

Health Council of the Netherlands

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# **The individual, collective and public importance of vaccination**

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To the Minister of Health, Welfare and Sport

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Subject : Presentation of advisory report *The individual, collective and public importance of vaccination*  
Your reference : -  
Our reference : U-7898/HH/LvR/db/693-K5  
Enclosure(s) : 1  
Date : October 3, 2013

Dear Minister,

Given the importance of obtaining an independent opinion in this matter, the Minister of Health, Welfare and Sport submits questions concerning the contents and composition of the public vaccination programme to the Health Council of the Netherlands. To perform this task effectively, the Health Council appointed the Committee on the National Immunisation Programme in 2001, on a five yearly basis. At the end of its first term, the Committee published an advisory report entitled *The future of the National Immunisation Programme: towards a programme for all age groups*. Your ministerial predecessor adopted the recommendations set out in that advisory report, since when the seven-criteria framework described in that document has been the touchstone for assessing whether vaccinations are worthy of inclusion in the National Immunisation Programme. Now, at the end of its second term, the Committee has produced another framework-setting advisory report, which I am delighted to be able to present to you. The advisory report has been reviewed by the Standing Committee on Infection and Immunity, together with members of the Standing Committee on Public Health.

The Committee proposes that a single general assessment framework be used for all vaccinations. It also presents its reasons for recommending that the associated scientific assessment work be carried out by the Health Council. I fully endorse both the advisory report itself, and the above recommendation. The proposed policy has organisational and formative implications for the Health Council's secretariat and for other organisations. This will require consultation, partly because related areas in the field of prevention are imposing an increasingly heavier burden on the Council.



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**Gezondheidsraad**

Health Council of the Netherlands



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Finally, I would like to draw your attention to the issue of supporting policy in the implementation of this advisory report. The Committee cites a number of important points (concerning training, public awareness and funding) that merit your attention, but which do not fall within the scope of this advisory report.

Yours sincerely,  
(signed)  
Professor W.A. van Gool,  
President

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to:

the Minister of Health, Welfare and Sport

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No. 2013/21E, The Hague, October 3, 2013

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The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is “to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research...” (Section 22, Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare & Sport, Infrastructure & the Environment, Social Affairs & Employment, Economic Affairs, and Education, Culture & Science. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

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# Executive summary

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## **Under-use of vaccines means potential health gains are being left untapped**

Vaccine development has been improved and accelerated by new biotechnological methods, especially DNA techniques. New vaccines are regularly becoming available. Efficacious vaccines are now available for the prevention of diseases such as chickenpox, gastroenteritis caused by rotavirus infection, and shingles. However, these are rarely used in the Netherlands. As a result, potential health gains are being left untapped.

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## **Reasons for the under-utilisation of vaccines**

There are no formal barriers to the use of these vaccines. Having been approved by the medicines authorities, the vaccines are – in theory at least – available to physicians and patients. The limited use of such vaccines is probably based on a lack of knowledge about vaccination among physicians, coupled with their lack of experience in this area. Other factors may be a limited awareness among the general public, and the fact that these vaccines are not included in the basic health insurance package, or are financially inaccessible for other reasons. In the Netherlands, vaccines are mainly used in the context of public vaccination programmes.

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## **Government responsibilities with regard to vaccination and vaccination programmes**

What are the government's responsibilities in terms of vaccination and vaccination programmes? Under what circumstances is it sufficient just to ensure the availability of safe, efficacious vaccines? Are there any situations in which the government needs to get involved in promoting the actual use of specific vaccines? Furthermore, under what circumstances should a given vaccination be included in a public programme, such as the National Immunisation Programme?

State intervention in public health is based on two principles. First, the government is tasked with protecting the population and the fabric of society. Secondly, it endeavours to achieve a fair distribution of care.

In situations where vaccines for individuals and groups in society can be designated as essential healthcare, the Committee that drew up this advisory report feels that (in keeping with the second principle) it is the government's responsibility to eliminate any barriers to their use. According to current thinking, the criterion of "individual disease burden" is a pivotal consideration when determining whether a given aspect of care should be designated as essential. If such care is also cost-effective, then it merits funding under the Health Insurance Act. The Committee feels that there is no fundamental reason why prevention and treatment should be dealt with differently.

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## **Deficiencies in the way vaccination care is currently organised**

All new medicinal products (i.e. vaccines too) are assessed for safety and efficacy by the medicines authorities. Once these have received marketing authorisation, they are theoretically available for use. Subsequently, part of the cost of such medicinal products has to be met by the users themselves, some is reimbursed by their health insurance company, and the remainder is met by the government. The current assessment frameworks for basic health insurance packages and for public vaccination programmes were created by the Health Care Insurance Board (CVZ) and the Health Council respectively.

The existing frameworks have demonstrated the effectiveness of assessing purely individual vaccinations (such as those for travellers) and of including specific vaccinations in a public programme. At the present time, however, the option of

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including vaccinations in the basic health insurance package is only available to children who have missed certain National Immunisation Programme vaccinations, and to individuals with specific disorders that involve a higher risk of infection or of complications. Potential health gains are being left untapped, mainly due to the way in which vaccination care is currently organised.

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### **A single assessment framework and a single assessment authority for all vaccinations**

The Committee proposes that a single assessment framework be used for all vaccinations. The starting point here spans the entire spectrum of vaccination care, from care charged directly to individuals or companies, to collectively funded essential healthcare, and public vaccination programmes (see table).

A general assessment framework can be relatively easily derived from existing frameworks. The assessment authority must have a remit spanning the entire spectrum of vaccination care if it is to determine a vaccine's status effectively. In many cases, public considerations will be involved in the use of vaccines as part of the health insurance package. This requires the sort of specific expertise that is readily available within the Health Council. Accordingly, the Committee recommends to assign the scientific advisory duties for the entire spectrum of vaccination care to the Health Council. Clearly, agreement must be reached with the Health Care Insurance Board regarding criteria for the inclusion of vaccinations in health insurance packages.

It is usually possible to operate more effectively and efficiently in the context of a public programme, as a result of the centralised organisation and procurement involved. The Committee recommends that an evaluation be carried out to determine whether similar economies of scale can also be achieved for vaccinations that are collectively funded under the Health Insurance Act.

The proposed assessment framework is in keeping with government initiatives to modernise vaccination care. The government is now also aware that, given the way in which vaccination care is presently organised, any vaccines not offered in the context of a programme tend to remain unused. As a result, major potential health gains are being left untapped, so the government is looking for ways to administer vaccinations outside the public programmes.

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### **Avoid situations that might undermine public vaccination programmes**

The public debates surrounding vaccination against cervical cancer, pandemic influenza, and seasonal flu have once again highlighted the importance of fine-tuning the profiles of public vaccination programmes. Partly for this reason, it is difficult to broaden the criteria for including vaccinations in public programmes. Conversely, creating greater scope for vaccination outside public programmes can help to ensure that these programmes' nature and content are more effectively safeguarded.

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### **More training and instruction on vaccines**

In itself, the adoption of a single general assessment framework does not resolve the problem of the under-utilisation of potentially useful vaccines. This probably results from a lack of knowledge about vaccination among physicians, coupled with a lack of experience, as well as limited awareness among the general public. Accordingly, the Committee recommends that modifications be made to training programmes and refresher courses for nurses and physicians in child healthcare, senior house officers, general practitioners, paediatricians and internists. This would involve a systematic focus on vaccinology and on the related interview techniques and information provision skills. Members of the public, too, should be better informed about vaccines and vaccinations. The Committee proposes that the National Institute of Public Health and the Environment be entrusted with the management of public information campaigns across the entire spectrum of vaccination care.

The spectrum of vaccination care and related government duties.

	Individual healthcare	Essential healthcare, collectively funded	Public healthcare
Justification for government involvement	Care charged directly to individuals or companies	Essential healthcare, collectively funded	Public programmes
	Make vaccines available for the protection of individuals	Promoting equal access to essential healthcare	Protecting the population and the fabric of society against serious infectious diseases
Government duties in the relevant area of vaccination care	<ul style="list-style-type: none"> <li>Granting vaccines marketing authorisation</li> <li>Public information campaigns</li> <li>Legislation, regulations, and healthcare monitoring</li> <li>Monitoring potential harmfulness (registration of adverse effects)</li> </ul>	<ul style="list-style-type: none"> <li>Decision on implementation and funding: inclusion in collective packages, possibly in the context of a programme, with funding under the Health Insurance Act or from the national budget, with a possible patient's own contribution</li> <li>Public information campaigns</li> <li>Legislation, regulations, and healthcare monitoring</li> <li>Monitoring the process to determine whether the intended effect (equality of access, and – in selected cases – effectiveness) has been achieved; monitoring adverse effects at individual level and population level</li> </ul>	<ul style="list-style-type: none"> <li>Decision on implementation and funding: details of what is being offered in the context of a programme, practical organisation, funding from the national budget</li> <li>Public information campaigns</li> <li>Legislation, regulations, and healthcare monitoring</li> <li>Monitoring the process to determine whether the intended effects (high vaccination coverage/herd immunity, effectiveness) have been achieved; monitoring adverse effects at individual level and population level</li> </ul>
	Assessment framework	<ul style="list-style-type: none"> <li>Assessment of quality, efficacy and potential harmfulness by medicines authorities</li> </ul>	<ul style="list-style-type: none"> <li>Criteria for collective funding</li> <li>Considerations for implementation in the context of a programme: urgency, effectiveness, efficiency, quality</li> </ul>
Examples	<ul style="list-style-type: none"> <li>Guidelines for medical practice</li> <li>Vaccinations for travellers</li> <li>Vaccination in the context of occupational healthcare (where this is in the interests of employees and/or employers)<sup>a</sup></li> </ul>	<ul style="list-style-type: none"> <li>Guidelines for medical practice</li> <li>Individuals with a defined disorder that involves a higher risk of infection or of complications are vaccinated against hepatitis A, hepatitis B, pneumococcal disease and rabies</li> <li>Vaccination (in the context of a programme) for vulnerable groups, e.g.: <ul style="list-style-type: none"> <li>The elderly and medical high-risk groups against seasonal flu</li> <li>Certain patient groups against Q fever</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Guidelines for medical practice</li> <li>National Immunisation Programme</li> <li>BCG vaccination of the children of a parent (or parents) from high-risk countries</li> <li>Vaccination against hepatitis B of individuals belonging to high-risk groups (gay men, intravenous drug users)</li> <li>Vaccination during public health emergencies, such as an influenza pandemic</li> <li>Vaccination in the context of occupational healthcare (where this is in the interests of third parties)<sup>a</sup></li> </ul>

<sup>a</sup> On 11 April 2013, the Health Council established a separate committee which, at the request of the Minister of Social Affairs and Employment, will advise on employers' duties and responsibilities regarding the vaccination of employees.





# Introduction

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## 1.1 Background to this advisory report

In 2007, the Health Council drafted an assessment framework for the inclusion of vaccinations in public programmes, such as the National Immunisation Programme.<sup>1</sup> That framework, which was adopted by the Minister of Health, Welfare and Sport, has now been in use for more than five years. It facilitates a systematic analysis of the arguments for and against the inclusion of specific vaccinations in public programmes, while providing insight into the choices involved.

In the Netherlands, there are few options for administering vaccinations outside the context of public programmes. The evidence indicates that, ultimately, little use is made of any vaccinations that are not included in such programmes. As a result, potential health gains are being left untapped. Even more importantly, perhaps, is that this lack of alternative vaccination options can undermine debates about the scope of the public vaccination programmes themselves. This shortcoming complicates the deliberations about whether or not a given vaccination should be included in a public programme. The public debates surrounding vaccination against cervical cancer, pandemic influenza, and seasonal flu have once again highlighted the importance of fine-tuning the profiles of these programmes.

