Between science and business

Public management letter

February 2015

NBA

Nederlandse
Beroepsorganisatie
van Accountants

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To directors and supervisory bodies in the sector and
other interested parties

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Dear Sir/Madam,

The Life Sciences sector is one of the most dynamic top sectors in the Netherlands. Biotechnology, medical technology and pharmaceutical companies are attracting a great deal of attention due to the discussions in society on the quality of health care. Monitoring the accessibility and affordability of health care is at the top of the political agenda. Furthermore, the sector is characterised by rapid growth, major risks and an international playing field. Therefore, it is fair to call Life Sciences a top sector of the future.

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In this public management letter (PML), Between science and business, we present six indicators and recommendations. The focus is on biotechnology and pharmaceutical companies. The indicators are intended for directors, supervisory bodies, sector organisations, accountants and other interested parties.

1. Flexible business model defines success
2. Tax is more than a financial risk
3. Government grants are a complex matter
4. Research and development are difficult to balance
5. Compliance is not to be underestimated
6. Increased transparency will be rewarded

Products in the Life Sciences sector often have a long development time and their chances of success are small. A company's success depends on a good business model. Dutch tax laws are so complicated that the tax system is increasingly seen as a strategic or even a reputational risk. Government grants are also varied and require expertise to avoid mistakes being made. The same applies to Dutch laws and regulations which are often strict: minor mistakes can have major consequences. Research programmes may be too costly as a result of the long turnaround times and the strong dynamics in the sector. Valuation is an important topic when it comes to reporting. However, transparent reporting on value creation will definitely be rewarded!

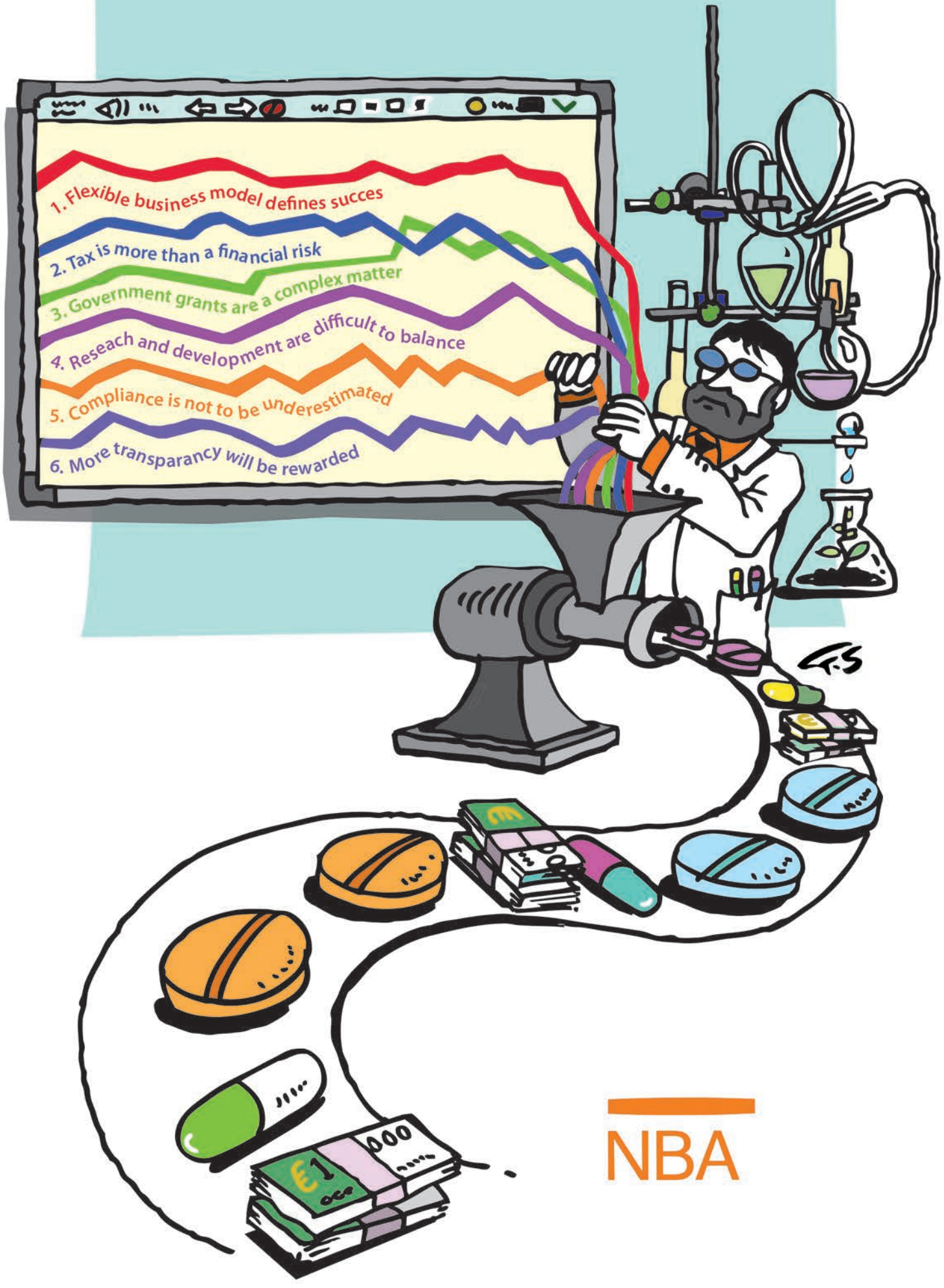
This PML is based on the knowledge of our members who work in the sector. Various interested parties, including Nefarma, HollandBIO, the Dutch Association of Venture Capital Firms (NVP) and Topsector LSH, have issued their comments to us. We are grateful to all of them for their contributions.

