right to continue conducting their own research, verify it, teach about and publish it. This enables them to continue using knowledge developed within the institution and to ensure that other researchers can verify the outcomes. It is an important precondition for collaboration with third parties that research results can be published within a reasonable time and that essential materials and techniques for further research remain available.

3. Academic institutions make licensing agreements exclusively with parties that can reasonably be expected to continue developing the knowledge and are committed to doing so.

The academic institutions will ensure that a potential partner is capable of developing the knowledge further. That can mean marketing a product or service themselves or taking the next logical development step towards marketing, like most spin-off companies. A suitable collaboration partner is a party which the knowledge institution can reasonably expect to take the next step in development, given its experience, expertise and financial means, and which will take it. This principle implies concretely, for example, that no rights will be granted to a company that is known to be a 'patent troll', or to a party that has no intention to develop the knowledge further (but, for example, wants to buy a patent to keep its own competitive discovery exclusive).

4. Academic institutions verify that partners with whom they have arranged a licensing agreement do not have societal objectives that are in conflict with their own.

The academic institutions will ensure that partners do not have goals that conflict with their own goals. It is important to focus on the core activity, reliability and transparency of the potential partner. For some industries (for example, the tobacco industry) it is difficult to conceive that their goals run parallel to those of a publicly financed knowledge institution. Great care must also be taken with companies in countries where the rule of law is less strongly established. It is naturally highly undesirable to do business with organisations operating outside the boundaries of the law/criminal law (even partially). In general, it is important to know enough about the proposed collaboration partner to be able to make an estimate of their motives, objectives and willingness to be optimally transparent. The knowledge institution should decide when making the agreement whether the intended partner can pass this test and must be able to support this decision with facts.

5. Academic institutions ensure that no traditional or indigenous knowledge or inventions based on it are included under intellectual property rights without appropriate agreements being made with the rights holders.

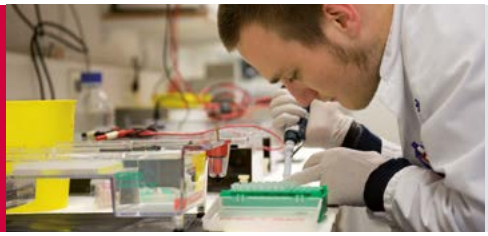
This principle concerns potential conflicts between intellectual property rights and indigenous and local knowledge. For example, genetic knowledge falls under the Nagoya Protocol and the associated legislation. It can also concern knowledge derived from long and local experience playing a role in society, behavior, agriculture, education or sustainability, as specified by UNESCO. The societal task and role of the knowledge institution require them to make the effort to ensure that such rules are followed.

6. Academic institutions, when applying these principles, take those parties that are directly concerned into account and ensure that they are adequately informed of the wishes and interests of those interested parties.

When the knowledge covered by the licensing agreement was discovered, various interested parties may have been involved, for example financiers of part projects. The knowledge institution is ultimately responsible for the agreements it concludes, within the framework of any other agreements made or subsidy conditions. It is part of the knowledge institution's social responsibility to take interested parties into account, preferably through umbrella (national) agreements.

7. Protection and licences must not conflict with the legal task and societal mandate of academic institutions.

Protection and licensing of knowledge is an instrument for arriving at business agreements. It is not an end in itself. Throughout the entire process of protection and licensing, it is thus important to question regularly whether the next step is desirable. Protection can extend too far, inhibiting scientific developments because payment is demanded for the application of knowledge. The licence holder may intend to develop the knowledge in a direction that is socially undesirable or damaging, for example the development of a drug that excludes groups of people from treatment for a non-medical reason, or seeds that produce sterile



offspring, or tobacco plants with a higher nicotine content (see also point 4). Even if the partner's goals match those of the knowledge institution, it can be desirable to record in the agreement documents which development or use is not permitted. Consideration should be given to legal elements such as ensuring enforcement is practically feasible and not hindered by the choice of law or forum.

8. Licences stimulate the development and use of technology and knowledge and bestow rights that are clearly defined and limited. Consideration must be given to both the commercial interests of the current partner and any other future applications. Plus unintentionally including future results or the results of others must be avoided.