In this advisory report, the Committee on the National Immunisation Programme systematically explores the basis for state intervention in vaccination

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and vaccination programmes. It also examines the issue of why opportunities for vaccination remain untapped and explores potential solutions. The Committee concludes that the best course of action is to establish a single, general assessment framework for all vaccinations.

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## 1.2 Committee and procedure

The Committee on the National Immunisation Programme (Annex A) was appointed by the President of the Health Council in 2001. On behalf of the Council, this committee reviews the existing scientific knowledge on vaccination, and advises the Minister of Health, Welfare and Sport on the content and composition of the National Immunisation Programme.

The Committee regularly issues recommendations on individual vaccinations, and critical evaluations of the programme as a whole. That was the case in 2007, for example, in *The Future of the National Immunisation Programme: towards a programme for all age groups*.<sup>1,2</sup> The basis for that advisory report was the National Immunisation Programme, which has traditionally had a strong focus on children. However, the assessment framework was developed and expanded into a tool that could be used to assess all vaccinations that serve a public purpose. The Committee drew up seven criteria to clarify the reasons for recommending that a given vaccination be included in a public programme.

In the advisory work that it has carried out to date, the Committee has limited its pronouncements to vaccinations with a clear-cut public purpose. It did not feel that its remit extended to advising on vaccinations involving a more individual dimension, such as those for travellers and specific groups (or patient groups). However, it now appears that, in the Netherlands, little use is being made of vaccinations outside the context of public programmes. Accordingly, for this advisory report the Committee has decided to broaden its scope of activities to include vaccinations in general.

In preparing this report, the Committee has built upon the assessment framework established in 2007 and the resultant experience gained in various dossiers. These include vaccinations against seasonal flu, cervical cancer, Q fever, hepatitis B, pandemic influenza A/H1N1 2009 (also known as New Influenza A or Swine Flu), pneumococcal disease and tuberculosis.<sup>3-21</sup> To garner the requisite knowledge, the Committee has also studied the scientific literature and consulted various experts. A list of the experts consulted can be found in Annex A.

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## **1.3 Definitions of various concepts**

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### *1.3.1 Vaccine and vaccination*

The Committee takes the term “vaccine” to mean a preparation that enables the immune system to develop a specific immune response to disease. The term “vaccination” refers to the administration or use of one or more vaccines. Typically, vaccines are administered by injection (into a muscle or under the skin), however some vaccines are also designed for delivery via the mouth (orally) or as nose sprays (nasal).

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### *1.3.2 Subsidiarity and proportionality*

By preference, more senior governmental bodies preferably should not tackle issues that can be effectively dealt with by lower-level authorities. By the same token, the government should not intervene in issues that can be left to private initiatives. In the course of its deliberations, the Committee has always kept this principle of administrative subsidiarity in mind. Accordingly, it only recommends state intervention in cases that, in its view, cannot be left to lower-level authorities or to private initiatives.

Proportionality is also important when assessing state intervention in vaccination and vaccination programmes. The principle of proportionality states that the means used must be reasonably proportionate to the scale of the problem involved. The question to be answered here (assuming that all measures in this area are automatically the responsibility of the government) is what other conditions must be met to justify state intervention in vaccines or vaccinations.

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### *1.3.3 Registration, availability, accessibility and actual use*

The Committee distinguishes between vaccines that have been registered, vaccines that are available on the market, and vaccines that are actually accessible. For instance, the vaccines against chickenpox, shingles, and gastroenteritis caused by rotavirus infections are all registered medicinal products, and they have all received marketing authorisation in the Netherlands (and throughout Europe). However, marketing authorisation does not necessarily mean that a vaccine will be accessible to physicians and patients. This requires that manufacturers actually market the vaccine in the first place. Even then, there

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are other obstacles to be surmounted. Due to their scant knowledge of vaccination, coupled with a lack of experience in this area, many physicians tend not to prescribe vaccines. The main considerations for members of the public are that modern vaccines are often expensive, especially when used by individuals, and that the cost involved is usually not covered by health insurance. Registration status, availability and accessibility all affect the extent to which a given vaccine is actually used. The Committee uses the term “under-utilisation” to indicate that a potentially useful vaccine is only being used to a very limited extent.

In order to explore the use of vaccines, the Committee obtained data from the Foundation for Pharmaceutical Statistics (*Stichting Farmaceutische Kengetallen*). This foundation collects data from local pharmacists throughout the Netherlands. In addition, a limited number of vaccines may also have been dispensed by hospital pharmacists. This system contains no details about that, however.

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## 1.4 Structure of the report

In the second chapter, the Committee uses three examples to illustrate the central issue addressed by this advisory report, which is that some vaccines that are useful for various sections of the population are under-utilised. If existing policy remains unchanged, the Committee anticipates that the discrepancy between supply and use will be further exacerbated by the arrival of new vaccines and new areas of application. In the third chapter, it considers the extent to which responsibility for tackling this issue can be laid at the government’s door. Chapter four addresses the existing frameworks for assessing vaccines, and their inclusion in the basic health insurance package and in public programmes. In the fifth chapter, the Committee suggests that the best course of action is to develop a single, general assessment framework and a single assessment authority for all vaccinations. In Chapter 6, it discusses issues that need to be addressed if the proposed system is to be introduced with all due care and attention. In the final chapter, the Committee summarises the principal recommendations made in the previous chapters.

## Potential health gains are being left untapped

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In the Netherlands, virtually no use at all is being made of some potentially useful vaccines. As a result, potential health gains are being left untapped. The arrival of new vaccines and new applications will probably exacerbate the identified issue still further.

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### 2.1 Virtually no use at all is made of some vaccines

Some effective vaccines for the prevention of various diseases have not been included in public vaccination programmes. These include good vaccines against chickenpox, gastroenteritis caused by rotavirus infections, and shingles. There are various reasons why vaccinations against chickenpox, gastroenteritis caused by rotavirus infections and shingles have not been included in the National Immunisation Programme, but the fact remains that these vaccines are useful for certain individuals and groups in society.<sup>1</sup> There are no formal barriers to the use of these vaccines. In theory, they are available to physicians and patients. In the case of some variants of the vaccines listed below, their manufacturers do not market these products in the Netherlands.

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#### 2.1.1 *Chickenpox*

Chickenpox (which is caused by the varicella zoster virus) is both common and highly contagious. The vast majority of chickenpox cases involve relatively mild

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symptoms and a full recovery; however, this disease can result in complications, residual symptoms, and even death. On average, individuals contracting this disease in the Netherlands are younger than those in neighbouring countries, where there is a higher incidence of serious complications and residual symptoms.<sup>22</sup> However, even in the Netherlands, there were about 1,650 hospital admissions over a period of three years, one third of which involved complications.<sup>23</sup>

A range of “individual” chickenpox vaccines are available (Provarivax© and Varilrix©), as well as combined vaccines against measles, mumps, rubella (or German measles) and chickenpox (ProQuad© and Priorix-tetra©).

Vaccination has a place in the care of patients with immune disorders, who can become seriously ill as a result of varicella infections. In addition to those with an immune disorder, this concerns individuals who have regular contact with such patients, especially professionals in the paediatric or obstetric sectors who have not previously been infected by the chickenpox virus. Other groups with an indication for vaccination are women undergoing fertility treatment, individuals (mostly children) scheduled for immunosuppressive treatment, children in complete remission from leukaemia, HIV-positive children, and the siblings of children undergoing chemotherapy (here too, to the extent that those involved have not previously been infected with the chickenpox virus). Pregnancy and reduced T-cell immunity are contraindications for vaccination against chickenpox. A complete list of indications is available in the relevant Dutch Institute for Healthcare Improvement (CBO) guideline.<sup>24</sup>

Countries which have included vaccination against chickenpox in their national vaccination programmes include the United States, Canada, Germany and Spain. In the United States in particular, experience has shown that vaccination against chickenpox can prevent a great deal of disease – and even mortality – in young children.<sup>25-27</sup>

In 2007, vaccination against chickenpox was assessed against the criteria for inclusion in the National Immunisation Programme. At that time, chickenpox was not listed as a public health problem, nor was vaccination against it designated as urgent. Accordingly, the Health Council did not recommend that it be included in the programme.<sup>1</sup> During that period, only limited data were available on the frequency of complications in chickenpox. In the face of evidence that neighbouring regions of Germany had a higher frequency of complications, the Committee recommended that more data be collected for the Netherlands. However, studies into the frequency of complications resulting from chickenpox failed to confirm the German pattern.<sup>23</sup> The Committee has yet

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to issue its final judgment concerning inclusion in a public programme (see Section 6.2).

It may be that the vaccine is not always actively offered to individuals in one of the above high-risk groups. Usage data supplied by the Foundation for Pharmaceutical Statistics show that, in other contexts too, virtually no use at all is made of this vaccine in the Netherlands. In 2010, 2011 and 2012 respectively, Provarivax© was dispensed 245, 241 and 315 times by local (non-hospital based) pharmacists. Over the same period, Varilrix© and the combined vaccines ProQuad© and Priorix-tetra© were not dispensed at all (J.D.L. Kroon, written communication, 2013).

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### 2.1.2 *Gastroenteritis caused by rotavirus infections*

At some stage, almost all young children contract gastroenteritis caused by a rotavirus infection. Accordingly, this involves tens of thousands of cases per year. Rotavirus infections in young infants can cause severe, acute effects, due to dehydration and electrolyte imbalance. This often requires hospitalisation. There is no complete record of the actual morbidity and mortality involved. To some extent, all of the available data are model-based estimates and extrapolations. The number of hospital admissions in the Netherlands is estimated at 3,000-5,500 per year. In the Dutch healthcare system, gastroenteritis caused by rotavirus infections responds well to treatment, yet it still causes a few deaths each year.<sup>28-31</sup>

There are two vaccines against gastroenteritis caused by rotavirus infections (the brand names are Rotarix© and Rotateq©). Both vaccines consist of a drop of liquid, administered orally. While vaccination against gastroenteritis caused by rotavirus infections has been assessed against the relevant criteria, it has not yet been included in the National Immunisation Programme. In its 2007 advisory report, however, the Health Council concluded that gastroenteritis caused by rotavirus infections can have a serious impact on affected individuals and that the number of cases is quite substantial.<sup>1</sup> In subsequent deliberations, the Committee on the National Immunisation Programme was unable to reach a consensus on the issue of whether gastroenteritis caused by rotavirus infections in the Netherlands constitutes a public health problem, and whether vaccination against it should be included in a public programme. The Committee has yet to issue its final judgment on these matters (see Section 6.2).

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As with chickenpox, there is a group of patients who are particularly vulnerable to rotavirus infections. They should have access to the vaccine as part of their care. In certain groups, it is relatively common for rotavirus infections to result in complications and even death. These include children born prematurely, children with congenital abnormalities of the heart and lungs, children with bowel disease, children with congenital immunodeficiency or immunosuppression caused by the use of steroids or the treatment of malignancies, and children with metabolic disorders.<sup>32-34</sup> Vaccinating these children against rotavirus infection is not standard procedure, but there is evidence to suggest that it would make sense to vaccinate this group of vulnerable children as a matter of policy.<sup>31</sup>

The use of vaccine can also prevent cases of illness and hospital admissions in many healthy children too. Countries such as Belgium, Luxembourg, Germany, Austria, Finland, the United States, Australia and South Africa have now acquired practical experience of this issue through their national vaccination programmes. Belgium has achieved a high level of vaccination coverage, even though this vaccination is not included in its national vaccination programme. This is also the case in parts of Germany.<sup>35</sup> In the United Kingdom and Germany, it was recently decided to include vaccination against gastroenteritis caused by rotavirus infections in the national vaccination programme.<sup>36,37</sup>

Data supplied by the Foundation for Pharmaceutical Statistics show that, in the Netherlands, virtually no use at all is made of vaccines against gastroenteritis caused by rotavirus infections. In 2010, 2011 and 2012 respectively, Rotarix© was dispensed 69, 41 and 14 times by local pharmacists. Over the same period, Rotateq© was not dispensed at all (J.D.L. Kroon, written communication, 2013).