Yours faithfully,

Drs. Huub Wieleman RA
NBA Chairman

Prof. dr. Martin Hoogendoorn
Member of NBA Identification Board

Between science and business



Inhoudsopgave

Sector of the future

The Life Sciences & Health sector (hereinafter referred to as: "Life Sciences") is part of the top sector policy of the Dutch government. The sector includes a wide variety of companies, ranging from small start-ups to major international business groups. Roughly speaking, the sector can be divided into three parts:

- medical technology (medtech): production of medical instruments and devices, irradiation devices and electromedical and electrotherapeutic devices.
- pharmaceutical companies (pharma): production of pharmaceutical raw materials and products (medicines).
- biotechnology (biotech): medical laboratories and companies operating in (biotechnology) research and development work.

More than any other sector, Life Sciences contributes to the quality of health, solutions for social issues, academic status and economic welfare[1]. Demand for Life Sciences products has increased significantly in recent years. Monitoring the accessibility and affordability of health care is at the top of the political agenda. People are living longer, the population is ageing rapidly and certain (lifestyle) diseases are more common. At the same time, they can be treated more effectively due to technological innovations, for example in the field of biological, genetic and stem cell research. Dutch scientific research in this area is world-class.

The other side of the coin is that healthcare costs are increasing to record heights. They already account for 13 per cent of Gross Domestic Product. The CPB[2] even expects this to increase to 31 per cent by 2040. The proportion of medicines in healthcare costs has reduced in recent years. This is mainly due to government pricing policies and the preferences of health insurance companies.

It is fair to call Life Sciences a sector of the future - a future with rapid growth, strong dynamics and an international playing field. However, it is also a sector with major risks, a need for transparency and a critical government that sets the necessary rules.

A relatively small sector ...

The scope of the Life Sciences sector is relatively small. According to the CBS[3], the sector had over 2.000 companies in 2010, which corresponds to 0.2 per cent of all companies in the Netherlands. In comparison, the sector made a relatively high contribution to Dutch production and added value, namely 1.1 per cent and 0.5 per cent. Despite its small scope, the sector accounts for some 700 million euros in research and development. That is 13 percent of all expenditure in this area in the Netherlands. In 2010 the sector exported 7.2 billion euros in goods. The average amount per exporter in the sector is four times higher than the Dutch average.

... with major risks

The Life Sciences sector has a high risk profile due to the strict safety requirements for products, the unpredictability of biological processes, the high level of investment and the absence of any guarantee of success. Experience has shown that most inventions do not manage to reach the stage of becoming a sellable product. The (subsequent) financing fails to materialise, research and development results are disappointing or the product's life cycle is too short. Therefore, transparency in terms of feasibility and continuity is a recurring theme.

1 Information on the website, topsectoren.nl
2 The future of health care, March 2013
3 Top sectors monitor 2012

Importance of collaboration

The sector owes its success to the so-called golden triangle of companies, government and knowledge institutions such as universities and university medical centres. The collaboration between large companies, SMEs and knowledge institutions in the Netherlands is unique in the world. SMEs have an unrivalled level of participation in public-private partnerships. These collaborations are not limited to the Netherlands, however, they are also international. The social interest of the Life Sciences sector and accompanying regulations make the government a partner of importance.

Collaborations in the Netherlands are mainly organised via regional knowledge centres. Pooling resources across regional boundaries ensures much greater levels of efficiency. Due to the combination of technology and automation, existing health care providers are increasingly being replaced by initiatives such as eHealth and teleHealth. Social media and smartphone apps are used to encourage patients to take more responsibility in relation to decisions on their health. Health care providers are focusing on the development of more efficient health care systems, for example by analysing so-called big data.

Simply being a country of expertise with an excellent scientific reputation is not enough to occupy a top position in the world. The challenge lies in cashing in on this expertise by way of specific products and solutions, together with the business world (also known as 'valorisation'). The key words are collaboration, co-creation and the connection of separate knowledge systems.

The tax paragraph

Those Life Sciences companies which operate internationally practice a deliberate location policy and usually set up shop where the tax conditions are the most favourable. Therefore, it is essential for the Dutch government to create an attractive investment climate, in terms of both tax and government grants. In this respect, it is important to take note of the countries surrounding us in Europe which, in a number of cases, have more favourable tax conditions for start-ups and companies making initial losses. The sector requires an enterprising government. A government with an eye for the collaboration between public and private parties that encourages this across the regions, paying attention to suitable tax frameworks.

Role of the accountant

According to existing law and regulations, the accountant[4] is not required to give his opinion on the content of the annual report. He can confine himself to its consistency with the annual accounts.

Unquestionably, there is a need for more extensive reporting from accountants due to the risk profile in the Life Sciences sector. For example, in the field of performance measurement, the status of research and development, the quality of the risk management and the issue of continuity. The fact that the sector is embracing integrated reporting (IR) may help. This requires the accountant to expand his view to the audit of non-financial and future-oriented information.

If the accountant wishes to assume this new role, he will need to be properly trained in the sector, in order to scrutinise the specific risks and ask the right questions. The Life Sciences sector requires specialisation and a critical view on the part of the accountant. It is not a marginalised sector.

4 Wherever 'he' is used in this publication, it can be taken to mean 'he/she'

Signal 1 | Flexible business model defines success

Relatively speaking, the Life Sciences sector has a lot of start-ups in the fields of biotech, pharma and medtech. Dutch universities and medical centres are often the starting point. Financing is obtained from private and public resources. There are many opportunities for developing innovative ideas into specific products. What is the right business model for success?

