

DLA PIPER REPORT

Pharmaceutical and medical sector in Poland

SECOND EDITION



Table of contents

Introduction.....	03
Summary.....	04
Preliminary questions.....	08
1.0 Long-term trends in the medical and pharmaceutical market.....	10
2.0 Marketing and relations with medical professionals.....	12
3.0 Clinical trials.....	17
4.0 Reimbursement and purchasing procedures.....	20
5.0 New technologies.....	25
6.0 Health system and patient rights.....	28
7.0 Market for medicines and medical equipment.....	32
8.0 Other effects of the current situation. Suggested solutions.....	39

Introduction

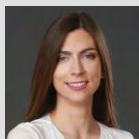
We would like to invite you to read our report summarising the second edition of the DLA Piper survey "Pharmaceutical and medical sector in Poland", which was conducted among the largest medical and pharmaceutical companies in Poland. Our intention was to gather information on the current state of the market, as well as forecasts for future trends and phenomena, based on answers provided by our respondents, who operate in the industry on a daily basis.

The second edition of the survey was completed in November 2022 (the first edition was completed in May 2021, and therefore still during the so-called third wave of the pandemic). The respondents were those operating within the medicines, dietary supplements and medical devices sector, as well as healthcare providers. The first group of questions concerned the practical functioning of the sector. The second group of questions concerned the respondents' anticipated trends and changes in the functioning of the sector in the coming years. The last part consisted of open-ended questions on the most important barriers to the development of the sector and respondents' suggestions for public policies to support the development of the sector. The report also includes a comparison of the results of the first and second edition of the survey.

The report was compiled from questionnaires collected from nearly 40 representatives of the largest companies in the medical and pharmaceutical industries.



Dr Andrzej Balicki
Partner, Head of *Life Sciences*
Practice, Attorney-at-law
+48 22 540 74 01
andrzej.balicki@dlapiper.com



Jolanta Dąbrowicz
Senior Associate | *Life Sciences*
Attorney-at-law
+48 22 540 74 91
jolanta.dabrowicz@dlapiper.com

Summary

We present below the results of the second edition of the report Medical and pharmaceutical sector in Poland. The first edition of the survey was conducted during the third wave of the pandemic, and the second during a global political and economic crisis also affecting the functioning of the pharmaceutical and medical market. The results of the survey show both how respondents perceive the current state of the sector and what their suggestions are for proposed solutions.

The second edition of the survey shows a picture – unfortunately far from ideal – of the current state of the medical and pharmaceutical sector in Poland. At the same time, a number of aspects can be seen on which the industry is optimistic, including the state's addressing of rare diseases, the growing role of modern digital solutions in healthcare, and Poland's role in the CEE region.



Respondents point to the *lack of a public strategy for the sector, including in response to the current economic crisis.*

This negative picture unfortunately does not change compared to last year's survey. The vast majority of respondents have a negative view of the actions undertaken by the state to reduce barriers to the medicinal products, medical equipment and medical services sector in Poland. There is also pessimism about the reimbursement budget, where it is projected to be effectively reduced with much more optimism on this topic a year earlier.

SUMMARY



Respondents raise *the risk of reduced availability of medicines for patients, as well as an increase in their prices.*

At the same time, they often highlight the difficulties and increasing costs within supply chains, including in terms of transport and logistics, especially for medicines and active substances produced in, for example, China.



Respondents point to *difficulties in attracting and retaining valuable employees,*

particularly those involved in the manufacturing, logistics and distribution of medicines, medical devices and dietary supplements. These problems affect not only manufacturing and distribution companies, but also the medical services sector.



There is clear *optimism regarding the development of digital tools,*

artificial intelligence solutions, particularly in clinical research, research and development or certain medical procedures and diagnostics. There is also optimism about the development of telemedicine.

SUMMARY



Respondents are similarly *optimistic about Poland's future role as a regional drug 'hub' for other Central and Eastern European (CEE) countries.*

At the same time, they point to the increasing role of locally produced products.



The survey shows *moderate optimism about the future availability of treatment of rare diseases.*

With regard to the treatment of so-called comorbidities, the predictions are considerably more pessimistic, especially when compared to the responses given in this respect in the survey carried out by the year ago during the last wave of the pandemic.

