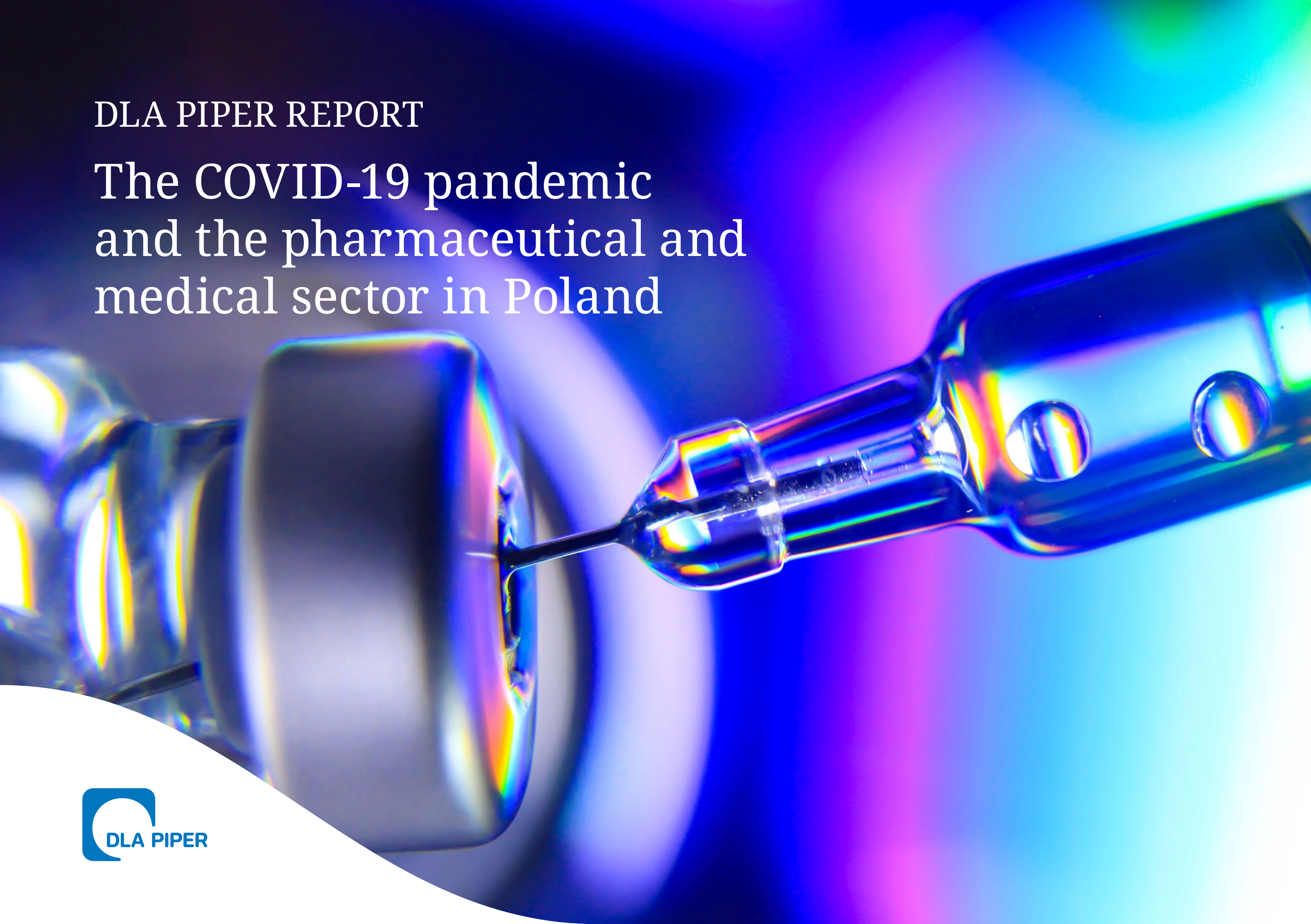
DLA PIPER REPORT

The COVID-19 pandemic and the pharmaceutical and medical sector in Poland



Basic information

We invite you to read the report which sums up DLA Piper's survey "The pandemic and the pharmaceutical and medical sector in Poland", which we conducted among our clients and business contacts from the pharmaceutical and medical sector. Our goal was to collect information on the current state of the market as well as forecasts for future trends and phenomena on the basis of the replies provided by our respondents who work in the sector on a daily basis.

The survey was conducted during the so-called third wave of the pandemic. The respondents were people operating in the medicine, dietary supplement and medical device sectors, as well as healthcare providers. The first group of questions concerned the practical functioning of the sector during the first 12 months of the pandemic. The second group of questions covered changes resulting from the pandemic in the operation of the sector in the years to follow as anticipated by the respondents. The last part consisted of open-ended questions concerning the most important barriers to the development of the sector and the respondents' suggestions for public policies to support its development.

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Summary of the respondents' answers

The majority of the respondents indicated that the COVID-19 pandemic will have a definite impact on the shape of the pharmaceutical and medical market in Poland. We briefly summarise the respondents' answers below, and present the details in the further part of the report.

Relationships with Medical Professionals

As a result of the COVID-19 pandemic, meetings between representatives and medical professionals will take place primarily online, with a reduction in company budgets to sponsor attendance at scientific conferences.
There is a general consensus that the employment of sales representatives will also decrease.