The Life Sciences sector is a dynamic environment. Technological advancement, demographic trends and the shift of economic power to emerging markets are extremely significant when it comes to developing the strategy. It is no longer sufficient to have a good idea or an efficacious medicine. Products must contribute to cost reductions and efficiency. The focus turns to developing products which are outcome-focused and which are evidence-driven in practice.

It is especially important for start-ups to reflect on their objectives, strategies and business models. Products have a long development time and there is no guarantee of success. What products contribute to the prevention of illness or cost reduction? What are the risks and how can they be managed? What are the trends in the sector and where will we be in five years' time? What restrictions are imposed by the government, for example in the form of maximum prices? Reporting on value creation and transparency about the risk-return ratio are important.

Collaboration is important for each stage of a business. During the stage in which a product does not yet have any commercial use (pre-competitive stage), there is often intensive collaboration between business and science. During the stage in which the product is marketed (competitive stage) big companies mainly focus on their core activities and outsource support activities. All of these types of collaboration, alliances and joint ventures require proper administration and transparent reporting.

No business model without appropriate financing. In the very first stage of a start-up company (pre-seed stage) it usually relies on the Technology Transfer Office of a university and on private investors. During the stage in which more capital is required (the seed stage), financing is obtained via government grants, crowd funding or a venture capitalist (VC). Ultimately, the company ends up being acquired by a large company or reaches the stage of being listed publicly. The further a company progresses in its stages of existence, the more requirements the financiers set in the fields of strategy, business model and risk management. In general, it is less difficult for medtech companies to obtain financing via more traditional sources such as banks. This is due to the much shorter investment horizon.

The government used to be an important source of grants for the sector. This came to an end as a result of the economic crisis. It was replaced by the top sector policy which takes into account the financial substantiation for the expenditure of public funds. This also requires more transparent reporting. Financing alone is not enough. The government should ensure a more uniform policy by getting the regional clusters to collaborate. Companies should not be relocating simply because the facilities in another region are slightly more favourable.

Negative example

Wrong focus

Company A was founded on the basis of a promising idea from a brilliant scientist. The initial financing was obtained by way of venture capital. A lot of funds are required for the next stage. The current investors would like the capital injection to be made by new investors. That didn't work out, however A tracks down a consortium in an adjacent academic area. All of the time and effort is devoted to obtaining the grant in that consortium. Although this does work out, the researchers must now comply with different terms and conditions for the grant. This affects product development, and the shareholders lose confidence, resulting in a reorganisation and A losing its prospects for the future.

Positive example

Financing arranged in plenty of time

Company B is a promising biotech company in the field of gene technology. After the first good indications during the final stage that the product works, Company B invests in a management team recruited from the pharmaceutical industry. This management team has the competencies which are needed to successfully launch the product. Furthermore, an option contract is entered into with a major pharmaceutical company. A round of financing is commenced well before funds run out. This gives Company B almost three years to complete the product and launch it on the market. The financiers are fully confident. If the product fails to work as expected after clinical tests, the management team has an adequate financial buffer to carry out further testing.

RECOMMENDATION 1: Provide clear insights into the business model

Entrepreneurs

- Ensure a clear strategy, business model and risk management. Focus on the core competencies and think well ahead. Take into account the company's stage of existence and its potential financing routes in the future.
- With regard to collaborations and financing, think about the terms and conditions of contracts and their effect on financial records. Make sure that all of the parties involved are properly documented. Seek assistance from the accountant well in advance when setting up financial structures. He can predict the consequences if the company switches to another reporting system in the future, for example IFRS.

Government

- Promote interregional collaboration on the basis of a sector-wide policy. In this respect, develop clear criteria for success and ensure proper financial facilities for public-private partnerships.

Accountants

- Ensure in-depth knowledge of the company's strategic environment. Pay extra attention to risks, risk management, continuity and the quality of the management team.
- Keep an eye out for complex reporting items such as reward options, recording revenue, in-kind contributions, related parties and loans with different interest rates. Pay attention to their effect on financial reporting. Assess the likelihood of the assumptions of continuity. Do not hesitate to ask the management team critical questions.

Signal 2 | Tax is more than a financial risk

Government bodies and other stakeholders are imposing more and more requirements on the scope and transparency of the tax policy in the Life Sciences sector. Tax is not an exact science. The risks are difficult to assess in a world that is constantly on the move. Strategic and reputational risks are easily suffered.

Life Sciences companies deal with long periods of research and development, with major risks and high costs. From a tax perspective, that is why many pharmaceutical companies and some biotech companies choose a central company model. In this respect, the development, improvement and protection of products are usually managed from a single jurisdiction and by a single company. The same applies to costs, risks and intellectual property rights. In this model the central company is usually designated as the entrepreneur. The other functions within the company such as production, research and development, sales and marketing are usually rewarded with a routine (fixed) margin. Transfer pricing may be based on costs or on turnover.

Margins are under pressure as a result of the crisis and the changing market. Governments are focusing on transfer pricing in order to protect or expand their own tax base. This means that companies must provide proper substantiation and documentation of transfer prices, in order to limit their tax risks.

Pharmaceutical companies are currently engaged in making their production, logistics and sales activities more efficient. Sales organisations that used to be set up by country are increasingly becoming regionally merged and of a more virtual nature. The question is whether the role of these centralised sales organisations will also change with regard to transfer pricing. On the other hand, a number of big countries such as Russia and Brazil are demanding that a large portion of the products sold in these countries is also produced there. This may affect the scope of the production locations in the Netherlands.