SUMMARY



Respondents also indicated

what the state should do to remove barriers to development for the sector.

The proposals for solutions were very similar to last year's, which naturally does not inspire optimism.



Respondents pointed out, among other things, the *need to increase public funding,*

introduce investment and tax incentives and streamline authorities. In their responses, they suggested

strengthening the social dialogue

– in particular by taking greater account of industry comments, longer comment periods for public consultations on draft legislation, etc., and

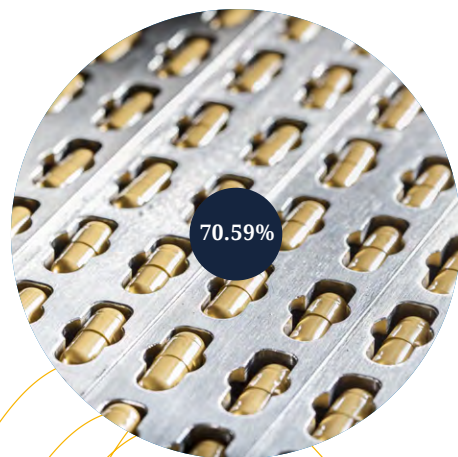
ensuring greater stability and predictability of the law.

Preliminary questions

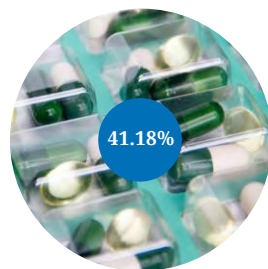


PRELIMINARY QUESTIONS

In your work you deal with



■ Medication



■ Dietary supplements



■ Medical equipment



■ Health services

More than two-thirds of respondents deal with medicines in their work, four in ten deal with dietary supplements.

Medical equipment is used by nearly a third of respondents, while health services are used by one in four.



Compared to the 2021 survey, we see a slightly higher proportion of respondents dealing with medicines.

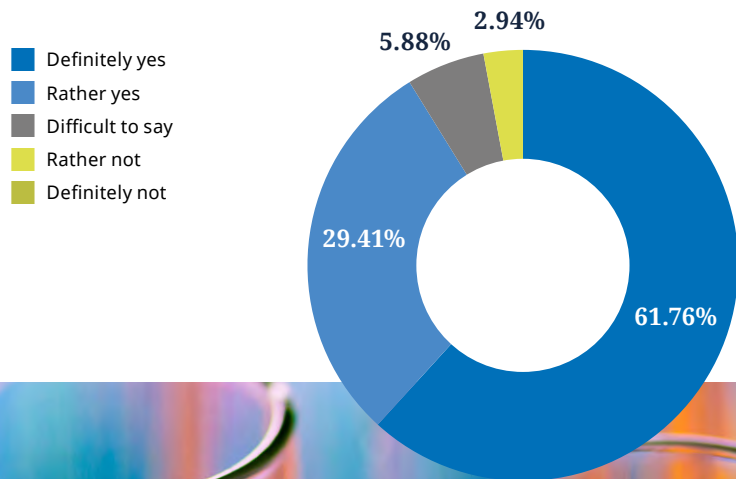
* Due to the nature of the question (multiple choice), percentages do not add up to 100%.

1.0 Long-term trends in the medical and pharmaceutical market



LONG-TERM TRENDS IN THE MEDICAL AND PHARMACEUTICAL MARKET

1.1 Will the current global situation and Polish situation have a significant impact on the future shape of the medical and pharmaceutical market in Poland?