Clinical trials

The respondents observed an extension of the length of time in which clinical trials are conducted in Poland during the pandemic, although the overwhelming majority believe that the use of digital technologies will result in greater efficiency of trials in the long run.

Summary of the respondents' answers

Reimbursement

In terms of reimbursement policy and practice, the respondents have not observed the development of any innovative reimbursement mechanisms. They are also very divided regarding predictions for increases or decreases in the reimbursement budget as compared to the pre-pandemic period. In terms of anticipated priorities within the reimbursement basket, the respondents expect increased funding for so-called comorbidities.

Organization of the healthcare system

An overwhelming number of the respondents anticipate increased centralisation regarding the management of medical facilities, as well as a more widespread use of central purchasing procedures.

Patients' rights

A prevailing view is that health data confidentiality laws will be less rigorously enforced as a result of the pandemic.

Summary of the respondents' answers

Product Market

With regard to the shape of the product market, the respondents are divided on a possible increase in the market share of innovative products as compared to generic ones. Similarly, there is no clear trend regarding the proportions between OTC and prescription products. A noticeable change that is anticipated is an increase in the share of locally manufactured products, with no impact of the pandemic on parallel imports within the European Union.

Other effects of the pandemic

] In response to open-ended questions about other possible effects of the pandemic, the respondents indicated, among other things, an increased demand for health services after the pandemic and an increased importance of online procedures, telemedicine and pharmaceutical care. As regards financing matters, the respondents mentioned possible price increases and increased benefit costs, including personnel costs, while predicting increased funding levels for the sector.

Summary of the respondents’ answers

Evaluation of state actions

90% of the respondents considered state actions to reduce barriers to the operation of the healthcare system to be inadequate. Similarly, nearly 80% of them considered such actions inadequate in relation to pharmaceutical and medical products.

Barriers to the operation of the sector

] In response to the open-ended questions about the biggest barriers to the operation of the sector, the respondents cited a lack of a clear strategy, too little funding, staffing constraints, and the limiting of the public perspective to COVID-19. In terms of drug reimbursement, the respondents observed the use of a “price only” approach by the public payer and a disregard for a ”value based” approach, as well as a lack of sufficient legal regulation in respect of medical devices.

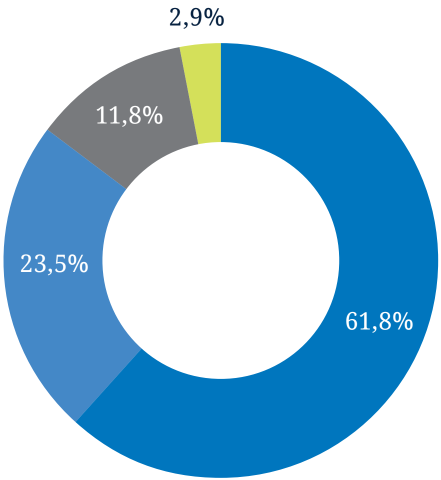
Summary of the respondents’ answers

Suggested actions

In response to the open-ended questions about what the state should do, the respondents indicated the need for a clear strategy for the sector, increased funding, the development of a private insurance system, decentralisation, and the creation of a real map of health needs. Regarding drug reimbursement, the need to increase reimbursement and to take, for example, clinical innovation into account, as well as to introduce uniform legislation for the reimbursement of medical devices, were indicated.

GENERAL EFFECTS OF THE PANDEMIC

In your opinion, will the COVID-19 pandemic have a significant impact on the future shape of the medical and pharmaceutical market in Poland?



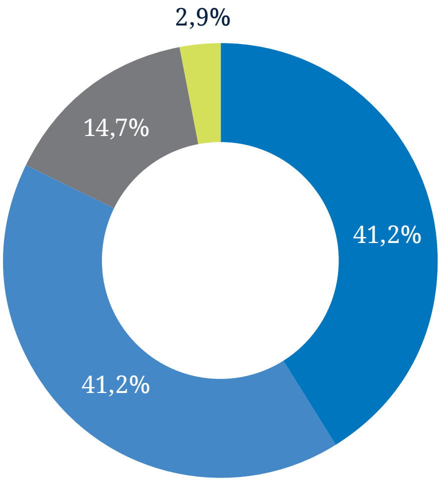
Definitely yes	61,8%
Rather yes	23,5%
Hard to say	11,8%
Rather not	2,9%
Definitely not	0%

Respondents clearly indicate that the pandemic will have an impact on the future shape of the market. More than 85% of the respondents are convinced of this, with more than 60% of the respondents saying „definitely yes".

These results are not surprising, of course, but they clearly confirm the great impact of the pandemic on the functioning of the sector.

RELATIONSHIPS WITH MEDICAL PROFESSIONALS

In your opinion, what will face-to-face meetings with medical professionals look like in 2022 and beyond as compared to 2019?