The sector has various kinds of partnerships with third parties for the development, production, packaging and sale of medicines. This cannot usually be factored into the standard framework for transfer pricing which means that tax consequences must be assessed on a case-by-case basis.

Other factors which set requirements for the connection between the business model and the transfer pricing system are the requirements in the area of substance. Companies which are based in a given country for tax reasons must have a certain substance in order to take advantage of the tax facilities. The presence of a physical office and key company positions (such as directors and managers) play a role in this.

Even more so than pharmaceutical companies, biotech companies deal with long periods of tax (start-up) losses. Using the central model will ensure that the losses incurred can be compensated in the country where they were incurred. In the Netherlands tax loss compensation has been limited to nine years. As a result of this measure, biotech companies run the additional risk that losses will expire and cannot be offset. This may affect liquidity if an activity in the field of production, research of sales is set up abroad during the period of loss. These will be rewarded via a routine (fixed) margin which means that tax will still need to be paid abroad. This will result in a large, but accountable increase in the effective tax rate in the annual accounts.

Internationally, the economic crisis and media reports on aggressive tax planning by companies have prompted the so-called Base Erosion and Profit Shifting (BEPS) discussion. This discussion will probably lead to more require-

ments for documenting transfer pricing and country-by-country reporting (to the tax authorities of each country). These reports will prompt more discussions with local governments about the profit that is reported in those countries. Some opportunistic countries will try to increase declared profits. Large countries like China will often demand a higher margin for the sales activities of a foreign company in their country. Other countries, including the United Kingdom, don't just use the discussion to increase tax revenue but mainly to better position their own country for foreign investment.

As a result of all of these developments, the taxation function of a company is becoming more and more important. Tax is more than just a financial risk. Increasingly, it is also seen as both a strategic and a reputational risk.

Negative example

Unexpected tax consequences

Company C enters into a partnership in Country X with Company Y. According to the contract, Y will carry out part of the development and production for C. Company C will also place some of its employees with Company Y on a long-term basis. Therefore, the tax authorities of Country X are of the opinion that C has a permanent base in Country X. As a result, Company C must take into account Country X's specific requirements for transfer pricing, profit allocation and tax deduction. If C had realised this in advance, it would have structured the contract with Y in a different way.

Positive example

Effective tax planning

In its annual accounts Company D is fully transparent about its tax strategy and the manner in which transfer prices will be determined. It has entered into agreements on horizontal supervision with the tax authorities. The fact that D will have to pay tax on its foreign branches, despite start-up losses, has been clearly explained. Company D's shareholders and stakeholders are very satisfied with this transparency.

RECOMMENDATION 2: Tax is not to be underestimated

Companies
- Ensure a robust tax strategy that forms an integral part of the general strategy. In the case of foreign branches, pay special attention to the issues around transfer pricing.
- Ensure that there is a position in the company for a tax expert. Always involve this person in the substantiation, documentation and monitoring of transfer pricing.

Government
- Investigate the options for carrying forward tax losses in Life Sciences start-up companies. Develop a targeted government policy for this purpose.

Accountants
- It is increasingly difficult to determine the tax position of international companies. Do not underestimate the audit of the tax rate in the annual accounts and seek the assistance of a tax expert well in advance.
- Take note if the tax rate is higher or lower than usual for similar companies. This may indicate different tax structures, the financial risks of which are not fully known. Determine whether the differences have been properly substantiated.

Signal 3 | Government grants are a complex matter

There are a large number of innovation grants in the Netherlands. It remains a full-time challenge for the government to promote access to these grants and to demonstrate that the Netherlands is an attractive country to start a business. Companies often underestimate the administrative requirements to which grants are subject or they abandon their application because of this. One of the drawbacks of a lot of tax schemes is that they only yield liquidity once a profit is made.

A company's place of establishment is also motivated by the incentives given by governments to start-ups and innovative companies. In the Netherlands these comprise grants and tax facilities. Grant schemes usually have a fixed end date. Once the allocated budget has been used up, the scheme can be discontinued in the same year. Tax measures do not usually have such a ceiling, however, the discount percentage may be reduced in a subsequent year.

The most important tax allowances for Life Sciences companies are the wage and contribution tax reductions ("WVA", also known as "WBSO"), the Research and Development Allowance ("RDA") and the Innovation Box which has a tax rate of 5 per cent. The WBSO and RDA focus on the development stage of a product. The Innovation Box is intended for the result that can be attributed to the innovation that is created. None of these facilities provides any direct funding for research and development. Unlike a grant, the RDA is a discount on the tax due. It does not represent additional funds that can be used to finance innovation. The RDA and the Innovation Box are only really attractive when a taxable profit is made. This makes these schemes less attractive for start-ups which usually make a loss in their first stage of existence. In a number of European countries the tax that has not yet been compensated may even be paid out. This gives these countries a competitive advantage over the Netherlands. Belgium in particular has a number of attractive stimulation arrangements, for example for salary costs.

In the case of pharmaceutical companies a proportion of their activities may not be covered by the scope of the tax schemes, no matter how related to innovation they are. For example, obligations imposed by supervisory bodies to obtain access to the market. Although those costs cannot be classified as research and development, they may be necessary to market the product. This may be the case if a medicine is registered in a certain country or if the effect of a medicine also extends to other age groups (such as children).

Tax incentives may place a different tax burden on the profit in the country where the company is registered. In the context of transparency, it is important to explain such a lower or higher effective tax burden in the annual accounts.