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### 2.1.3 *Shingles*

Shingles can be severe and highly debilitating. The disease affects individuals of all ages, but mainly the elderly. Like chickenpox, the disease is caused by the varicella zoster virus. Individuals become re-infected by viruses emerging from ganglia where they have lain dormant for protracted periods of time. The viruses spread along the axons of dermal nerves, giving rise to the characteristic clinical picture of blisters in the areas served by the nerves in question. The disease often has a prolonged course. It can sometimes cause permanent changes in sensation, as well as persistent pain in the affected area (postherpetic neuralgia).<sup>38</sup> In the case of shingles in the elderly, too, a vaccine has been around for several years.

Every year more than a thousand people are hospitalised due to shingles. The frequency of hospitalisation depends to a large extent on the individual's age.

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There are few such cases in those below the age of 50 (approximately 1 per 100,000). This increases with age to 2.4 per 100,000 in the 50-54 age group, and to 19.4 per 100,000 in those aged 85 and above. Of the deaths reported to Statistics Netherlands each year, shingles is listed as the primary cause of death in about twenty cases.<sup>22,39</sup>

In 2007, vaccination against shingles was assessed against the criteria for inclusion in the National Immunisation Programme. The Committee concluded that vaccination against shingles was a potentially important intervention. However, a lack of data on the effectiveness, safety, acceptability and efficiency of vaccination precluded a more accurate determination of its status.<sup>1</sup> Since then, additional data on vaccination against shingles has become available, but the Committee has yet to issue its final judgment concerning inclusion in a public programme (see Section 6.2).

In the Netherlands, virtually no use at all is made of the shingles vaccine: in 2010, 2011 and 2012 respectively, Zostavax© was dispensed 38, 28 and 23 times by local pharmacists (J.D.L. Kroon, written communication, 2013).

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#### **2.1.4** *Possible reasons for this limited usage*

One possible reason for the limited usage of the vaccines in question is that physicians working outside the National Immunisation Programme have only a scant knowledge of vaccination, coupled with a lack of experience in this area. A second explanation is that the general public, too, is largely unaware of vaccines that could be important for certain groups of patients or for the wider population. A third explanation for this limited usage might be that, while the vaccines in question have received marketing authorisation in the Netherlands, they have not been included in the basic health insurance package or in any other scheme that might render them financially accessible to the public.

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## **2.2 Further exacerbation of the problem by new vaccines and new applications**

If this policy remains unchanged, the identified under-utilisation of vaccines will probably become further exacerbated. Vaccine development has been improved and accelerated through the use of new biotechnological methods, especially DNA techniques. Partly as a result of this, new vaccines are regularly becoming available.

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Those working in this area have accumulated a considerable body of experience with vaccines against infectious diseases. Gradually, vaccines are also being developed against non-infectious diseases and the associated risk factors. This research effort is also focusing on vaccines against diabetes, asthma and smoking, for example. As in the case of vaccines against infectious diseases, these are vaccines that can prevent the above-mentioned diseases. If the goal is to trigger the immune system to target a pre-existing disease (such as a rheumatic disorder or cancer), the vaccines in question are described as therapeutic vaccines. In such cases, however, it would be more appropriate to describe them as immune modulators. Therapeutic vaccines, too, will become available in the future.

The issue of how to safeguard the assessment and accessibility of new vaccines in the future should be addressed as a matter of urgency, to avoid exacerbating the problem of vaccine under-utilisation.

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### **2.3 Conclusion**

The Committee discussed chickenpox, gastroenteritis caused by rotavirus infections, and shingles. There are effective vaccines against all of these diseases, yet virtually no use at all is made of them in the Netherlands. While vaccination against the diseases in question has been assessed against the relevant criteria, it has not yet been included in the National Immunisation Programme. For groups of patients with certain underlying conditions, the use of vaccines against chickenpox and gastroenteritis caused by rotavirus infections is part and parcel of adequate healthcare. Their use could also be considered in individuals outside the high-risk groups in question, but these vaccines are rarely used in the Netherlands. There are no formal barriers to the use of these vaccines. In theory, they are available to physicians and patients. The limited use of such vaccines is probably based on a limited awareness among the general public. Other factors may be a lack of knowledge about vaccination among physicians, coupled with their limited experience in this area, and the fact that these vaccines are not included in the basic health insurance package or in any other scheme that might render them financially accessible to the public.

As a result of new techniques, new vaccines are regularly becoming available. In the future, vaccines against infectious diseases will be supplemented by vaccines against non-infectious diseases. If policy remains unchanged, the development of new vaccines and new applications will probably serve to further exacerbate the

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under-utilisation of vaccines that we have identified. The issue of how to safeguard the assessment and accessibility of new vaccines in the future should be addressed as a matter of urgency, to avoid exacerbating the problem of vaccine under-utilisation.



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## **Government responsibilities**

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In the previous chapter we saw how various potentially useful vaccines are rarely used in the Netherlands, resulting in potential health gains being left untapped. Does the responsibility for taking action in this matter rest with the government? What are the government's responsibilities in terms of vaccination and vaccination programmes?

In the first two sections of this chapter, the Committee summarises the government's responsibilities in terms of public programmes. In the following sections, it explores the extent to which such responsibilities also apply outside the context of these public programmes, and the issues to be addressed in this regard.

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### **3.1 Two principles, a single objective**

State intervention in vaccination and vaccination programmes is based on two principles. First, the government is tasked with protecting the population and the fabric of society. Secondly, it endeavours to achieve a fair distribution of care. In 2007, reasoning on the basis of these principles, the Committee defined the objective of public vaccination programmes as: protecting the population and the fabric of society against serious infectious diseases by means of vaccination. The framework drawn up by the Committee contains seven criteria for the inclusion of vaccinations in public programmes.<sup>1,2</sup>

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### 3.1.1 *Protecting the population and the fabric of society*

What does the Committee mean when it states that a vaccine should be used to protect the population and the fabric of society? The most basic task of government is to protect the public, as a collective. In and of itself, health is worthy of protection, in terms of people's well-being or quality of life, for example. However, it is also a prerequisite for a flourishing social fabric. Creating conditions that facilitate this is a key government task. The task of protecting the population and the fabric of society can involve a range of different aspects:

- Creating the conditions in which people can live a safe and carefree life, both individually and collectively, more particularly by ensuring that they do not harm one another, either intentionally or unintentionally.
- Providing protection against the risks of serious illness, both in people's social circles and in their social interactions, under circumstances in which it is difficult for individuals to protect themselves.

Against a background of increasingly disruptive threats to the fabric of society, where individuals are less able to protect themselves, it becomes ever more important for the state to intervene and protect the population and the fabric of society. This is particularly applicable in the case of infectious diseases. An infectious disease can undermine the health of individual members of the public. Those individuals, in turn, may inadvertently harm the health of others. When a dangerous micro-organism starts spreading rapidly through a community, the burden of disease and fear of contamination can paralyse the fabric of society. That is particularly applicable where infection can occur through everyday social interactions, at work, in schools, or on the streets.

If large numbers of people fall ill, this can impact the continuity of vital sectors, such as the utilities, the health service, and the food supply and distribution chains. Fortunately, situations like this are not a frequent occurrence. One instance was the 1918-1919 influenza pandemic, others included the HIV and AIDS pandemic in various parts of the world during the 1980s and 1990s, and the threat posed by the spread of the SARS coronavirus in 2002-2003. In some cases, there can be a threat to the fabric of society even when relatively small numbers of people fall ill. That was the case, for example, with the epidemic of infections caused by meningococcus C, which mainly affected the southern regions of the Netherlands between 1999 and 2001. The emergence of clustered

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cases of disease caused a great deal of anxiety among parents, thus posing a threat to the fabric of society in some parts of the country.

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### 3.1.2 *Facilitating a fair distribution of care*

In addition to providing optimum protection for the population as a whole, the Health Council formulated a second principle for state intervention in the form of vaccination: a fair distribution of care across the population, which involves protecting those groups that are most urgently in need of protection.

In the context of public vaccination programmes, achieving a fair distribution is not usually a problem. Most programmes are universal in nature, so they provide protection to everyone. Where vaccination targets specific subgroups, these are generally the ones that are in the most urgent need of vaccination. That is fair and, for specific diseases, it usually delivers the greatest health gains for the population as a whole.

Nevertheless, the principle of a fair distribution of care – even in the context of public vaccination programmes – is certainly not irrelevant. For example, when assessing vaccination against cervical cancer, the accessibility (to all girls) of this important form of protection against a serious disorder, as well as the potential health gains at population level, were major factors behind the Health Council's recommendation that the vaccination should be included in the National Immunisation Programme.<sup>5</sup>

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## 3.2 **Use in public vaccination programmes**

Under Article 22 of the Constitution, the government is required to take measures to promote public health. The Constitution specifies neither the nature nor the scope of the measures to be taken. Political choices need to be made, to determine how the government's responsibility relates to that of individual members of the public. This is exactly the sort of theme on which there are conflicting views in political circles. However, that plurality of opinions does not detract from the fact that almost all political/philosophical schools of thought agree that some of the tasks associated with promoting public health fall naturally to the government. Administrative subsidiarity is an important principle here. The government tends not to intervene in issues that can be left to private initiatives.

There is a broad consensus regarding the nature of the initiative that the government needs to take to protect public health and the fabric of society.

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Providing this essential protection is the main justification for state intervention in public vaccination programmes.<sup>1</sup>

There is scope for further debate about the extent to which the government should promote a fair distribution of care. The issue of exactly what is meant by “essential” healthcare (prevention, therapy or support) is the subject of public debate, but here too there is a widely shared assumption that every member of the public must have access to certain key elements of basic healthcare provision. Given the special status of health, we feel it is vital for the quality and accessibility of healthcare to be effectively regulated.

Both of these principles are always applicable to public programmes, albeit to varying degrees. Providing protection against diseases that pose major public health problems is also important from the perspective of a fair distribution of care. Conversely, in the case of severe diseases, the accessibility of healthcare is a major consideration in the protection of public health.

The government’s responsibility to protect its citizens by means of vaccination is most evident in the case of the classic childhood illnesses. In 1956, there was a polio epidemic involving 2,200 cases and over 70 deaths. This led to the establishment of a national vaccination programme, specifically aimed at children, for the prevention of diphtheria, whooping cough, tetanus and poliomyelitis. The National Immunisation Programme was subsequently expanded to include vaccinations against rubella, measles, mumps, hepatitis B, invasive infections by *Haemophilus influenzae* type b, invasive meningococcal C disease, invasive pneumococcal disease, and cervical cancer.

The substantive and procedural aspects of public vaccination programmes are not carved in stone, but evolve in step with social developments and technological advances. The Health Council outlined a number of these developments in the advisory report entitled *The future of the National Immunisation Programme: towards a programme for all age groups* (2007).<sup>1</sup>

Public vaccination programmes are currently limited to infectious diseases. In the future, when they finally become available, it will still be some time before vaccines against non-infectious diseases are included in public programmes. The reason for this is the special status accorded to protecting the population and the fabric of society in the case of infectious diseases (Section 3.1.1).



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### 3.3 What type of healthcare is essential?