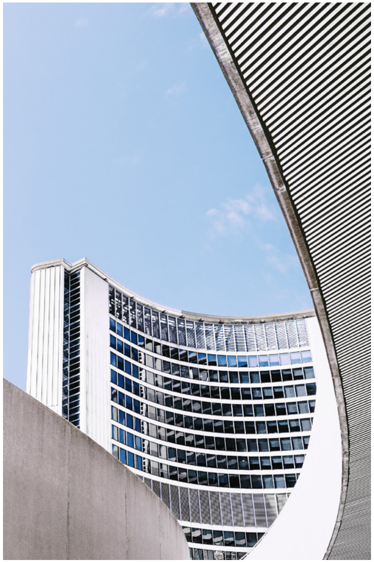
Much more often online	41,2%
More often online	41,2%
No change – in the same way	14,7%
Less often online	2,9%
Much less often online	0%
Hard to say	0%

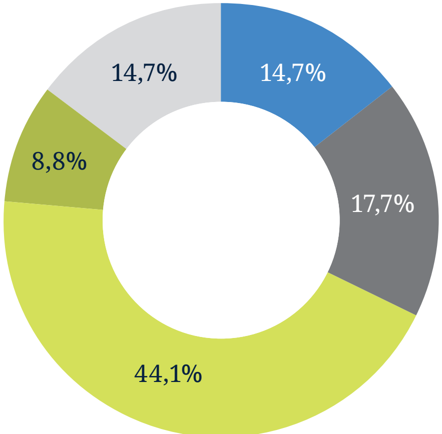
An overwhelming majority of the respondents, more than 80%, believe that face-to-face meetings with professionals will take place more often online in the years to come, with half of this group believing it will be „much more often".

It is worth noting that these contacts do not refer to „office" relationships, where online meetings were already common before the pandemic, but to contacts with medical professionals that took place in the traditional way.

RELATIONSHIPS WITH MEDICAL PROFESSIONALS

How do you think company budgets for sponsoring attendance at scientific conferences will evolve in Poland in 2022 and beyond as compared to 2019?



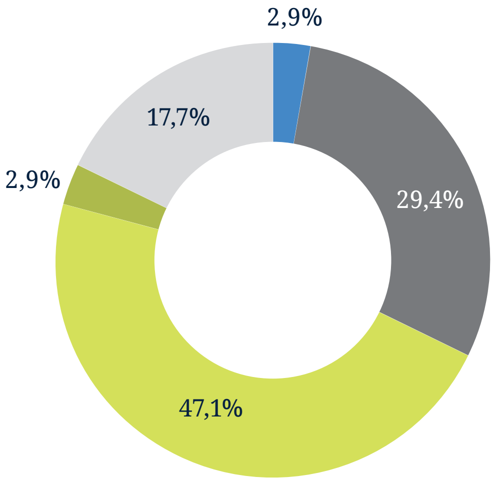


Increase considerably	0%
Increase	14,7%
No change	17,7%
Decrease	44,1%
Decrease considerably	8,8%
Hard to say	14,7%

More than half of the respondents believe that corporate budgets for sponsoring attendance at scientific conferences will decrease in the years to come as compared to the pre-pandemic period. Only about 15% believe these budgets will increase.

RELATIONSHIPS WITH MEDICAL PROFESSIONALS

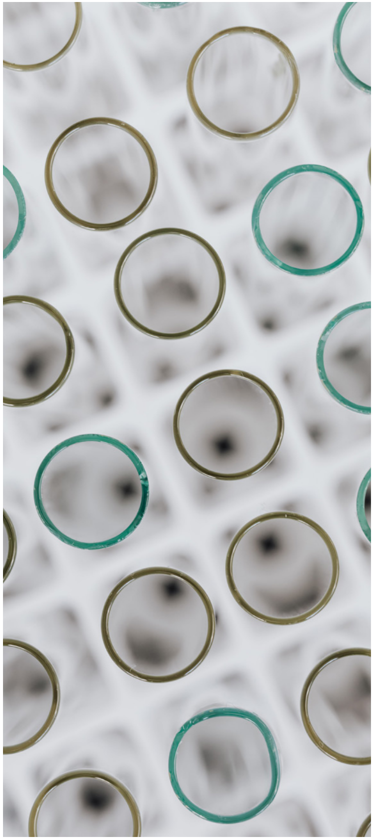
How will the employment of sales representatives change in Poland in 2022 and beyond as compared to 2019?



Increase considerably	0%
Increase	2,9%
No change	29,4%
Decrease	47,1%
Decrease considerably	2,9%
Hard to say	17,7%

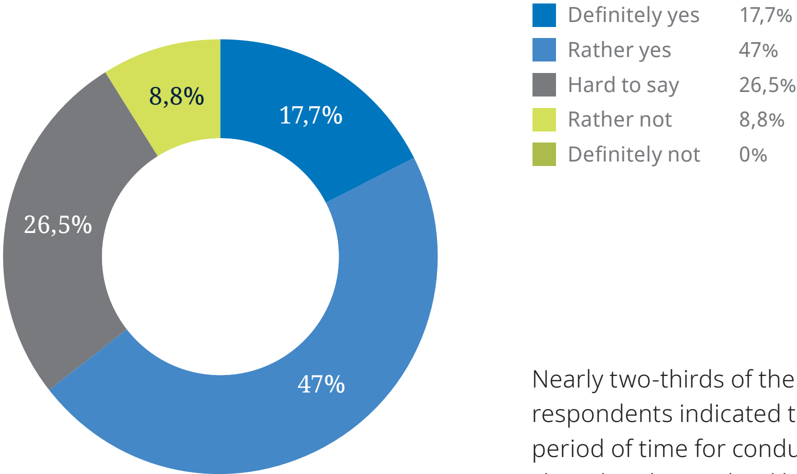
Half of the respondents believe that the employment of sales representatives in Poland will decrease in the coming years as compared to the situation before the pandemic. Nearly one-third believe there will be no change. A statistically negligible group of the respondents believe that employment will increase.