In addition to tax schemes there is an extremely large number of grants and financing facilities. The website of the Netherlands Enterprise Agency ("Rijksdienst voor Ondernemend Nederland - RVO") alone lists 83 entries[5] for grants. In addition, there are the required schemes at EU level such as Horizon 2020 and the ERDF. A lot of in-depth knowledge is required to avail oneself the schemes. The hiring of external experts is therefore common. In particular, European-wide schemes set the necessary administrative requirement, for example in the area of cost allocation. The company's goals may be different from the goals of the grant which will require a different administration system. The complexity of the application procedure may cause companies to abandon participation altogether. This means that the grant funds will not get used.

5 Theme of subsidies and financing on the website, rvo.nl.

The WBSO and the RDA have administrative and accounting obligations. If these are not met, there is a chance that benefits will be lost or penalties will be imposed. This may be an issue if certain details are not clearly reported or if it is difficult to retrieve them from the administration system.

Negative example

Underestimating terms and conditions of the grant

Company E applies for a European grant scheme for its multi-annual research programme. Since the submission deadline has almost expired, E focuses on getting the grant. And it works. Since all of the attention has been given to creating the programme, the administrative conditions have been forgotten. It is only after submitting the application that E discovers the administration system should have recorded certain details which are difficult to trace back. As a result, E is at risk of losing a portion of the grant.

Positive example

Fiscal transparency

Company F has an Innovation Box, as well as major start-up losses. The prospects are good and a profit is in sight. F wishes to value the losses but the question is at what rate. Innovation losses can be compensated at the nominal rate of 25 per cent, although they increase the barrier to using the Innovation Box. In its annual accounts F provides clear insights into the manner in which the losses are valued and the principles used to do so. F also states that the tax authorities have confirmed the use of the scheme. Investors view the use of the Innovation Box as a positive development and of F being in control.

RECOMMENDATION 3: Don't forget about the grant administration

Companies

- Always involve the research and development department in a grant application, in order to map out the correct costs and amount of work. Also involve this department in the administrative records for the grant, as the department will also be required to keep the primary records.
- Establish the terms and conditions for the Innovation Box. Record the agreed calculation method, preferably laid down in a settlement agreement with the tax authorities. If there is a succession of losses, it is important to determine what result is offset at what rate.

Government

- Provide an integrated stimulation policy for Life Sciences companies so that the Netherlands is competitive in comparison with other countries. Pay special attention to start-up companies. Research the option of paying the RDA to companies which are unable to use the RDA directly due to losses.

Accountants

- When checking grants and their terms and conditions, determine whether or not the research and development department was involved. Make an estimate of the level of preparedness to consistently update the required paperwork for the accounting records.
- For each grant that is awarded, determine whether the company pays attention to the administrative requirements. Assess the quality of the primary records and determine whether or not it can meet the terms and conditions of the grant. Determine the risk of the grant having to be repaid if the terms and conditions are not met.

Signal 4 | Research and development are difficult to balance

The development of medicines is complicated, prolonged and labour-intensive. On the other hand, there are cost-saving measures by governments and health insurance companies. As a result, the investments made may not be profitable and therefore they are valued too highly in the books. The continued existence of the company may be at stake. One of the dilemmas in this regard is when research becomes development and needs to be included as an asset on the balance sheet.

The development of medicines takes up a large proportion of the capital of a Life Sciences company. For example, the total development time for a medicine is 10 to 16 years on average, barring exceptions. On average, it costs over one billion euros to develop a new medicine. Since there are a lot of existing medicines for known illnesses, the sector now focuses primarily on illnesses that are difficult to treat and on alternative medicine. Research and development costs can only be influenced to a certain degree, as all of the clinical stages and tests need to be completed carefully. Take for example, laboratory hours, the procurement or manufacture of test products, the cost of the various development stages and carrying out practical testing, as well as the interest rate and repayment of financing. Medical equipment usually has a normal payback period and leads to development costs that can be greatly influenced. Even in that case however, a good product is no guarantee of success: the equipment must contribute to more efficient handling or better management of health care costs.

In addition to long turnaround times, Life Sciences companies have to deal with a variety of financiers, each with their own terms and conditions. The funds are usually obtained from a combination of shareholder capital, government grants, investments by venture capitalists and bank loans. All of these risks require the company to take a serious look at the composition of its research programmes. Can the scheduled milestones or development stages be achieved? Is the financing adequate? Can the investments really be recouped, given the government's strict pricing policy? Is there a market for the product? What is the revenue model?

Failing to achieve milestones may mean that the financiers' terms and conditions are no longer met. They may impose additional requirements or withdraw the financing altogether. The continued existence of the company may be jeopardised. There is no point in deciding to postpone the cancellation of programmes or the downgrading of investments. This will provide incorrect insights into the company's return. The wrong decision may be taken, which will have the opposite effect.

Right from the start it is important to have actual prospects and a clear strategy which factors in the company's strengths and weaknesses. In this respect, it helps to make calculations for different future scenarios and to choose a clear revenue model that fits in with the overall business model. This will come in handy when examining how and when research programmes should be valued in the annual accounts.

According to the reporting rules[6], the expenditure during the research stage must be entered as a direct cost. The expenditure from the development stage belongs on the balance sheet, provided a number of terms and conditions have been met. For example, the condition that the product is expected to provide economic benefits in the future. It is often difficult for start-up Life Sciences companies to define the boundary between the two stages, which regularly leads to discussions with financiers and accountants. Venture capitalists usually favour activating research programmes as little as possible on account of the uncertain prospects. On the other hand, Life Sciences

6 DABS Standard 210, Intangible Fixed Assets.

entrepreneurs find it difficult to accept that the real value of their company is not reflected in the annual accounts. It is therefore important to be as transparent as possible about the development, management and valuation of ongoing programmes.