The government's responsibility for promoting the fair distribution of care is not limited to public vaccination programmes. The accessibility of healthcare has been identified as being fundamental to the fair distribution of care across the population.

But what is really meant by “essential” healthcare? Which elements of healthcare should be included in the collective health insurance package? And which ones should not? As long ago as the 1980s, there was a growing realisation that there are limits to the growth of the health insurance coverage. That realisation has fueled a debate about the criteria that need to be applied here. As this debate is still in full swing, the Committee has provided a summary.

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#### 3.3.1 *The Dunning Committee criteria*

A milestone in this regard was the 1991 report by the Government Committee on Choices in Healthcare (also known as the Dunning Committee) entitled “*Kiezen en Delen*” (Making the Right Choices). According to the Dunning Committee, “necessity of care” is one of the key criteria for assessing whether a given element of healthcare provision should be included in the health insurance package.<sup>40</sup> In addition to “necessity of care”, the Committee proposed three other criteria or “sieves”: effectiveness, efficiency, and the unreasonableness of insisting on personal payment and personal responsibility for the intervention (in other words, the need for collective funding).

Based on these criteria, the Dunning Committee specified three categories of amenities that, from a community perspective, should be regarded as constituting essential healthcare. The category of amenities that focus on maintaining or restoring the opportunities to participate in social interactions also includes forms of preventive care, such as antenatal care, preventive care for children, vaccinations and the detection of health risks.

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#### 3.3.2 *Later effects: individual disease burden and effectiveness (and cost effectiveness)*

It has proved difficult to put “Necessity of care” (the Dunning Committee's first criterion) into practice. The former Health Insurance Funds Council, the Health

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Care Insurance Board, and the Health Council suggested that this should be replaced by the criterion of “disease burden”, which is easier to put into practice.<sup>41-43</sup> This refers to the individual, disease-related burden of disease: the reduction in quality of life or life expectancy as a result of a disease, or other somatic or mental health problems, when no use is made of a given element of healthcare provision. In its advisory reports, the Council for Public Health and Healthcare uses the individual burden of disease as a criterion for determining the nature of essential healthcare.<sup>44-46</sup>

It is important to distinguish between the individual concept of “disease burden” and the social concept of the same name, as applied in the criteria for the inclusion of vaccinations in public programmes, for example. The concept of social disease burden involves both the burden placed on affected individuals and the prevalence (the number of cases of disease in the population). However, it is the individual disease burden that is important when assessing the need to incorporate a given treatment into a collective health insurance package. This is because, according to the Health Care Insurance Board, the sense of solidarity in Dutch society is motivated by the individual disease burden rather than by any wider impact on society.<sup>45</sup>

In addition to the burden of disease, effectiveness (including cost effectiveness) is an important criterion for including an intervention in the health insurance package. There is a broad consensus in the scientific literature that individual disease burden and effectiveness, followed by cost-effectiveness, are the criteria for a basic health insurance package founded on solidarity.<sup>42</sup>

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### **3.4 Vaccination: option, fee, or public programme?**

Vaccinations are used across the spectrum of individual and public healthcare. Table 1 gives details of vaccinations with a predominantly individual dimension (left column) and of those that are offered in the context of a public programme (right column). Between these two extremes, there is a category of vaccinations that do not primarily have a public dimension, but which can nevertheless be designated as essential healthcare for individuals and groups in society.

An indication is given, in each of the three segments, of the reasons for state intervention and of the tasks that are the specific responsibility of the government.

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### 3.4.1 *Making vaccines available for the protection of individuals*

Vaccines are medicinal products within the meaning of the law. In some cases it will be sufficient for the government to arrange for effective vaccines to be available to protect individuals (left-hand column in Table 1: Care charged directly to individuals or companies). Those who stand to benefit from the availability of effective vaccines include travellers and individuals who could become infected in the course of their professional activities.

A programmatic approach could be selected for individual care, for reasons of urgency, effectiveness, efficiency or quality. In the area of occupational healthcare, for example, considerations of effectiveness and quality might result in the use of a programmatic option for the systematic vaccination of workers identified by a risk inventory and evaluation (RI&E) as being at risk of becoming infected.

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### 3.4.2 *Promoting equal access to essential healthcare*

The Minister of Health, Welfare and Sport may decide that a given vaccination should be designated as essential healthcare, and that it should therefore be accessible to specific groups or to the general public (middle column of Table 1: Essential healthcare, to be funded collectively). This generally involves funding under the Health Insurance Act. This is about vaccination as a form of remuneration.

Programmatic approaches may sometimes be adopted to promote equal access to essential healthcare. One example would be vaccinating the elderly against seasonal flu, another is the vaccination of individuals in medical high-risk groups. Vaccination against seasonal flu is in the interests of many in the community. As a result, the government has opted to use a programmatic approach in order to achieve significant economies of scale in terms of effectiveness and efficiency. In still other cases, a programmatic approach is needed to ensure the quality of vaccination. That was the case in 2010-2011, when specific categories of cardiovascular patients were vaccinated against Q fever. The strict safety guarantees involved in that vaccination meant that a programmatic approach, monitoring, and evaluation were seen as essential.

Table 1 The spectrum of vaccination care and related government duties.

	Individual healthcare	Essential healthcare, collectively funded	Public healthcare
	Care charged directly to individuals or companies		Public programmes
Justification for government involvement	Make vaccines available for the protection of individuals	Promoting equal access to essential healthcare	Protecting the population and the fabric of society against serious infectious diseases
Government duties in the relevant area of vaccination care	<ul style="list-style-type: none"> <li>Granting vaccines marketing authorisation</li> <li>Public information campaigns</li> <li>Legislation, regulations, and healthcare monitoring</li> <li>Monitoring potential harmfulness (registration of adverse effects)</li> </ul>	<ul style="list-style-type: none"> <li>Decision on implementation and funding: inclusion in collective packages, possibly in the context of a programme, with funding under the Health Insurance Act or from the national budget, with a possible patient's own contribution</li> <li>Public information campaigns</li> <li>Legislation, regulations, and healthcare monitoring</li> <li>Monitoring the process to determine whether the intended effect (equality of access, and – in selected cases – effectiveness) has been achieved; monitoring adverse effects at individual level and population level</li> </ul>	<ul style="list-style-type: none"> <li>Decision on implementation and funding: details of what is being offered in the context of a programme, practical organisation, funding from the national budget</li> <li>Public information campaigns</li> <li>Legislation, regulations, and healthcare monitoring</li> <li>Monitoring the process to determine whether the intended effects (high vaccination coverage/herd immunity, effectiveness) have been achieved; monitoring adverse effects at individual level and population level</li> </ul>
Assessment framework	<ul style="list-style-type: none"> <li>Assessment of quality, efficacy and potential harmfulness by medicines authorities</li> </ul>	<ul style="list-style-type: none"> <li>Criteria for collective funding</li> <li>Considerations for implementation in the context of a programme: urgency, effectiveness, efficiency, quality</li> </ul>	<ul style="list-style-type: none"> <li>Criteria for the inclusion of vaccinations in public programmes</li> <li>Views of the WHO and other international public health organisations</li> <li>International context</li> </ul>
Examples	<ul style="list-style-type: none"> <li>Guidelines for medical practice</li> <li>Vaccinations for travellers</li> <li>Vaccination in the context of occupational healthcare (where this is in the interests of employees and/or employers)<sup>a</sup></li> </ul>	<ul style="list-style-type: none"> <li>Guidelines for medical practice</li> <li>Individuals with a defined disorder that involves a higher risk of infection or of complications are vaccinated against hepatitis A, hepatitis B, pneumococcal disease and rabies</li> <li>Vaccination (in the context of a programme) for vulnerable groups, e.g.: <ul style="list-style-type: none"> <li>The elderly and medical high-risk groups against seasonal flu</li> <li>Certain patient groups against Q fever</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Guidelines for medical practice</li> <li>National Immunisation Programme</li> <li>BCG vaccination of the children of a parent (or parents) from high-risk countries</li> <li>Vaccination against hepatitis B of individuals belonging to high-risk groups (gay men, intravenous drug users)</li> <li>Vaccination during public health emergencies, such as an influenza pandemic</li> <li>Vaccination in the context of occupational healthcare (where this is in the interests of third parties)<sup>a</sup></li> </ul>

<sup>a</sup> On 11 April 2013, the Health Council established a separate committee which, at the request of the Minister of Social Affairs and Employment, will advise on employers' duties and responsibilities regarding the vaccination of employees.

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### 3.4.3 *Protecting the population and the fabric of society*

The government conducts public vaccination programmes to protect the population and the fabric of society against serious infectious diseases, where possible (right-hand column of Table 1: Public programmes). In this context, the best known example is the National Immunisation Programme with its clear-cut objective, principles and strategies. Another such public programme involved the vaccination of children up to the age of four during the 2009 pandemic of influenza A/H1N1. Vaccination during a public health emergency (such as an influenza pandemic) is the responsibility of central government, which uses this measure as a means of preventing social disruption. Children in the specified age group were vaccinated mainly as a result of the finding that their peers in countries previously affected by this pandemic had been more likely to require hospitalisation, intensive care treatment and ventilation. Since capacity is limited, intensive care for young children in general might be jeopardised, not only for those with influenza. The government felt that it was responsible for preventing such a situation from arising.

The objective of public vaccination requires a programmatic approach. A programmatic approach provides the best guarantee of high levels of vaccination coverage and effectiveness, while also providing opportunities for evaluation. Accordingly, the government organises and implements public information campaigns free of charge, and checks to see whether they are effective (monitoring and evaluation). Public vaccination care is, therefore, programmatic by definition.

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### 3.5 **Herd immunity, pressure, paternalism and compulsion**

Public programmes require a high level of vaccination coverage to achieve the desired effects. The goal of a very high level of vaccination coverage is not merely to directly protect as many individuals as possible. First and foremost, it is intended to protect the population as a whole. Herd immunity is an important means of achieving that goal. Herd immunity means that even those who have neither had the disease nor been vaccinated still enjoy a certain degree of protection, as many others in the population are immune. In other words, the effect of vaccination can be enhanced by herd immunity, much more so, in fact, than might be expected on the basis of the number of vaccinated individuals in a population. In many infectious diseases, there is a critical level of immunity in the population above which the disease in question cannot continue spreading.

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Measles, for example, cannot sustain itself in a population if more than 95 per cent of individuals have been vaccinated and are immune. Smallpox has been eradicated, through concerted international action. The World Health Organization (WHO) has identified polio, measles and congenital rubella syndrome as candidates for elimination\*.

If the goal is to protect the entire population, it is not a good idea for each individual to freely decide, based solely on their own risk (or that of their child), whether or not they want to be vaccinated. Herd immunity can reduce that risk to very low levels, so individuals may see this as a reason for refraining from vaccination, thereby undermining (albeit unintentionally) the protection of the group as a whole. An active approach is made to the vaccination's target group and, if necessary, its members (or their parents) are sent a reminder. Collective vaccination is usually much more effective and efficient than when individuals are left to take the initiative. These arguments can justify the application of pressure.<sup>47,48</sup>

Vaccinations that are reimbursed or provided in accordance with the principle of equal access to essential healthcare involve a greater degree of individual discretion than vaccinations that serve the purpose of protecting the population and the fabric of society. Even so, the government must make every effort to achieve the highest possible level of coverage for these vaccinations too. The primary argument here is not that this will protect the population and the fabric of society, but rather that it will benefit the health of the individuals to be vaccinated. In cases such as these, insisting that individuals are vaccinated may be paternalistic but an approach of this kind is easily defensible (especially in the case of children) as it helps to ensure that they too have genuinely equal access to the healthcare in question. Equal access is not merely a matter of "free vaccination", it also involves dealing as effectively as possible with other obstacles, such as forgetfulness or incorrect assumptions on the part of parents. Accordingly, it may also be appropriate to insist on vaccination outside the context of public programmes. Mild forms of pressure, such as general public information campaigns, will usually suffice.