Therefore, the respondents agree that the pandemic will not have a positive impact on the employment of sales representatives in Poland in the coming years. According to the respondents, employment will decrease, although it is worth emphasising that the vast majority of the respondents anticipating such a reduction think it will not be significant.



CLINICAL TRIALS

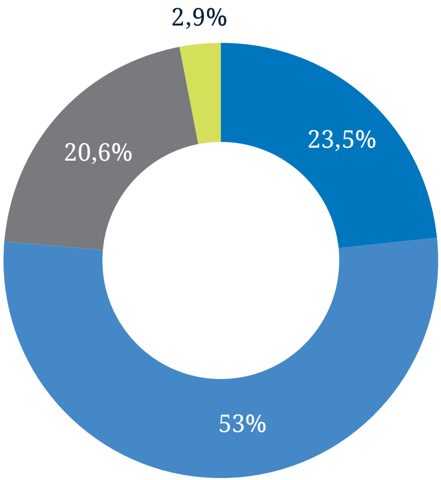
Has the period of clinical trials become longer in Poland during the COVID-19 pandemic?



Nearly two-thirds of the respondents indicated that the period of time for conducting clinical trials in Poland became longer during the COVID-19 pandemic.

CLINICAL TRIALS

Will the use of digital technologies in clinical trials in Poland during the COVID-19 pandemic result in more efficient conduct of such trials in the long run?

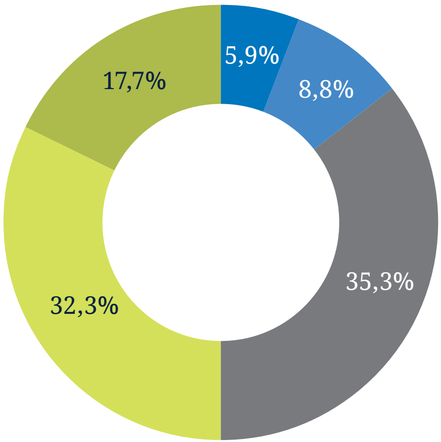


■	Definitely yes	23,5%
■	Rather yes	53%
■	Hard to say	20,6%
■	Rather not	2,9%
■	Definitely not	0%

Digital technologies are developing faster and faster and the pandemic period has only accelerated this trend, especially in the area of communication, sales, and online services. According to more than three quarters of the respondents, the use of digital technologies during the pandemic will bring about greater efficiency in conducting trials in the long run.

REIMBURSEMENT AND FINANCING

Has there been a greater emphasis on developing innovative reimbursement mechanisms in Poland during the period of the pandemic?



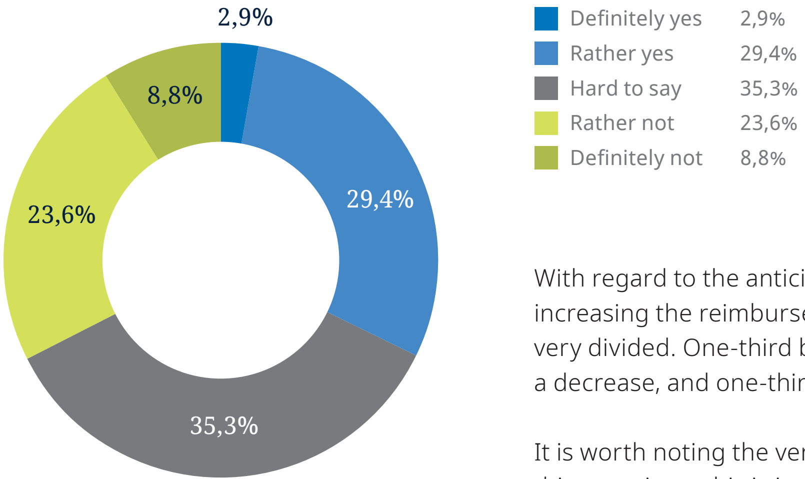
Definitely yes	5,9%
Rather yes	8,8%
Hard to say	35,3%
Rather not	32,3%
Definitely not	17,7%

According to the respondents, the pandemic has not contributed to the development of innovative reimbursement mechanisms. Only a small percentage of the respondents (less than 15%) indicated such developments.

All the other respondents believe that during the pandemic there has not been an increased focus on developing such innovative mechanisms.

REIMBURSEMENT AND FINANCING

In your opinion, will the COVID-19 pandemic contribute to increasing the reimbursement budget in Poland as compared to 2019?