Negative example

Unclear earnings model

Company G wants to develop as many medicines as possible. G therefore set up a large number of research programmes. However, G failed to make the proper calculations for the market prospects and the expected returns. Another calculation is made a few years later which reveals that G spent too much money on programmes that will not yield any income in the future. G has a shortage of funds and its continued existence is in danger.

Positive example

New collaboration

The management of Company H has decided to seek to collaborate directly with a big pharmaceutical company on the initial research programme. As a result, the expensive research stages are financed by the pharma company. The clear contractual agreements mean that the inclusion of the valuation on the balance sheet does not cause any problems. H can use the income it generates from the programme to finance its other research programmes without any problems.

RECOMMENDATION 4: Be transparent about research and development

Entrepreneurs

- Be clear in the annual accounts about on-going programmes and their progress. Do not let the recording and valuation come as a surprise to users of the annual accounts. Explain the assumptions and principles clearly. Take charge and do not let the valuation take on a life of its own for the financiers and other stakeholders.
- Make sure the annual accounts reflect the valuation trend. Explain how the company creates value. It may help to use integrated reporting for this purpose. Be open to the strong and weak points of the company and the scenarios used. Do not conceal any disappointing or failed projects.

Accountants

- Regardless of the type of assignment, always pay attention to the recording and valuation of research and development. This applies to start-up companies in particular. Assess the quality of the financial features. Be critical during the transition from research to development and when it comes to capitalising costs. Look at the principles that were used and the assumptions that were made. If necessary, make sure the company hires an independent expert specialist or hire one yourself.
- Periodically discuss the earnings model which forms the basis for recording programmes in the annual accounts. Ask the management team critical questions about the prognoses in order to avoid future continuity issues. Examine the availability of alternative methods that can be used to assess continuity. For example, the company's track record, the management team's reputation and the quality of the risk management. Pay extra attention when it comes to start-ups.

Signal 5 | Compliance is not to be underestimated

More than other sectors, Life Sciences has to deal with strict law and regulations. The requirements for the development, safety and effectiveness of medicines and medical equipment are increasing. Ethics, integrity and transparency are at the top of the social agenda. Small violations may have major consequences for reputation and continuity.

The Life Sciences sector is tightly regulated. The standards for clinical studies are increasing, such as more participants per study and stricter medical procedures per patient. In Europe and the United States companies have to deal with long-term and capital-intensive registration obligations before medicines and medical equipment are allowed onto the market. The requirements of supervisory bodies such as the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) are getting stricter and stricter. For example, the FDA has the authority to have research shut down or to close a factory.
It is important for every Life Sciences company to set up a comprehensive quality management system and to keep it updated. Every stage of research and development should be documented carefully in order to be well-prepared when applying for a registration. Many companies seek the counsel of specialist law firms in this area.

In addition to requirements in fields such as clinical studies, registrations and research safety, the law and regulations are addressing more social themes ranging from ethical dilemmas over the acceptable cost of a treatment to maximising income. All Life Sciences companies, from small research laboratories to big pharmaceutical groups, have to deal with this. Some examples:

- **Ethics in research**. Rules on patient research, stem cell research and animal testing.
- **Ethics in marketing and sales**. Since 2012 the Dutch Health Care Transparency Register has been providing insights into the collaboration between healthcare providers and pharmaceutical companies. There is a similar scheme in the United States (the Sunshine Act).
- **Rivals and competition**. Legislation in the field of anti-corruption and bribery (such as the American Foreign Corrupt Practices Act) and recent discussions on the parallel import of medicines (importing outside of normal sales channels).
- **Safety**. The pharmaceutical industry must comply with the EU's Falsified Medicines Directive by 2017: goods must be identifiable and traceable (serialisation).
- **Income**. Researchers in (semi-)public centres have had to deal with the Dutch Top Incomes Standardisation Act (WNT) since 2013.

Violations of the law and regulations may have major consequences due to the negative publicity connected with this. The regulator often has a zero tolerance policy: every violation counts. A minor error or dubious payment abroad may have serious consequences for continuity. The more a company deals with long production lines spread out across several countries, the more difficult it is to manage compliance with all law and regulations. Therefore, compliance with law and regulations is increasingly a strategic and reputational risk.

The management of patents requires special attention. A patent gives the holder the exclusive right to exploit a scientific discovery. This may seem like a long time but it also includes the period required to turn the discovery into a commercial product and to register it. In addition, the law and regulations do not always provide adequate protection. Competition is always lurking due to the major financial interests. It is important for Life Sciences companies to keep a close eye on developments among competitors and parties purchasing those licences. That way patent infringement can be detected promptly. Securing and

shielding facilities and systems is a top priority. When it comes to patent applications, companies may claim more than the actual invention in order to be awarded the right patent during the awarding stage. On the other hand, big pharma companies and small start-up companies are collaborating more and more. Since the patents of a number of widely used medicines are expiring in the foreseeable future, the search is on for new products.

There are many sides to the increasing complexity of the law and regulations. In addition to a greater risk of violations, implementation costs also need attention. Companies need to factor these costs into their return calculations at an early stage. The business model must allow for investments in the accompanying administrative organisation and risk management. The accountant should keep an eye out for this, as any violation of the law and regulations may also have financial consequences for the annual accounts.