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\* Here, "elimination" means the removal of a disease from a defined region. Elimination always involves the risk of reintroduction from another region. When a pathogen has been completely removed from the environment, such that the disease in question can never return, this is referred to as "Eradication".

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Accordingly, the use of pressure is justified in connection with public programmes, but the same is not generally true of compulsion. The issue of whether compulsion is permissible (in particular, whether parents should be forced to vaccinate their child) was widely debated following the most recent outbreaks of poliomyelitis. Advisory reports issued by the Health Council in 1974, 1982 and 1995<sup>49-51</sup>, and by the National Council for Public Health in 1993<sup>52</sup> all dismissed this option. A number of practical considerations (how might compulsion be applied?) and points of principle (parental autonomy) are also involved. In curative healthcare, medical intervention against parents' wishes is possible in certain circumstances, but only when the child in question is exposed to a genuine (or life-threatening) hazard. Generally, when parents opt to refrain from vaccination, there is no specific risk involved. This is only likely to be the case during an epidemic.

Aside from issues relating to the health of individual children, compulsory vaccination could be a useful instrument for achieving a high, effective level of vaccination coverage. This collective argument is generally in keeping with a programme that is designed to protect the population. Compulsory vaccination, however, is a major infringement of the autonomy of individuals. In this sense, such an approach can only be justified where a high level of vaccination coverage is needed, for instance to satisfy the public interest in terms of herd immunity. That is rarely the case. After all, very high levels of participation are already being achieved without the use of compulsion. Accordingly, compulsion cannot be justified in the present context.<sup>53,54</sup>

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### **3.6 A comparison with the situation abroad**

The Committee felt that it would be a useful exercise to focus on a number of neighbouring countries as well. What form does vaccination care take there? How do they rise to the challenges posed by the availability of new vaccines?

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#### **3.6.1 *In many cases there is no separate organisation for the national vaccination programme***

Several European projects have explored the procedures for recommending vaccines for these countries' national vaccination programmes, which vaccinations are being recommended, and the ages of the subjects involved.<sup>55-58</sup> However, there are few details about how exactly the various national vaccination programmes are organised.<sup>59,60</sup> The website of the European VENICE project offers a limited amount of information, on a country-by-country

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basis.<sup>61</sup> With regard to national immunisation programmes (NIP), few countries have a separate infrastructure like that of the Netherlands' National Immunisation Programme. In Finland, Norway, Sweden, Iceland and Italy, children are vaccinated in centres that are, to some extent, comparable to Dutch child health centres. Like its Dutch namesake, the United Kingdom's National Immunisation Programme is strongly programmatic in nature, with the important difference that GPs are responsible for implementation. This system is subject to strict controls imposed by the National Health Service.

Thus, in many countries, vaccination is not carried out within the context of a separate infrastructure. Instead, regardless of its purpose, it takes place in the setting of individual contacts between physicians and patients. In some cases, these physicians are general practitioners, in others they are self-employed paediatricians, or specialists in hospital outpatient clinics. Many countries have formal national immunisation programmes, with recommended vaccinations in national schedules. Accordingly, the governments of these countries have largely (or entirely) delegated their public responsibilities for protecting the population and the fabric of society by means of vaccination to individual physicians. However, in the absence of genuine control and evaluation, can these arrangements really be described as programmes? In addition, the national immunisation programmes of some countries receive some financial support from the individual health insurancesystem.

In many countries, therefore, it is not unusual for vaccination to be embedded in the individual healthcare system, without any strongly programmatic control. This approach suffers from the drawback that it is difficult for the government to safeguard the quality of vaccination and to determine whether the intended objectives have been achieved. To this end, an umbrella organisation for monitoring, registration and evaluation is essential. Such cases probably do not always achieve the same level of vaccination coverage as the Dutch National Immunisation Programme. Also, it is not always clear whether these vaccinations take place at the scheduled time. Finally, the potential for major economies of scale in terms of effectiveness and efficiency remains untapped.

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### 3.6.2 *Greater flexibility due to the involvement of the individual healthcare system*

Implementing the national immunisation programme through the individual healthcare system does make the system more flexible. In countries where healthcare professionals in the individual healthcare system are involved in the

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national immunisation programme, these individuals are more used to taking responsibility for vaccination. On average, therefore, they tend to have more experience than their Dutch counterparts. Members of the public in these countries discuss with their physicians whether vaccination is indicated in their case, and make choices in this regard. This may well increase the perceived level of personal influence that they are able to exert. Given the government's limited involvement in the process, there is a much smaller risk that people will view vaccination as unwarranted state intervention. Some countries achieve a higher level of vaccination coverage against cervical cancer than the Netherlands. One factor that might explain this is a greater involvement of professionals in individual healthcare.

In many countries, the national immunisation programme is embedded in individual healthcare. This creates additional options for vaccinations that are not included in the national programme. This is the situation in Belgium, Spain and Germany, for example. Belgium has achieved a relatively high level of vaccination coverage against gastroenteritis caused by rotavirus infections.<sup>62</sup> In parts of Spain and Germany, about 50 per cent of all infants are vaccinated against gastroenteritis caused by rotavirus infections, even though this vaccination is not included in their national programmes.<sup>63</sup>

The situation in the UK, where GPs are responsible for implementing the national vaccination programme (subject to strongly programmatic control), is an interesting case. The UK recently decided to vaccinate infants against gastroenteritis caused by rotavirus infections, young children against influenza, pregnant women against whooping cough (as a temporary control measure) and the elderly against shingles.<sup>36,64-66</sup> These four cases are, to some extent, in keeping with the profile of the vaccinations that feature prominently in Chapter 2 of this advisory report. In the case of these vaccinations, any considerations of protecting the population and the fabric of society are less pronounced than in the case of the classic National Immunisation Programme diseases, which tends to undermine the case for state intervention. Rather, these are vaccinations that can be characterised as essential healthcare for the target groups in question. As a result, it is appropriate for individuals to exercise a greater degree of personal responsibility in this regard (Section 3.1.2). It is reasonable to ask whether the course of action adopted by the British government in respect of these difficult cases was facilitated by the integration of the National Immunisation Programme into individual healthcare. On the one hand, this approach benefits from the considerable trust that individuals generally have in their GP. On the other hand, there is a relatively small risk that vaccination will be seen as unwarranted state

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intervention. Finally, control by the National Health Service enables significant economies of scale to be achieved, in terms of effectiveness and efficiency.

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### 3.6.3 *Procedures specifically used by the National Immunisation Programme*

Comparisons with other countries highlight the special nature of the procedures followed by the National Immunisation Programme in the Netherlands. The Dutch programmatic approach has numerous advantages, both from the perspective of government responsibilities and in terms of effectiveness and efficiency. Dutch vaccination care, however, leaves much to be desired with regard to flexibility and to the perceived level of personal influence that people are able to exert on vaccine provision. The challenge is to maintain the benefits of today's highly programmatic approach to public programmes and to combine them with a greater involvement of healthcare providers in individual healthcare.

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## 3.7 **Conclusion**

The government's responsibilities with regard to vaccination and vaccination programmes fall into three categories: 1) making vaccines available for the protection of individuals, 2) promoting equal access to essential healthcare, and 3) protecting the population and the fabric of society. All that is generally required to make vaccines available for the protection of individuals only is to arrange for such vaccines to have access to the market. Providing funding under the Health Insurance Act is an effective way of promoting equal access to essential healthcare. The use of a programmatic approach may occasionally be appropriate in this context. The government's duties in the area of public vaccination always require a programmatic approach. Accordingly, it is appropriate for the government to fund, implement and evaluate such programmes.

Comparisons with other countries highlight the special nature of the procedures followed by the National Immunisation Programme in the Netherlands. The Dutch programmatic approach has numerous advantages, both from the perspective of government responsibilities and in terms of effectiveness and efficiency. Dutch vaccination care leaves, however, much to be desired with regard to flexibility and to the perceived level of personal influence that people are able to exert on vaccine provision.

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## Current assessment frameworks

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In the previous chapter, the Committee described the government's responsibilities with regard to vaccination and vaccination programmes. In this fourth chapter, the Committee explores the extent to which existing frameworks are fit for this purpose.

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### **4.1 Care charged directly to individuals or companies**

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#### *4.1.1 Assessment of quality, efficacy and potential harmfulness*

A vaccine is a medicinal product within the meaning of the law. The Medicines Evaluation Board (or, in the case of a European assessment, the European Medicines Agency) assesses the quality, efficacy, and potential harmfulness of vaccines. On the basis of this assessment, the Minister of Health, Welfare and Sport (or the European Commission) makes a decision regarding marketing authorisation. The vaccine then becomes available in the individual healthcare system, and vaccination is an "option". Physicians are responsible for administering the vaccine, based on medical practice guidelines drawn up by the profession itself. The government monitors quality by means of legislation and safety monitoring (registration of adverse effects).

In the vast majority of cases, the government leaves the development, manufacture, and marketing of vaccines to commercial parties.

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With regard to the vaccination of travellers, physicians refer to the recommendations of the National Coordination Centre for Travellers' Health Advice ([www.lcr.nl](http://www.lcr.nl)).

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#### 4.1.2 *Evaluation*

As far as the Committee is aware, there are no major problems with regard to the assessment of vaccines for purely individual use (Column 1 of Table 1). Vaccinations for travellers are readily available from municipal medical and health services, specially equipped outpatients clinics, and more than 1,600 general practitioners.

There is no clear assessment framework for the vaccination of workers in the context of occupational healthcare. On 11 April 2013, the Health Council appointed a separate committee which, at the request of the Minister of Social Affairs and Employment, will advise on employers' duties and responsibilities regarding the vaccination of employees.

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### 4.2 **Essential healthcare, collectively funded**

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#### 4.2.1 *The means of promoting equal access*

Any healthcare that is deemed to be essential must be available to all those who stand to benefit from it. If such care is expensive and cannot reasonably be charged to the individual in question, collective funding can be an important tool for safeguarding equal access and for promoting fair distribution.

In situations like this, collective funding is usually sufficient to achieve equal access. In exceptional cases, the government itself shall ensure that the vaccine in question is available and that it can be used responsibly. That was the case in 2010-2011, for example, when specific categories of cardiovascular patients were vaccinated against Q fever, in line with individual healthcare. The vaccine that had been developed was only available in Australia. It had not received marketing authorisation in the Netherlands or, indeed, in Europe.

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#### 4.2.2 *Funding under the Health Insurance Act*

Depending on the importance and efficiency of the medicinal product in question, the government may decide to invoke the Health Insurance Act and have the costs involved reimbursed. Any assessment of collective funding will

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usually involve inclusion in the basic health insurance package. However, it is also possible for the cost of a medicinal product to be charged to the national budget. The latter model is used, for example, when vaccinating the elderly and individuals in medical high-risk groups against seasonal flu.