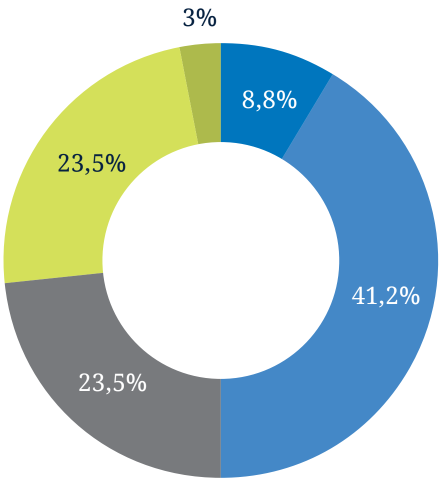


With regard to the anticipated impact of the pandemic on increasing the reimbursement budget, the respondents were very divided. One-third believe it will increase, one-third predict a decrease, and one-third indicate no change.

It is worth noting the very clear differences in the responses to this question – this is in contrast to the other questions in the survey, where the respondents tended to be of a more similar opinion in indicating a clear direction of anticipated changes.

REIMBURSEMENT AND FINANCING

In your opinion, will the COVID-19 pandemic contribute to increasing funding for the most common comorbidities as compared to other diseases in Poland?



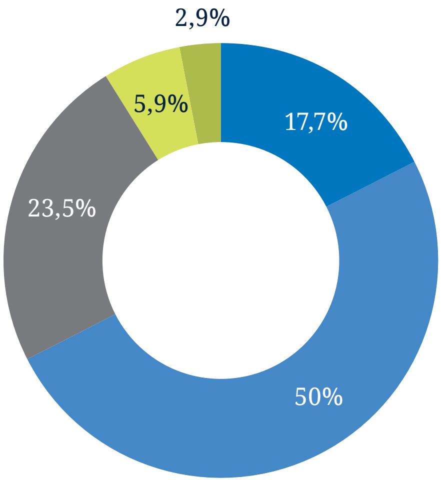
Definitely yes	8,8%
Rather yes	41,2%
Hard to say	23,5%
Rather not	23,5%
Definitely not	3%

The answers of the respondents show that the COVID-19 pandemic will contribute to increasing funding for so-called comorbidities. Half of the respondents believe so, while one quarter have an opposite view.

Therefore, the respondents anticipate a significant change in the direction of increasing disease-related funding in Poland, with a particular focus on so-called comorbidities, which are commonly cited as a risk factor for severe COVID-19.

ORGANISATION OF THE HEALTHCARE SYSTEM

In your opinion, will the COVID-19 pandemic lead to an increased centralisation of the management of medical institutions?



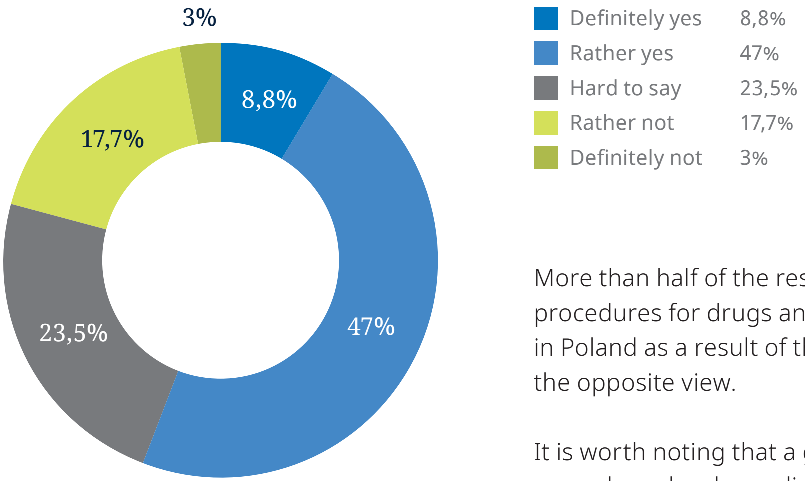
Definitely yes	17,7%
Rather yes	50%
Hard to say	23,5%
Rather not	5,9%
Definitely not	2,9%

The overwhelming majority (over two-thirds) of the respondents believe that the pandemic will result in increased centralisation of the management of medical facilities in Poland. Less than 10% have an opposite opinion.

Centralisation of the management of medical institutions has been a topic of public discussion in the context of an effective model of functioning of the healthcare system, especially during the so-called second and third waves. The changes predicted by the respondents may lead to a significant modification of the healthcare system in Poland.

ORGANISATION OF THE HEALTHCARE SYSTEM

In your opinion, will central procurement procedures for drugs and medical equipment be introduced in Poland as a result of the COVID-19 pandemic?

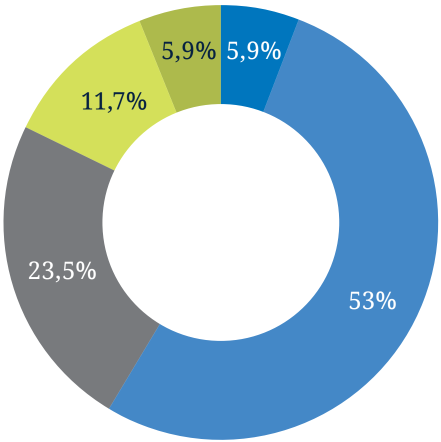


More than half of the respondents believe that central purchasing procedures for drugs and medical equipment will be introduced in Poland as a result of the pandemic, with only one in five holding the opposite view.