Negative example

Patent infringement

Company I had to shut down after 10 years of research as the patent application for technology X was rejected. Three months before the patent application by I, its competitor J recorded a similar patent in several countries. I has insufficient financial resources to initiate long legal proceedings in order to fight J's patent.

Positive example

Patent application in stages

While researching medicine Y, company K patented the intellectual property periodically. As a result, the actual patent period of 20 years only starts when the medicine has been fully developed and the marketing authorisation has been received. Using this approach, K ensures that medicine Y can only be supplied to the market by K for the full 20 years.

RECOMMENDATION 5: Integrate compliance in the business model

Entrepreneurs

- Take into account the increasing cost of compliance with the law and regulations into the strategy and business model. Pay special attention to the legal risks and costs when making cost-benefit analyses. Make this an integral part of the internal management system.
- In the annual report be transparent about the legal procedures and the measures that have been taken to manage them. Be open about patents, their terms and any legal cases in this area. In this context, consider switching to integrated reporting in order to provide stakeholders with better insights into future profitability and the associated risks of investment programmes.

Accountants

- Assess the internal risk management in the area of intellectual property and patents. Periodically discuss the procedures for managing legal risks and ensure adequate measures have been taken in order to prevent disputes. Pay attention to on-going legal cases and disputes about compliance with law and regulations.
- Ensure there is sufficient knowledge of the law and regulations in the Life Sciences sector. Even though many regulations do not have a direct link to the annual accounts, they may lead to large financial claims.

Signal 6 | Increased transparency will be rewarded

Integrated reporting (IR) is the latest development in the world of reporting. The key is a company's value creation over time. In addition to financial values, there is also reporting on intellectual, human, social and ecological capital. It is precisely in the Life Sciences sector, with its high risk profile, robust dynamics and broad social discussions, where the step towards greater transparency over value creation is desirable and perhaps even necessary.

Integrated reporting is a process that results in a periodically integrated report on a company's value creation for a given period. The report indicates how strategy, government, performance and outlook lead to value creation in the short-term, the mid-term and the long-term[7]. This goes beyond financial values alone. Non-financial values also determine a company's future value. For example, intellectual capital (the organisation's intellectual property and expertise), human capital (employee's competencies and experience), social capital (image and relationships with stakeholders) and natural capital (sustainability). An integrated information system is required to facilitate integrated reporting. The processes and risk management must be optimised in order to measure non-financial performance. Since a company cannot report on everything, it must make a selection of the material (key) topics. By discussing this with its stakeholders, the company involves each stakeholder in the decision-making process. This will prevent a one-sided vision among the management team and ensure that the integrated reporting matches the users' wishes as closely as possible.

Transparent reporting on the strategy, the business model and performance is important in the Life Sciences sector. The degree to which that is the case is mainly determined by the company's stage of existence. Big pharma companies often publish reports on Corporate Social Responsibility (CSR) or they are in the process of introducing integrated reporting. The more stakeholders are involved in the company, the more transparency increases. In the case of start-ups that is often during the stage in which financing is required from outside investors. Transparency on funding is important to investors. They want to know the answer to questions such as: what stage is a given programme at? What are the expectations and what is the remaining turnaround time? Why was this product chosen over others?

Investors want to know whether the management team is capable of making the right decisions about their investments. These concerns are easier to weigh up if the management team is transparent about its strategy. The reporting must be balanced and it should not just show the positive developments. Failures can be interesting too. What went wrong and why? What did the management team learn from this and how did the organisation improve? Potential investors are more prepared to invest in professional and transparent companies. That's why start-up companies will often have themselves audited by an accountant voluntarily.

There is also a need for social and intellectual capital in the sector. Companies are looking for highly educated scientists. This calls for a strategy to attract and retain talent. In addition, Life Sciences companies must take social and ethical discussions into account, for example in the field of animal testing or privacy-sensitive innovations.

A common argument against transparency is sensitivity to competition. It is in precisely those areas where little progress has been made that companies are inclined to provide little or no information. In today's information society it would be an illusion to think that such information can remain secret. Information is distributed rapidly thanks to the Internet and social media. It is precisely by communicating actively with the outside world that companies can

7 Information on integrated reporting can be found on the website, theiirc.org.

turn risks into opportunities. Transparency offers the opportunity to illustrate nuances and provide insights into the dilemmas with which the company has struggled, where necessary.

Naturally, it is the company's responsibility as to what it communicates to its stakeholders, and how. The accountant also plays a role in this in terms of his role of trustee of public interest. Based on his expert knowledge and experience with the company, he can play a role in the discussion on material topics and in the dialogue with the stakeholders. Given the need for more reliable non-financial information, he could focus more on auditing non-financial performance future-oriented (risk) information in the annual report. The new model for the auditor's report which, among other things, may provide a basis for paying attention to continuity. Take for example the development of an integrated auditor's report for integrated reporting.

Negative example

Insufficient attention to image

Company L is ordered to remove medicine Z from the market due to side effects that were not described. A journalist writes about this and suggests that L's quality system is unsatisfactory. After all, L did not mention it in its annual report. There are calls on various social media for a full boycott of L's medicines. L's turnover is halved and L is forced to be transparent about its quality process. However, L's image has taken a serious beating and as a result, a new round of financing must be postponed.

Positive example

Transparency about dilemmas

Company M provides transparent reporting on the status of its research into a revolutionary medicine against cervical cancer. M describes the possible effects of the medicine and it also indicates the potential risks. M highlights the need for the further development of the medicine and for additional financing. M launches an appeal to raise a considerable proportion of the financing via crowd funding. The appeal gets noticed on Facebook and Twitter and it even reaches the national media. The necessary financing is raised within a month.