When assessing medicinal products for inclusion in the basic health insurance package, the Minister of Health, Welfare and Sport refers to the recommendations of the Health Care Insurance Board (CVZ). The assessment framework used by the CVZ in such cases addresses necessity, therapeutic value (efficacy, effectiveness, adverse effects, experience, applicability and ease of use), cost-effectiveness ratio and absolute costs (burden on the package as a whole).<sup>46</sup> In this way, not only treatments and medicines but also vaccines could be made accessible, through the individual healthcare system, to those individuals and groups in the community that stand to benefit. At the present time, however, little use is made of the option of including vaccinations in the basic health insurance package. It is only available to children who have missed certain National Immunisation Programme vaccinations, and to individuals with specific disorders that involve a higher risk of infection or of complications as a result of infections (against hepatitis A, hepatitis B, pneumococcal disease and rabies; Health Insurance Regulations, Section 1.3 Pharmaceutical Care, Article 2.5, Annex 2).<sup>67</sup>

This situation arose because, when making recommendations about the inclusion of medicines in the health insurance package, the Health Care Insurance Board (CVZ) restricted itself to care based on individual demands for care.<sup>68</sup> The CVZ takes the view that the Health Insurance Act (2006) is not intended for collective prevention. In a recent report on rigorous package management, the CVZ stated that any care insured under the Health Insurance Act is generally based on individual demands for care. In essence, according to the CVZ, this is simply indemnity insurance.<sup>46</sup> It takes the view that preventive interventions like behavioural or lifestyle changes can only be included in the range of insured care if they are targeted at high-risk individuals. This view precludes the use of preventive medicinal interventions in healthy individuals.

Accordingly, the Health Care Insurance Board takes the view that collective prevention should not be organised under the Health Insurance Act. The CVZ sees this as the exclusive, joint responsibility of central government and local authorities, as provided for under the Public Health Act. The Public Health Act defines public health as “health protection and health promotion measures for the

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population or specific groups within it, including the prevention and early detection of diseases”.<sup>69</sup>

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#### 4.2.3 Evaluation

This Committee takes the view that the distinction between individual and collective prevention is not as clear cut as the CVZ suggests. As already stated, the National Immunisation Programme embodies the public interest that the government, where possible, must protect the population and the fabric of society against serious infectious diseases. Yet the vaccinations included in this programme are also important to the vaccinated individuals themselves. Conversely, the current basic health insurance package includes many preventive activities that also represent a collective interest. These include preventive medications, such as cholesterol-lowering drugs for those who are at high risk of cardiovascular disease. The contraceptive pill, preventive check-ups for pregnant women by obstetricians, preventive dental check-ups for young people, and dietary advice are also included in the basic health insurance package.

Prevention is a government policy priority. The proposed policy for the period from 2011 to 2015 is described in a policy document on prevention, entitled “*Gezondheid dichtbij*” (Health Up Close) (2011). The three central themes are: personal choices about lifestyle, confidence in health protection and care, and sporting activities in the neighbourhood. Public vaccination policy is covered by the theme of “confidence in health protection”. Members of the public must be able to feel confident that the government will protect them, wherever possible, from collective risk factors that are beyond their individual control.<sup>70</sup> The policy document does not specifically address the issue of vaccination in individual healthcare.

In the Framework Letter entitled “Vision of health and prevention”, the Minister announced that the basic health insurance package will be expanded to include further preventive measures. These will specifically address the five priorities set out in the 2006 policy document on prevention: smoking, alcohol abuse, obesity, diabetes and depression. The Ministry of Health, Welfare and Sport wants to use the Health Insurance Act to make individual prevention a natural part of everyday practice in care provision.<sup>71</sup> Further details of the Ministry of Health, Welfare and Sport’s prevention policy are set out in the agenda for a National Prevention Programme (2013). The latter memorandum contained the following passage: “As time goes on, an increasing number of new vaccines will not be automatically suitable for use in the context of the National Immunisation Programme (e.g. because their effects are more targeted at

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individuals and less at the protection of groups). Accordingly, we are now working to identify the contexts in which they might best be used".<sup>72</sup>

Use of the Health Insurance Act to fund vaccinations that represent essential healthcare is in keeping with the prevention-oriented thrust of government policy.

The Committee feels that there are no fundamental reasons why preventive interventions should be treated any differently to interventions that are curative in nature.

In terms of medicinal products, the Health Insurance Act is the obvious channel for regulating preventive interventions that involve a collective interest. If a vaccination is deemed to constitute essential healthcare, then it is the government's duty to promote its fair distribution by including it in the basic health insurance package, for example.

The way in which the assessment framework for inclusion in the basic health insurance package is currently used therefore poses an unwarranted obstacle to the collective funding of vaccinations. As a result, major potential health gains are being left untapped.

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## **4.3 Public vaccination programmes**

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### **4.3.1 *Assessment of worthiness for inclusion in the National Immunisation Programme***

In its advisory report entitled *The future of the National Immunisation Programme: towards a programme for all age groups (2007)*, the Committee drew up seven criteria (Table 2) to clarify the reasons for recommending that vaccinations be admitted to the National Immunisation Programme. The Committee based this approach on the two principles for state intervention in vaccination and vaccination programmes: 1) protection of the population and the fabric of society, and 2) a fair distribution of care (Section 3.1). The manner in which the criteria are formulated means that they can be used to determine whether a specific vaccination for a specific target group should be recommended for inclusion in the programme. When assessing the effectiveness, acceptability and efficiency of vaccinations, it is crucially important to make the right choices in terms of the target group for vaccination (the entire population, all infants and young children, or one or more specific groups or subpopulations). Furthermore, in practice, this assessment may sometimes involve exploring and comparing a range of different options in parallel, with the

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seven criteria for guidance. This is true not only of the target group (or groups) but also of different vaccination schedules.

*Table 2* Criteria for the inclusion of vaccinations in public programmes

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*Seriousness and extent of the disease burden*

- 1 The infectious disease causes considerable disease burden within the population
  - The infectious disease is serious for individuals, and:
  - The infectious disease affects or has the potential to affect a large number of people.

*Effectiveness of the vaccination*

- 2 Vaccination may be expected to considerably reduce the disease burden within the population.
  - The vaccine is effective for the prevention of disease or the reduction of symptoms.
  - The necessary vaccination rate is attainable (if eradication or the creation of herd immunity is sought).
- 3 Any adverse reactions associated with vaccination are not sufficient to substantially diminish the public health benefit.

*Acceptability of the vaccination*

- 4 The inconvenience or discomfort that an individual may be expected to experience *in connection with his/her personal vaccination* is not disproportionate in relation to the health benefit for the individual concerned and the population as a whole.
- 5 The inconvenience or discomfort that an individual may be expected to experience *in connection with the vaccination programme as a whole* is not disproportionate in relation to the health benefit for the individual concerned and the population as a whole.

*Efficiency of the vaccination*

- 6 The ratio between the cost of vaccination and the associated health benefit compares favourably to the cost-benefit ratio associated with other means of reducing the relevant disease burden.

*Priority of the vaccination*

- 7 The provision of vaccination may be expected to serve an urgent or potentially urgent public health need.
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The seven criteria and their guidance notes provide a framework for systematically discussing the pros and cons of including specific vaccinations in public programmes, including prioritisation issues.<sup>1,2</sup> Each question is based on the assumption the preceding question was answered in the positive, so it really should not be necessary to assess a vaccine's effectiveness if the disease it was designed to treat is either rare or not serious. Moreover, there is no need to add cost-effectiveness to the equation until it is clear that the vaccination is both effective and safe for the target group in question. However, everyday practice is even more rigorous than the framework itself. So the criteria cannot be seen as a simple checklist that generates a clear conclusion about whether or not the vaccination can be included in a public programme. The criteria require the relevant scientific knowledge to be thoroughly appraised before any conclusion can be reached. Moreover, the verdicts are always subject to qualifications. For example, no vaccine is 100% effective or entirely free of adverse effects. The



situation becomes even more complex when there is a range of options to consider, each with its own strengths and weaknesses.

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#### 4.3.2 Evaluation

It has now been more than five years since the Minister of Health, Welfare and Sport adopted the assessment framework recommended by the Health Council. Since then, the criteria have been the yardstick for determining whether a candidate vaccination is worthy of inclusion in the National Immunisation Programme.

To date, the assessment framework has been of great use in assessing the importance of new or existing vaccinations to public vaccination programmes, such as the National Immunisation Programme.

In 2007, *Influenza vaccination: revision of the indication* was the first advisory report in which the Health Council made use of the new framework.<sup>3</sup> On the basis of the assessment framework outlined above, the Health Council recommended that the National Immunisation Programme be used to vaccinate all 12-year-old girls against cervical cancer (2008), to vaccinate all infants against hepatitis B (2009) and pneumococcal disease (2010), and to vaccinate against tuberculosis all children whose parents were born in countries with an incidence of tuberculosis in excess of 50 per 100,000 individuals per year.<sup>5,7,13,18</sup> During the epidemic of Q fever in 2007-2010, the Health Council used the assessment framework to establish that there was no basis for public vaccination programmes against this disease. Nor did the Council feel it necessary to recommend that future animal husbandry professionals or individuals who may occasionally be exposed in the course of their professional activities should be vaccinated in the context of a public programme. However, the Council did recommend that specific groups of cardiovascular patients be vaccinated against Q fever.<sup>6,15,16</sup> During the 2009 influenza A/H1N1 pandemic, the Health Council recommended public vaccination programmes for individuals in medical high-risk groups, the elderly, pregnant women and children.<sup>8-12</sup> The Health Council takes the view that the arguments in favour of vaccinating pregnant women and children during that pandemic were insufficient to justify the vaccination of these same groups in the context of seasonal flu.<sup>14,17</sup> In the aftermath of the pandemic, some questioned *every aspect* of the effectiveness of vaccination against seasonal flu. Accordingly, in 2011 (in response to a request from the Minister of Health, Welfare and Sport), the Health Council once again summarised the considerations that led it to recommend this vaccination. The Council concluded that, at that point in time, there was no reason to revise the recommendations

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regarding influenza vaccination.<sup>19</sup> In 2011, the Health Council presented the Minister of Health, Welfare and Sport with an evaluative and generic advisory report concerning the role of vaccination in preparation for an influenza pandemic.<sup>20</sup> In every case, the Council made use of the assessment framework for the inclusion of vaccinations in public programmes. In each case there was consensus regarding the importance of the above-mentioned vaccinations in terms of the two principles for state intervention in vaccination, i.e. protection of the population and the fabric of society, and equal access to essential healthcare.

Vaccination against cervical cancer is a special case.<sup>5</sup> Cervical cancer imposes a substantial social disease burden, involving approx. 600 to 700 new cases – and about 200 deaths – per year. In the light of that burden of disease, the Health Council recommended that vaccination against cervical cancer be included in the National Immunisation Programme. A second reason for this recommendation was the desire to make this important protection against a severe disorder accessible to *all* girls. Provision through the National Immunisation Programme also makes sense given the complexity of the information campaign, the importance of follow-up, and the link to the cervical cancer screening programme (“the smear test”).

Determining the status of vaccination against gastroenteritis caused by rotavirus infections proved to be rather more difficult. Preparatory work on an advisory report on this topic commenced quite some time ago. Some members of the Committee feel that the social burden of disease (the public health interest of vaccination) involved is not sufficient to justify inclusion in a public programme. This fact, together with the lack of options for vaccination outside the context of the National Immunisation Programme, makes it difficult for the Committee to reach consensus on this dossier. The Committee has yet to issue its final judgment on these matters (see Section 6.5).

The process of defining the choices required for public vaccination programmes can help clarify matters. However, it has also made it clear that the underlying criteria and considerations are not particularly “firm”. It has not proved possible to develop more objective, quantifiable criteria.<sup>2,73</sup> The Committee members differed mainly in their interpretation of the criteria used to establish whether a disease poses a public health problem (Criterion 1) and whether there is an urgent need for vaccination (Criterion 7). Discussions about the interpretation of criteria should be guided by the underlying principles (Section 3.1).

The above-mentioned lack of options for vaccination outside the context of public programmes will also impact on debates about the scope of the public

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vaccination programmes themselves. This shortcoming complicates the deliberations about whether or not a given vaccination should be included in a public programme. However, the public debates surrounding vaccination against cervical cancer, pandemic influenza, and seasonal flu have once again highlighted the importance of fine-tuning the profiles of these programmes. These debates in the public arena also prompted a further examination of the principles and practices of public vaccination programmes. The fruits of this examination include the present advisory report.