It is worth noting that a greater use of central purchasing procedures has been discussed for a long time. The respondents believe that the pandemic will strengthen the centralisation process in this regard.

PATIENTS' RIGHTS

In your opinion, will health data confidentiality laws be less strictly enforced as a result of the COVID-19 pandemic?



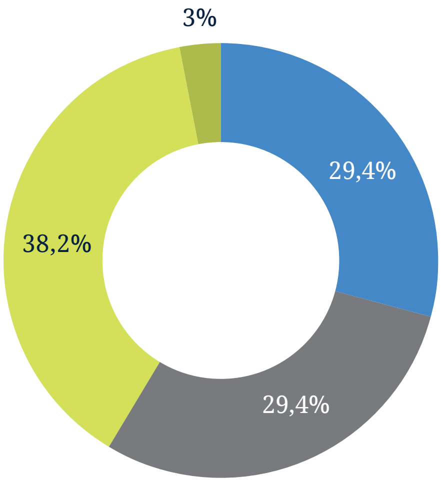
■	Definitely yes	5,9%
■	Rather yes	53%
■	Hard to say	23,5%
■	Rather not	11,7%
■	Definitely not	5,9%

Nearly 60% of the respondents believe that the pandemic will lead to the liberalisation of application of health data confidentiality laws. Only less than 18% of the respondents hold an opposite view.

The changes envisioned by the respondents appear to be related to the issue, widely discussed in the public domain, of the limitations resulting from medical data confidentiality as a barrier to effective pandemic control, particularly given the „European" approach to data protection.

DRUG AND MEDICAL EQUIPMENT MARKETS

In your opinion, will the COVID-19 pandemic increase the market share of innovative products as compared to generic ones?



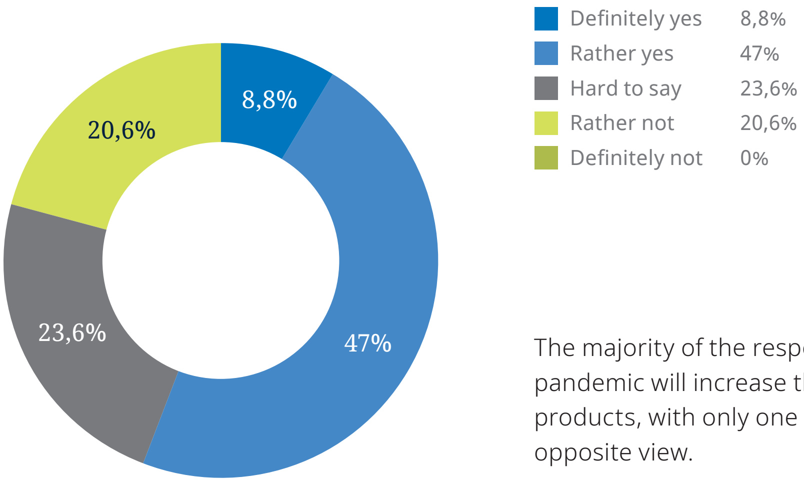
■	Definitely yes	0%
■	Rather yes	29,4%
■	Hard to say	29,4%
■	Rather not	38,2%
■	Definitely not	3%

The respondents are divided on the impact of the pandemic on the increase in the market share of innovative products. 30% think there will be an increase, 40% think not, and 30% have no opinion.

In general, the respondents do not anticipate a significant impact of the pandemic on this aspect of the market.

DRUG AND MEDICAL EQUIPMENT MARKETS

In your opinion, will the COVID-19 pandemic increase the market share of locally produced products?

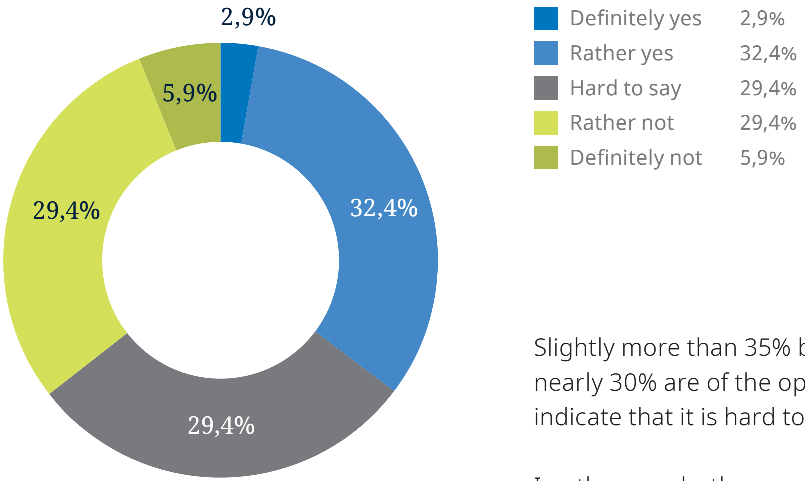


The majority of the respondents believe that the COVID-19 pandemic will increase the market share of locally manufactured products, with only one in five respondents holding an opposite view.

These results also seem to correlate with other manufacturing industries where the shortening of the supply chain is predicted.

DRUG AND MEDICAL EQUIPMENT MARKETS

In your opinion, will the COVID-19 pandemic increase the market share of over-the-counter products?