RECOMMENDATION 6: Choose transparency!

Company

- Together with the stakeholders, determine the material topics that will be reported. In this respect, be transparent about the objectives and the strategic choices that were made. Describe the decision-making process, including the weighing up of risks.
- In the annual report describe the positive and negative developments from the past year and provide the company's vision on this. Pay attention to the ethical dilemmas, discussions with stakeholders and the considerations that were made.

Accountants

- Challenge the company to provide a balanced combination of the year's positive and negative developments in the annual report. Assess the quality of the underlying non-financial information system. Keep an eye out for excessive optimism on the part of the management team.
- Talk to the management team about getting the non-financial information audited too. Determine the consequences for the auditor's report and make sure the team has sufficient knowledge and experience to audit the non-financial information.

Summary of stakeholders' responses

At the request of the NBA, four stakeholders in the life sciences sector have responded to the public management letter. Their responses have been incorporated in their entirety in the Dutch PML. What follows below is a brief summary:

Nefarma

Nefarma welcomes the NBA's initiative and identifies with the signals. However, Nefarma considers the threefold division of biotech, medtech and pharma as outdated. Due to technological developments the sector can better be divided in (bio) pharma and medtech. It would also be recommendable to pay more attention to medtech than to focus only on biotech and pharma.

In terms of the first signal, Nefarma is of the opinion that the Dutch market is of marginal significance internationally, although the Netherlands is at the forefront of care development and has attractive facilities for clinical research. That's why the Netherlands is still important to international companies. The financing of Life Sciences companies is also taking place on an increasingly international basis, which places high demands on reporting and control. The government should promote the development of new drugs by implementing a consistent, long term policy. This has not been successful during the last ten years, resulting in a multitude of temporary initiatives which inhibit the market rather than stimulating it. Other countries have been more successful in this, for example Belgium.

In terms of the third signal Nefarma observes that most subsidies are unsuitable for Life Sciences companies. This is due to the terms and conditions of the subsidy, the high capital requirement or high development costs. In addition, a number of widely used subsidies have been phased out in recent years. As a result the Netherlands is not currently competitive with foreign companies.

As regards the fourth signal Nefarma notes that the classic earnings model is under pressure. Companies must consider the ultimate value of their product at a very early stage. This involves the added value compared to treatments currently in use. This means that dialogue with the authorities responsible for reimbursement must be sought at an early stage, certainly for new developments for which little clinical experience exists. This is also relevant to smaller companies wishing to cooperate with larger pharmaceutical companies.

Nefarma endorses the fifth signal that the sector is heavily regulated, not only concerning research and development, but also production and distribution. Companies must take this into account in their business strategy. Nefarma observes that the new European regulation on clinical research is not so much a burden as a harmonisation of terms and conditions. In this way all countries are subject to equal circumstances and application procedures are simplified. The regulation therefore provides all sorts of opportunities for the Netherlands to further promote clinical research. The parties involved in this are working hard to return the Netherlands to the top position.

HollandBIO

HollandBIO endorses the conclusion that the Life Sciences sector can rightly be referred to as a top sector, due to the high level of added value in the field of health, the relatively large contribution to Dutch production and high investment in research and development. HollandBIO also notes that not all subsidy schemes in the Netherlands are suitable for Life Sciences companies. They are highly fragmented, the administrative burdens are high and their availability has been reduced. The sector benefits from a clear and consistent government policy. The packaging of resources and corresponding conditions contributes to the development of the sector. The sector is strongly regulated and compliance with statutory requirements is a significant priority. In addition to a good quality system and a well-conceived phased plan it is important that companies instigate dialogue with the regulatory authorities at the earliest possible stage. There are also new developments taking place in this area, whereby more and more attention is being paid to custom work. This provides new opportunities.

Dutch Association of Venture Capital Firms (Nederlandse Vereniging van Participatiemaatschappijen - NVP)

The NVP read this management letter with interest. After consulting several board members who are active in this sector, the NVP has arrived at the conclusion that it has no further comments and that the findings of the management letter can be heartily endorsed.

Topsector LSH

Topsector LSH acknowledges the image of a dynamic sector with many opportunities but also risks. It is a very swiftly growing sector which is of increasing economic and social importance. An accountant who is expert in this field is therefore indispensable. Topsector LSH welcomes the initiative of the NBA to enhance the professionalism of the sector even further.

Colofon

Knowledge Sharing

In the NBA Knowledge Sharing policy programme the expertise of accountants is collectively applied to signal risks early in social sectors or relevant themes. In doing so the emphasis is on governance, operations, reporting and audit. In this public management letter (PML) the NBA is presenting six recommendations for the Life Sciences sector. This sector is the twelfth theme to be selected by the Identification Board of the NBA.

A working group of public accountants in the sector gathered and discussed anonymous findings. This was then discussed at a sector meeting with stakeholders. The Identification Board then gauged the signals from a social perspective and applied a social assessment to the signals. The stakeholders in the sector were willing to respond in writing to the PML. Coordination and final editing was provided by the Knowledge Sharing programme team.

More information

A public management letter is one of the publications issued by the Knowledge Sharing policy programme. The NBA has previously published public management letters on: Insurance (2010), Long-term Care (2010), Commercial Property (2011), Greenhouse Horticulture (2011), Municipalities (2012), Charities (2012), VET colleges (2013), Transport & Logistics (2013) and Risk Management (2013). Further publications include an open letter on Pensions (2011) and a discussion report about Tone at the top (2012). All publications are public and intended for a wide audience.

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Prof. dr. M.N. Hoogendoorn (till June 2014)
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