In the Netherlands, optimum use is made of vaccinations that have been incorporated into public programmes. In general, a high level of vaccination coverage (around 95% or more) is guaranteed. There were public debates about vaccination against cervical cancer and pandemic influenza A/H1N1 2009. While these vaccinations had a lower coverage, it was still almost 60% in the case of cervical cancer, and even more in the case of pandemic influenza.

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#### **4.4 Conclusion**

The Committee concludes that there are no major problems with regard to the assessment of vaccines for purely individual use (Column 1 of Table 1). For the time being, however, there is no clear assessment framework for the vaccination of workers in the context of occupational healthcare. At the present time, however, little use is being made of the option of collectively funding (Column 2) vaccinations that represent essential healthcare. Accordingly, it is recommended that the current assessment system be subjected to a critical review. The existing frameworks have demonstrated the effectiveness of assessing the inclusion of vaccinations in public programmes (Column 3).



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# **Towards a single general assessment framework for vaccinations**

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In the previous chapters, the Committee showed that some useful vaccines tend to fall between two stools, due to the use of separate assessment frameworks for the basic health insurance package and for public vaccination programmes. The Committee therefore proposes that a single general assessment framework be established.

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## **5.1 Principles**

With regard to the design of a single general assessment framework for all vaccinations, the Committee is thinking in terms of the entire spectrum of vaccination care (Table 1, Section 3.3).

There are major points of similarity between the criteria governing the inclusion of vaccinations in public programmes (Table 2) and the criteria for essential care that have been proposed by a variety of agencies (Section 3.3). The formal assessment framework used by the Health Care Insurance Board also has significant areas of similarity. It is, therefore, a relatively simple matter to transform the criteria set out in Table 2 into criteria for the collective funding of vaccinations. In conjunction with the existing framework for public vaccination programmes, this would then give rise to a single general assessment framework for all vaccinations.

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## 5.2 Distinction between public programmes and essential healthcare

In terms of the distinction between vaccinations that represent essential healthcare for certain individuals and groups in society and vaccinations that serve a particular public interest, the clauses of the first criterion are of importance: “.. (1) the disease (or infectious disease) in question is serious for individuals and (2) it affects a large (or potentially large) group”. Only if there is no doubt whatsoever that both clauses apply, in other words where there is a substantial social burden of disease, would inclusion in a public programme seem reasonable. If the individual burden of disease alone is substantial (Criterion 1 of Table 3), then it is appropriate to conduct a further review of the vaccination’s importance for individuals and groups in society.

Effectiveness and safety are assessed on the basis of modified criteria 2 and 3 (Table 3). Before granting a marketing authorisation, the registration authorities assess vaccines for individual use in terms of their efficacy and potential harmfulness. This assessment is sufficient, provided that the initiative for vaccination lies with the individuals concerned or with their parents.\*

A formal assessment of the acceptability of vaccination (both of the individual vaccination and of the entire programme; criteria 4 and 5) is a major element of public programmes. The assessment can be simplified if the goal is to determine whether essential healthcare is involved, where the initiative for vaccination lies with the individual in question or with their parents. In situations like this, the acceptability of vaccination is actually determined in the course of a dialogue between physicians and their patients. The physician’s responsibility to provide information for this purpose and to raise the question of acceptability are part and parcel of medical practice (Medical Treatment Agreements Act; WGBO). Accordingly, when assessing funding under the Health Insurance Act, formal testing is not appropriate.

Cost-effectiveness analysis is an important tool for assessing efficiency (Criterion 6). In its 2007 framework-setting advisory report on public vaccination programmes, the Committee proposed that an analysis (carried out

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\* Public programmes are subject to more demanding requirements in terms of effectiveness and, especially, of safety. This is partly because the government has taken the initiative and actively offered vaccination, and partly because of the larger scale involved. Here, additional assessments of effectiveness and safety (testing on an appropriate scale, monitoring of adverse effects) are required. Additional testing may also be necessary, in cases where the government actively recommends vaccination (in the “essential healthcare” category) for groups in society, while taking no active part in providing the vaccination in question.

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by non-partisan, expert scientists) should always be available, for the purpose of assessing the relationship between the costs and benefits of vaccination.<sup>1</sup> This approach differs from the assessment (by the Health Care Insurance Board) of medicinal products for inclusion in the basic health insurance package. The Health Care Insurance Board argues that manufacturers themselves should carry out the cost-effectiveness analysis (or arrange for a third party to do so), and that the results should be inserted into the dossier prior to submission.

One requirement specific to infectious diseases is that the models should also make allowance for the indirect effects of prevention. For instance, vaccinating part of the population can curtail the circulation of the micro-organism in question. This, in turn, can have beneficial effects in terms of reducing the frequency of disease in non-vaccinated individuals. The indirect effects of vaccination can be very substantial, and this can have a major impact on the cost-effectiveness ratio. A prime example of this is the vaccination of children against pneumococcal infections, and its knock-on effects in terms of the burden of disease in the elderly. The static models currently in use make no allowance for this. While dynamic models do take this into account, they also impose a requirement for detailed contact data. So dynamic models are more complex, but they are also more in keeping with the nature of infectious diseases. For a cost-effectiveness analysis of infectious diseases, dynamic models are often the preferred option.

Further consultation with the Health Care Insurance Board is needed to determine the best way of obtaining a reliable, independent assessment of the cost-effectiveness ratio.

It is usually possible to operate more effectively and efficiently in the context of a public programme, due to the centralised organisation and procurement involved. The Committee recommends that vaccinations designated as essential healthcare (i.e. which are funded under the Health Insurance Act) be reviewed to determine whether a similar approach could deliver efficiency gains here too.

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### **5.3 A single, general assessment framework for essential healthcare or for inclusion in public programmes**

If the proposed approach is used to link together the assessment frameworks for essential healthcare and for inclusion in a public programme, this would create a single, general assessment framework for all vaccinations. The situation is primarily assessed on the basis of the modified criteria 1, 2, 3, and 6, to determine whether the vaccine should be designated as essential healthcare. If the assessment is favourable, a recommendation will be made that the

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vaccination should be funded under the Health Insurance Act. As the Government Committee on Choices in Healthcare has previously indicated, an additional requirement is that the costs in question would have to be too great for it to be reasonable to insist on personal payment and personal responsibility for the intervention.

The criteria that must be met before a vaccination can be designated as essential healthcare are summarised in Table 3. The numbering used here corresponds to the numbering of the criteria for the inclusion of vaccinations in public programmes (Table 2, Section 4.3.1).

Unlike the assessment for inclusion in public programmes (Sections 3.1 and 3.2), when assessing vaccinations for designation as essential healthcare, it would not make sense to restrict this to infectious diseases alone. Accordingly, in future, Criterion 1 will cover both “infectious diseases” and “non-infectious diseases”.

*Table 3 The criteria that must be met before a vaccination can be designated as essential healthcare.*

*Severity and scope of the burden of disease*

- 1 The disease (or infectious disease) in question leads to a substantial individual disease burden.

*Effectiveness and safety of the vaccination*

- 2 The vaccination in question leads to a substantial reduction in the burden of disease: the vaccine is effective in preventing disease or in reducing symptoms.
- 3 Any deleterious health effects of the vaccination in question (adverse effects) do not detract significantly from the health gains.

*Efficiency of the vaccination*

- 6 The relationship of costs to health gains is favourable in comparison to other means of reducing the burden of disease.
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With regard to inclusion in a public programme, the existing criteria set out in Table 2 in Section 4.3.1 apply in full.

The proposed assessment framework is in keeping with government initiatives to modernise vaccination care. The government is now also aware that, given the way in which vaccination care is presently organised, any vaccines not offered in the context of a programme tend to remain unused. As a result, major potential health gains are being left untapped, so the government is looking for ways to administer vaccinations outside the public programmes.



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## 5.4 Urgency and other considerations for implementation in the context of a programme

With regard to the inclusion of a vaccination in a public programme, urgency is assessed in the light of the seventh criterion. When assessing a medicinal product for collective funding, the Health Care Insurance Board does not carry out any such formal urgency assessment. However, the Committee feels that considerations of urgency can also play a part here, at least in terms of vaccines. In practice, considerations of urgency will favour coupling a programmatic implementation with remuneration of the vaccine in question. Accordingly, when a vaccination is being assessed for collective funding, the Committee recommends that the seventh criterion be used to determine whether a programmatic implementation is required. The issue of exactly how these considerations should be put into practice is beyond the scope of this advisory report. That question merits an analysis of its own. With regard to this topic, the Committee has listed a number of points for consideration below.

In addition to urgency, a programmatic approach to individual care can be adopted for reasons of effectiveness, efficiency, and quality. The four considerations listed above are interrelated. It is precisely when health problems are urgent that effective, efficient and good quality countermeasures are needed. Urgency, effectiveness, efficiency and quality also have an impact on the way an intervention is implemented.

In principle, the primary responsibility for carrying out vaccinations under the Health Insurance Act lies with the health insurance companies. However, it should be possible for the government to reach agreements (including quality agreements) in this regard. In the case of funding under the Health Insurance Act, the seventh criterion (urgency) could be used to determine the requirements (from a public perspective) to be met by such provision, in the interests of effective operation. A check could be made, on a case-by-case basis, to establish whether agreements need to be reached with the health insurance company in this regard, and whether there is a need for built-in safeguards. An example of legitimate state intervention in vaccination as essential healthcare is the above-mentioned vaccination against Q fever. The strict safety guarantees involved in that vaccination meant that a programmatic approach, monitoring, and evaluation were seen as essential. A second example is the specific expertise required to administer an intradermal BCG injection. Incorrect administration can impact the effectiveness of the vaccination and give rise to unnecessary

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adverse effects (abscess). Accordingly, the government can impose requirements on those who administer the vaccination. Thus, for reasons of effectiveness and quality, the BCG vaccination is usually implemented in the context of a programme that includes evaluation and monitoring activities.

In this connection, public considerations associated with the use of vaccines in the health insurance package (see Section 6.1) may also be involved. The previously discussed vaccination against chickenpox, for example, can only take place in the context of the health insurance package if it is subject to the safeguard of effective monitoring.

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## **5.5 Pros and cons, risks**

The proposed amendment to the assessment framework is expected to ensure that no other vaccinations will fall between two stools in future. It is also expected that vaccinations will generally be more accessible in individual healthcare. Moreover, these changes will also ensure that the healthcare system is better equipped to provide scope for future vaccines and new vaccine applications. They might also help to ameliorate a potential lack of flexibility and a perceived lack of personal influence on vaccine provision. As a result of their greater involvement in individual healthcare, the medical staff concerned would be able to improve their knowledge of vaccination and gain experience in this area. However, these healthcare professionals will need to be better trained with regard to vaccinations (Section 6.2).

One drawback is that, in this scenario, a range of different agencies will be responsible for vaccinations. In addition to the child healthcare staff at post-natal clinics, school or municipal medical and health services, these will include professionals in individual healthcare. This could lead to the fragmentation of care, so it is important to remain alert to this risk.

The failure to create and maintain a clear profile for public vaccination programmes is another potential risk. The public debates surrounding vaccination against cervical cancer, pandemic influenza, and seasonal flu have once again highlighted the importance of fine-tuning that profile. Partly for this reason, it is difficult to broaden the criteria for including vaccinations in public programmes. Conversely, creating greater scope for vaccination outside public programmes can help to ensure that the nature and content of these programmes are more effectively safeguarded. In Section 6.3, the Committee explores the requisite public information campaigns in greater depth.