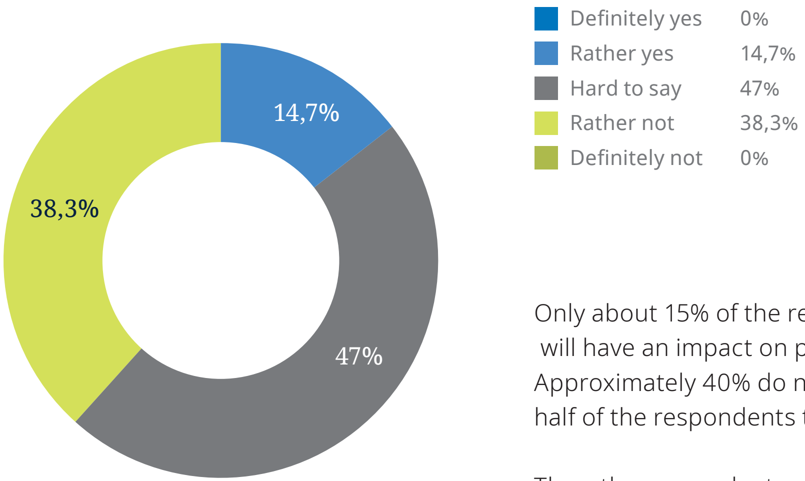


Slightly more than 35% believe such an increase will occur, nearly 30% are of the opposite opinion, and similarly nearly 30% indicate that it is hard to say.

In other words, the respondents do not foresee a definite impact of the pandemic on the current proportion of market share between over-the-counter products and prescription products.

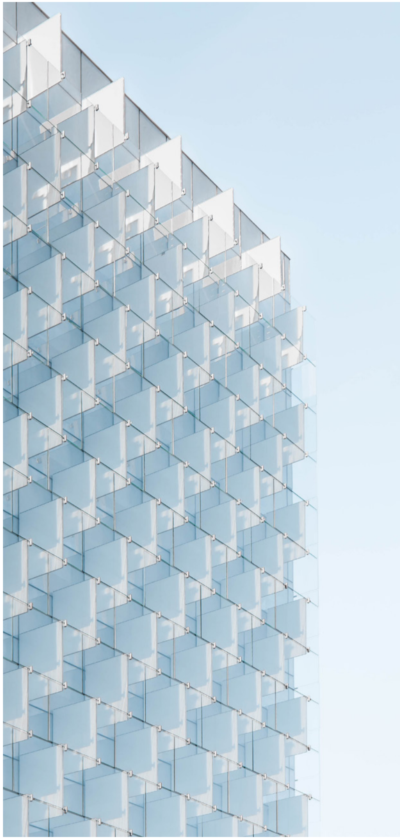
DRUG AND MEDICAL EQUIPMENT MARKETS

In your opinion, will the COVID-19 pandemic have an impact on reducing the level of parallel imports within the European Union?



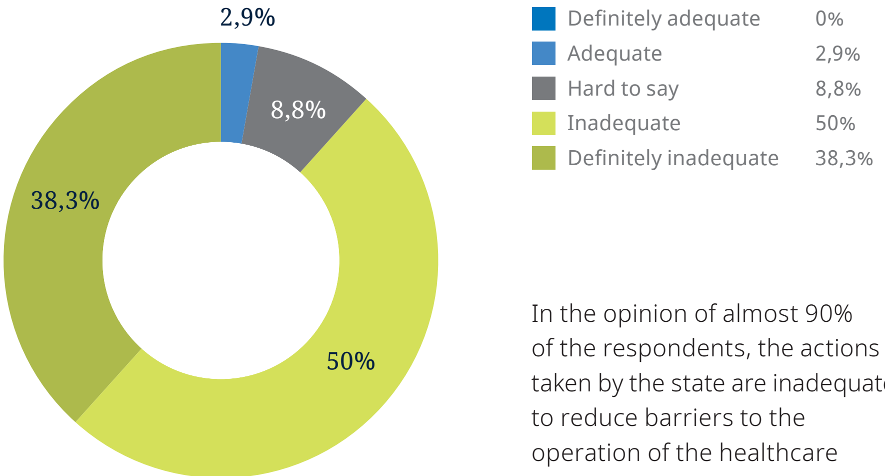
Only about 15% of the respondents believe that the pandemic will have an impact on parallel imports within the European Union. Approximately 40% do not expect such an impact and nearly half of the respondents think it is difficult to say.

Thus, the respondents anticipate that parallel imports between EU countries – unlike many other aspects of the industry – are unlikely to be affected by the pandemic.



EVALUATION OF STATE ACTIONS

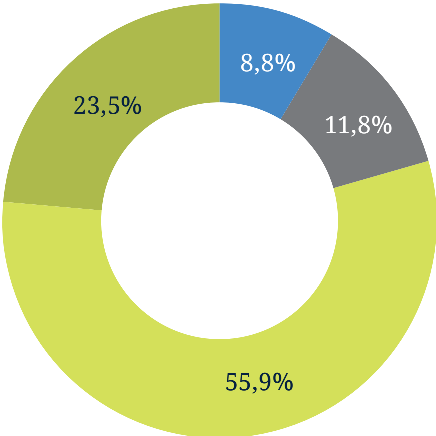
State actions to reduce barriers to the operation of the healthcare sector in Poland are:



In the opinion of almost 90% of the respondents, the actions taken by the state are inadequate to reduce barriers to the operation of the healthcare sector in Poland. A negligible percentage of the respondents were of an opposite opinion.