This principle concerns the scope and nature of the licence. A narrowly circumscribed licence to develop a product or service is commercially uninteresting for a partner. An overly broadly defined licence, in contrast, can have disadvantages for other interested parties. If, for example, the insight into certain disease mechanisms or a biomarker is protected by a patent and a licensing agreement, this restricts further research and sometimes even the diagnosis and treatment of patients. It is also possible that an invention can have a new application in another context. A technology for an application in DNA, for example, can be developed in a medical context, but also be useful in agriculture or the production of complex biochemical compounds. A broadly defined licensing agreement that focuses solely on medical applications would hinder further development of this knowledge.

In addition, the partner must take action to develop the product or service. This can be specified in more detail for certain countries or regions where the licence holder is expected to make commercially reasonable efforts to market the product or service. This could be the Netherlands, Europe, Africa or specific developing countries. It is important to agree how the efforts will be reported to and checked by the knowledge institution.

Which existing or future rights will be licensed must be clear. If future rights are concerned, they must be sufficiently identifiable by work, maker or outcome. Licences for future results can hinder the development of new results, because it is not possible to decide what the best route for use is and/or who the best partner would be for that. It is also important to document whether certain background knowledge, obtained outside or for a project, should remain accessible; it is possibly important for future research to retain physical access to genetic material or bio-markers, along with the legal approval to use them.

9. In certain countries, licences provide space to encourage or ensure marketing access or development, where possible. They can also offer possibilities to encourage or ensure application in certain sectors.

The knowledge institution can use the licensing agreement to exercise some guidance in the way in which the licence holder markets a product or service to be developed. To compensate for this restriction of the licence holder's freedom, the knowledge institution can, for example, waive certain payments, or make another concession to the licence holder. For example, it could be determined that products will be offered in due course at a reduced rate (based on 'cost-plus') in developing countries. Other possibilities include non-exclusive licences (partially) in certain countries, the right to grant them, agreements about a lack

of protection in certain countries, agreement not to enforce such rights or grant access to local producers. The extent to which such agreements are possible depends partly on the commercial possibilities in developed countries, the cost of developing the product further, and the importance that the licence holder attaches to social responsibility. The possibility to guide offered by the licensing agreement can also be used to promote preferential access of the product in the Netherlands, for example in the context of research. Or, in a more coercive manner, as compensation for obtaining marketing authorisation.
When granting the licence, the access to certain sectors can be considered. Semi-exclusive licences (exclusively for certain sectors), if sufficiently distinctive, can give partners room and security and offer a chance of wider use.
Bij het verlenen van de licentie kan ook worden gekeken naar toegankelijkheid voor bepaalde sectoren. Semi-exclusieve licenties (exclusief voor bepaalde sectoren) kunnen, wanneer voldoende onderscheidend, partners ruimte en zekerheid geven en bieden tevens kans op bredere benutting.

10. Licences ensure that the price-setting of the final products and/or services does not endanger accessibility.

A patent offers the patent holder/licence holder a legal monopoly. That can have undesirable consequences, particularly with products or services for which there is a widespread or even urgent need, like medicines and medical devices. When arranging a licence, it can therefore be agreed that the partner will endeavour to make a reasonable commercial effort to ensure that the final price of the product or service will not hinder its availability in a particular market. The criterion to determine what is acceptable depends on the context at the time that the product or service is marketed. That is more realistic than setting a price in advance, although the development can take years. Such an agreement protects against excesses, when knowledge supported by public funding leads to products that are unaffordable for the public. Likewise, there should be an agreement that this arrangement will not be undermined by the partner setting unreasonably burdensome conditions that make availability unnecessarily complex or unfeasible.

Conclusion

Socially responsible licensing is an ideal that cannot be captured in comprehensive definitions. The principles presented here provide a clear direction, but it is not possible to determine what is desirable and undesirable for all conditions. Many considerations are involved when arranging an agreement. Ultimately, from the perspective of UMCs, the primary concern is that knowledge from publicly financed research should actually contribute to society, health and the economy, thus to the effective availability of the outcomes of research in the form of products and services. Along with the interests concerned with a specific agreement, broader interests also have an influence.

Our intention is that the entirety of these principles will contribute to an attitude of social due care when arranging agreements with commercial partners. This attitude of social responsibility is already present to a great extent in the Dutch UMCs and their KTOs. The principles set out here can hopefully contribute to greater awareness when considering potential collaboration partners and arranging agreements.

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