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## 5.6 Conclusion

The existing frameworks present an obstacle to the reliable determination of a vaccine's status. Within that spectrum, there is now little ambiguity regarding both purely individual vaccinations (such as those for travellers) and the vaccinations in public programmes. There is some ambiguity surrounding vaccines that do not fall into either of these categories but which may nevertheless be important for individuals and groups in society. At present, vaccines of this kind are relatively or entirely inaccessible.

The Committee proposes that a single, general assessment framework be used for all vaccinations throughout the entire spectrum of vaccination care. The starting point here embraces the entire spectrum of vaccination care, from care charged directly to individuals or companies, to collectively funded essential healthcare, and public vaccination programmes. It is a relatively simple matter to derive a general assessment framework from the existing frameworks.

Economies of scale usually enable public programmes to operate more effectively and efficiently, as a result of the centralised organisation and procurement involved. The Committee recommends that an evaluation be carried out to determine whether similar economies of scale can also be achieved for vaccinations that are collectively funded.



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## **Aspects of implementation**

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In the preceding chapters, the Committee discussed the problem that, in the Netherlands, potential health gains are being left untapped as a result of the under-utilisation of vaccines. The separate assessment of vaccines for inclusion in basic health insurance packages and public programmes increases the risk that vaccinations will fall between two stools. Accordingly, the Committee has proposed that a single, general assessment framework be established. However, this alone will not resolve the problem of the under-utilisation of potentially useful vaccines. The limited use of potentially useful vaccines is associated with a lack of knowledge about vaccination among physicians, coupled with their lack of experience in this area, and with limited awareness among the general public. Accordingly, in this chapter the Committee explores a number of major aspects relating to implementation.

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### **6.1 Assessment authority**

The assessment authority must have a remit spanning the entire spectrum of vaccination care if it is to determine a vaccine's status effectively. On occasion, public considerations will be involved in the use of vaccines as part of the health insurance package. Some examples of this are beneficial and adverse effects at population level, similarities and differences between the strain of micro-organism used in the vaccine and the strain circulating in the population, the age dependence of some infectious diseases, and the selection of virulent strains by

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vaccination pressure. Vaccination can reduce the spread of micro-organisms, thus increasing the average age at infection. If the occurrence of symptoms in the disease in question is age-dependent, large-scale but insufficient vaccination coverage at population level can produce adverse effects.

That could be the case with vaccination against chickenpox, for example. The risk of increasing both the average age at infection and the frequency of complications should be taken into account when answering questions about whether the government 1) should promote equal access to vaccination against chickenpox as essential healthcare and 2) whether it should include that vaccination in a public programme. In addition, in the case of vaccination against chickenpox, it is not entirely clear how vaccination interferes with the dynamic equilibrium between chickenpox and shingles, since these are caused by the same virus. It is possible that vaccination against chickenpox could result in a temporary increase in the number of cases of shingles. For this reason, large-scale vaccination against chickenpox should be considered in combination with vaccination against shingles, whether this takes the form of collective vaccination or a public programme.

To avoid the present pitfall of separate assessment frameworks, it would seem sensible to assign the advisory role for all vaccinations to a single authority. However, none of the existing organisations is fully equipped to assess the full spectrum of vaccinations. The Health Council already has access to a large part of the requisite expertise, as a result of the current advisory process on public vaccination programmes. That same expertise is also a significant asset in connection with the public considerations (referred to in the preceding paragraphs) concerning the use of vaccines in the health insurance package. It therefore stands to reason that the Health Council should play an important part in the development of the general assessment framework proposed in Section 5.3.

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## **6.2 Vaccinations that require further evaluation**

In the introduction to this advisory report (Section 1.1), the Committee referred to the fact that, in the Netherlands, there are few opportunities for vaccination outside the context of the public programmes. It pointed out that this constitutes an obstacle to discussions about the scope of the public programmes themselves. This partly accounts for the Committee's difficulty, to date, in determining the status of vaccinations against chickenpox, shingles, and gastroenteritis caused by

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rotavirus infections. The proposed general assessment framework for all vaccinations should eliminate this difficulty.

The decision to re-evaluate the vaccination of healthy, elderly individuals against seasonal flu had already been taken.<sup>74</sup> Mention had also been made of the importance of reaching a verdict concerning additional measures for the protection of young infants against whooping cough and for the vaccination of older children and adults against this disease.<sup>1,75</sup> These assessments could well benefit from the new framework.

Table 4 provides a summary of current vaccinations that require assessment under the above-mentioned, proposed system.

It will also be possible to use the proposed system to determine the status of future vaccines against infectious and non-infectious diseases.

*Table 4 Vaccinations that have yet to be assessed.*

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- The vaccination of infants against gastroenteritis caused by rotavirus infections
  - The vaccination of infants against chickenpox
  - The vaccination of the elderly against shingles
  - Additional measures for the protection of young infants against whooping cough (preconception vaccination, vaccination during pregnancy, cocooning, neonatal vaccination)
  - The vaccination of older children and adults against whooping cough
  - The vaccination of children against influenza
  - The vaccination of the elderly against influenza
  - The vaccination of infants against invasive meningococcal B disease
  - The vaccination against hepatitis A of children whose parents (one or both) were born in countries where this disease is common
  - The vaccination of first and second-generation immigrants from countries where hepatitis B is endemic
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### **6.3 Use of the assessment frameworks in the Dutch Caribbean**

Each of the Committee on the National Immunisation Programme's advisory reports on the National Immunisation Programme includes a consideration of the situation in the Caribbean Netherlands. Accordingly, a draft version of this advisory report has been submitted to contacts on the six islands in question. This consultation process has not generated any specific observations, comments or recommendations.

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### **6.4 Professional development**

As a result of the concentration of vaccinations in the National Immunisation Programme, many medical professionals in individual healthcare have only a

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scant knowledge of vaccination, coupled with a lack of experience in this area. The Committee recommends that modifications be made to training programmes and refresher courses for nurses and physicians in child healthcare, senior house officers, general practitioners, paediatricians and internists. This would involve a systematic focus on vaccinology and on the related interview techniques and information provision skills.

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## **6.5 Public information campaigns**

The effective provision of information has become even more important in the face of increasing public empowerment and a decline in the visibility of the diseases targeted by public vaccinations. The Health Council discussed these developments in detail in the advisory report entitled *The future of the National Immunisation Programme: towards a programme for all age groups* (2007).<sup>1</sup> A solid scientific basis for communication and information campaigns is enormously important to the continued effectiveness of public vaccination programmes. The Committee recommends that the information campaigns associated with public vaccination programmes be designed to encourage the intended participants to actively process information on the pros and cons of vaccination. One aspect of this is that members of the public are encouraged to participate both in their own individual interest, and in the interest of the population as a whole.

Public information campaigns are also important in terms of vaccinations outside the context of public programmes. Limited awareness among the general public contributes to the under-utilisation of potentially useful vaccines. Public information campaigns are important in raising awareness about potentially useful vaccines among the general public. In addition, they can help to prevent the improper and excessive use of vaccines. Accordingly, the Committee recommends that public information campaigns about vaccines and vaccinations should be augmented, and that the National Institute of Public Health and the Environment be entrusted with the management of public information campaigns across the entire spectrum of vaccination care.

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## **6.6 Monitoring**

It is essential for the effects of public vaccination programmes to be monitored. This involves the intended effects of a high level of vaccination coverage, herd immunity, and effectiveness, as well as the adverse effects at individual level

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(registration of adverse effects) and at population level (as described in Section 6.1). The government will carry out this evaluation itself. In many cases it will assign these duties to the National Institute for Public Health and the Environment.

If state intervention in a vaccination (in the middle column) is justified solely on the grounds of promoting equal access to essential healthcare, then it is sufficient for the government to assess the extent to which that goal has been achieved. However, essential healthcare in particular quite often involves a degree of urgency and a need to explore the health effects of government policy. The monitoring activities to be undertaken will have to meet these requirements. The only way to assess any undesirable effects at individual and population level is to compare and contrast them to data on the desired effects. When monitoring the effects of preventive interventions that are considered to constitute essential healthcare but where no clear public interest is involved, the government has greater freedom than it does in the case of public programmes to outsource these monitoring activities, rather than carry them out itself.

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## **6.7 The use of public programme infrastructure**

Public programmes include vaccinations that are considered important in terms of protecting the population and the fabric of society, and of safeguarding equal access to essential healthcare. Foremost among these programmes is the National Immunisation Programme, which targets children and young people up to the age of 19.

The programmatic approach can provide greater access (= effectiveness) to target groups, while delivering economies of scale (= cost-effectiveness). What about vaccinations that are designated as essential healthcare but which do not qualify for inclusion in public programmes? Might it nevertheless be possible to use the public programme infrastructure to provide such vaccinations, without including them in such programmes?

The Committee feels that this is possible, subject to strict conditions. One such condition would be that any application of this kind must not be inconsistent with the character of public programmes. Stringent requirements must also be imposed on public information campaigns and communication. To avoid confusion, it is vital to ensure that participants, parents and administrators are always clear about the various objectives. Any failure to clarify the distinction or to respect it may have an adverse impact on public vaccination programmes.

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# Recommendations

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The Committee summarises the principal recommendations made in the previous chapters as follows:

- 1 A single, general assessment framework must be established for all vaccinations throughout the entire spectrum of vaccination care.
    - Candidate vaccinations for collective funding are primarily assessed on the basis of the modified criteria 1, 2, 3, and 6 (Table 3, Section 5.3).
    - Subsequent evaluation for inclusion in a public programme will involve an assessment on the basis of the existing seven criteria (Table 2, Section 4.3.1).
  - 2 The scientific advisory process for the entire spectrum of vaccination care can best be entrusted to the Health Council. Clearly, agreement must be reached with the Health Care Insurance Board regarding criteria for the inclusion of vaccinations in health insurance packages.
  - 3 The Health Insurance Act is the obvious channel for providing individuals with access to preventive interventions that are considered to constitute essential healthcare, but which do not serve a clear public interest.
  - 4 In the case of funding under the Health Insurance Act, the seventh criterion (urgency) can be used to determine whether programmatic implementation is necessary, what built-in safeguards (from the public perspective) will be needed, and what arrangements need to be made with the health insurance company in this connection.
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- 5 The feasibility of boosting the efficiency of collectively-funded vaccinations by leveraging economies of scale needs to be examined.
- 6 Training programmes and refresher courses for nurses and physicians in child healthcare, senior house officers, general practitioners, paediatricians and internists need a systematic focus on vaccinology and on the related interview techniques and information provision skills.
- 7 Steps should be taken to increase public awareness of vaccines and vaccinations. The National Institute of Public Health and the Environment is ideally placed to handle public information campaigns across the entire spectrum of vaccination care.

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A The Committee members and other experts consulted

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## **Annex**



## A

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# The Committee members and other experts consulted

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### National Immunisation Programme Committee

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#### The Health Council and interests

Members of Health Council Committees are appointed in a personal capacity because of their special expertise in the matters to be addressed. Nonetheless, it is precisely because of this expertise that they may also have interests. This in

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itself does not necessarily present an obstacle for membership of a Health Council Committee. Transparency regarding possible conflicts of interest is nonetheless important, both for the chairperson and members of a Committee and for the President of the Health Council. On being invited to join a Committee, members are asked to submit a form detailing the functions they hold and any other material and immaterial interests which could be relevant for the Committee's work. It is the responsibility of the President of the Health Council to assess whether the interests indicated constitute grounds for non-appointment. An advisorship will then sometimes make it possible to exploit the expertise of the specialist involved. During the inaugural meeting the declarations issued are discussed, so that all members of the Committee are aware of each other's possible interests.

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**The Committee consulted the following experts and institutes:**

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