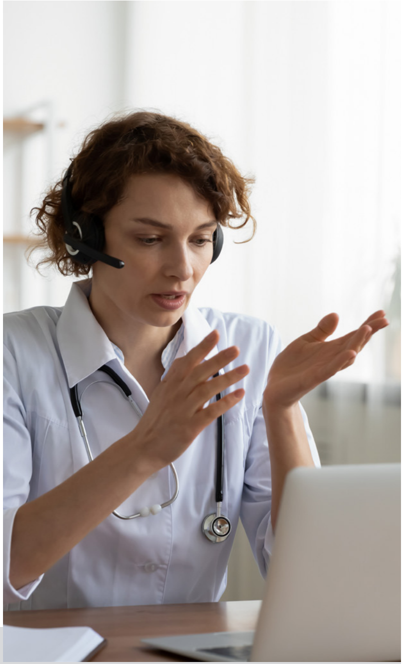
EVALUATION OF STATE ACTIONS

State actions to reduce barriers to the operation of the pharmaceutical and medical product sector in Poland are:



Definitely adequate	0%
Adequate	8,8%
Hard to say	11,8%
Inadequate	55,9%
Definitely inadequate	23,5%

In the opinion of more than 80% of the respondents, actions taken by the state are inadequate to reduce barriers to the operation of the pharmaceutical and medical product sector in Poland. Only less than 9% of the respondents believe that they are adequate, and no respondent considered such actions to be definitely adequate.



increase in telemedicine services

OTHER EFFECTS OF THE PANDEMIC

The COVID-19 pandemic will also have other effects

The respondents most frequently mentioned the following phenomena as possible impacts of the pandemic:

Public health – increased mortality and demand for health services resulting from reduced hospitalisations and diagnoses during the pandemic, especially in oncology and chronic diseases

Availability of services – reduced availability of services with increased demand and increased costs of healthcare services

Health awareness of the population – increased interest in both the healthcare system and medical and health-related education

Infectious diseases – increased prevention of infectious diseases, increased interest and demand for vaccinations (not only against COVID-19)

Online procedures – increase in telemedicine services, e-prescribing, online collaboration platforms, digital marketing, etc.

OTHER EFFECTS OF THE PANDEMIC

Pharmaceutical care
– increased role of pharmaceutical care and scope of pharmacies' operation (not only vaccinations)

Sector financing – increased funding, especially public funding, for the healthcare sector, increased investment in healthcare infrastructure

Medical personnel – increased personnel costs in the healthcare sector, reduced availability of specialists, professional burnout

Prices – increased prices

increased role of pharmaceutical care

no visible strategy for healthcare sector development

BARRIERS TO THE OPERATION OF THE SECTOR

What are the current main barriers to the operation of the sector?

The respondents most frequently mentioned the following phenomena as barriers to the operation of the pharmaceutical and medical sector:

Lack of strategy – no visible strategy for healthcare sector development

Financing – too low level of public funding, also in comparison with other EU countries; underfunded infrastructure

Medical Staffing – staff shortages at various levels, including specialist, nursing etc., low salaries

Access to healthcare services – insufficient access to services for patients

Functioning of hospitals – lack of "administrative" assistance on the ward; the doctor as a „scribe" who reports to the National Health Fund (NFZ)

Overregulation – complicated legal procedures

Public perspective is limited to COVID-19 – organizational and financial constraints for other medical procedures in 2020/2021

BARRIERS TO THE OPERATION OF THE SECTOR

Reimbursement of medicines|
– price-only approach by the public payer,
no value-based strategy, manufacturers come up against a brick wall in reimbursement negotiations, to the detriment of patients;
insufficient coverage of drug programmes

Reimbursement of medical devices
– lack of adequate regulations for the financing of medical devices;
lengthy procedures on the public payer's side

no value-based strategy,
insufficient coverage of drug programmes

SUGGESTED ACTIONS

What should the state do to eliminate barriers to the operation of the sector?

The following were the respondents' most frequent answers to the question of what the state should do to reduce barriers to the operation of the pharmaceutical and medical product sector in Poland:

Strategy for the sector
– need for a clear strategy to overcome the current crisis and the collapse of the system; immediate resumption of other procedures in addition to COVID-19 procedures; monitoring medical needs after the pandemic

Funding
– increase funding, especially public funding; tie funding to the quality of services

Private insurance
– introduce competition against the public payer

Administrative staff
– change the approach to the partnership with the sector rather than simply enforce regulations and punish

Medical staff
– reform the education system; facilitate specialist development; increase salaries

Decentralisation
– moving away from a centrally controlled policy; decentralise management of the sector

SUGGESTED ACTIONS

Health needs mapping
– better identify and define actual healthcare needs of the population

Reimbursement of drugs
– increase reimbursement of new products, take clinical innovation into account

Reimbursement of medical devices
– introduce uniform legislation on reimbursement of medical devices