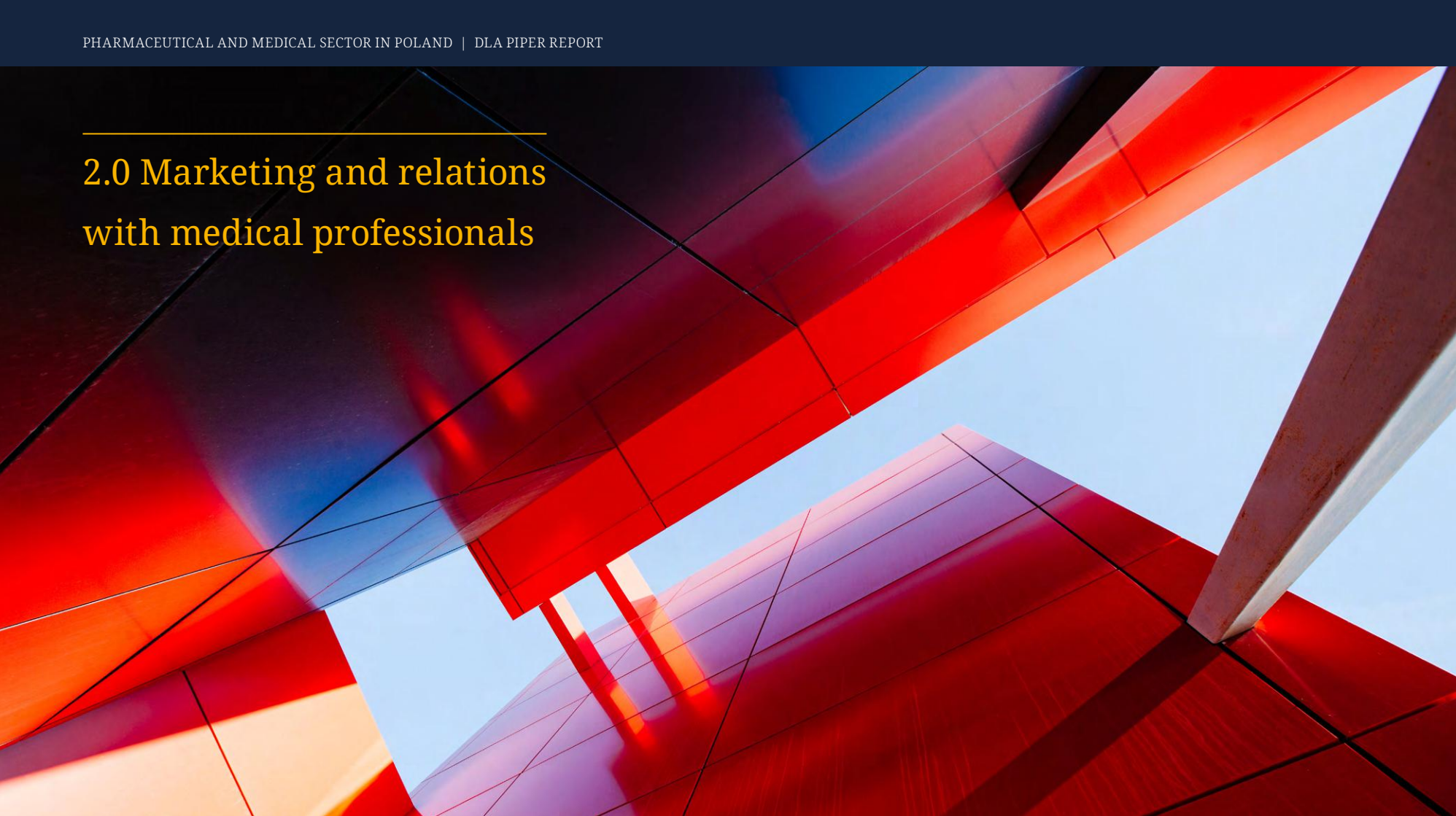
Respondents clearly indicate that the current global and Polish situation will influence the future shape of the market. In total, more than 90% of respondents answered “yes”.

The responses strongly indicate the critical importance of the current situation for the future shape of the medical and pharmaceutical market in Poland.



In the first edition of the survey, the response “definitely yes”/“rather yes” was given by a similar proportion of respondents (nearly 85%).

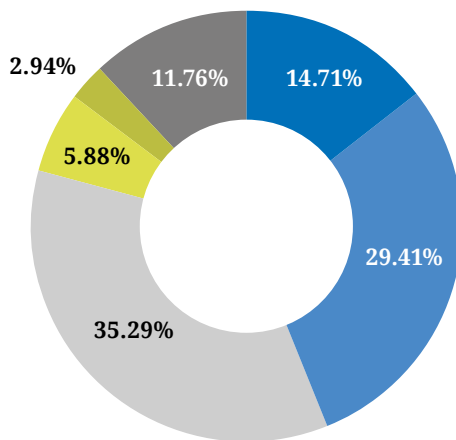
2.0 Marketing and relations with medical professionals

The background of the slide is an abstract, low-angle photograph of a modern building's facade. The structure is composed of large, angular panels in vibrant shades of red, orange, and blue, set against a clear blue sky. A network of thin black lines crisscrosses the image, creating a complex geometric pattern that adds depth and a sense of architectural precision.

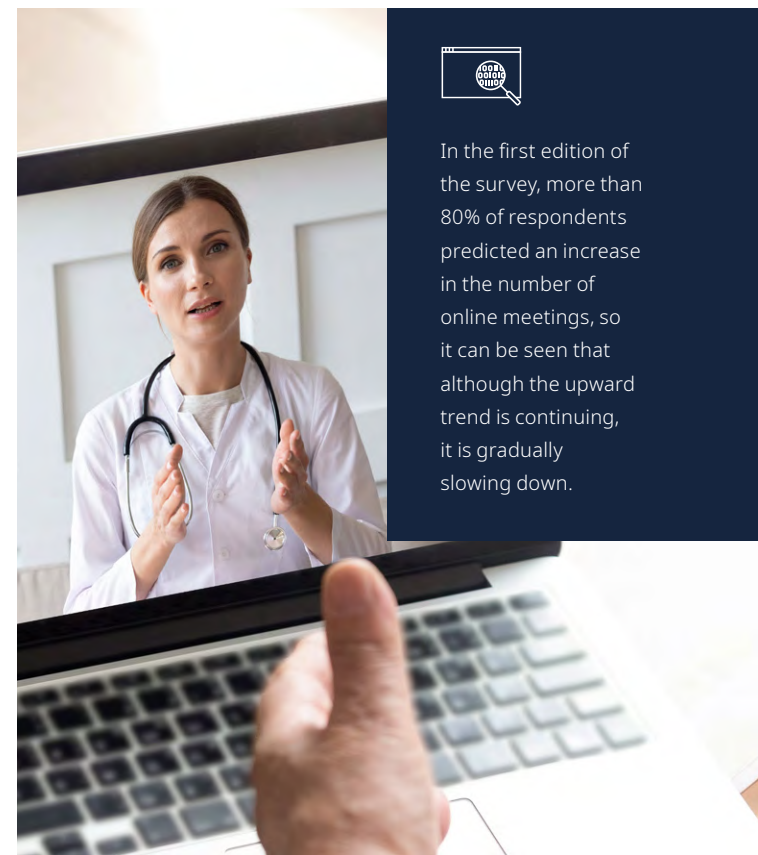
MARKETING AND RELATIONS WITH MEDICAL PROFESSIONALS

2.1 How will face-to-face meetings with medical professionals in 2023 and beyond compare with the current situation?

- Much more often online
- More often online
- No change – in a similar way
- Less frequently online
- Much less frequently online
- Difficult to say



Nearly half of the respondents (44%) continue to anticipate an increase in the importance of online meetings with medical professionals (answers "more often" or "much more often"). According to one third, the situation will not change in the future.



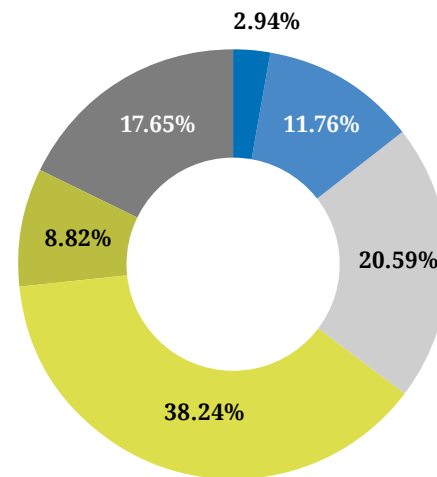
In the first edition of the survey, more than 80% of respondents predicted an increase in the number of online meetings, so it can be seen that although the upward trend is continuing, it is gradually slowing down.



MARKETING AND RELATIONS WITH MEDICAL PROFESSIONALS

2.2 What will the marketing budgets of pharmaceutical companies in Poland look like in 2023 and subsequent years compared to the current situation?

- There will be a significant increase
- There will be an increase
- They will not change
- There will be a reduction
- There will be a significant reduction
- Difficult to say

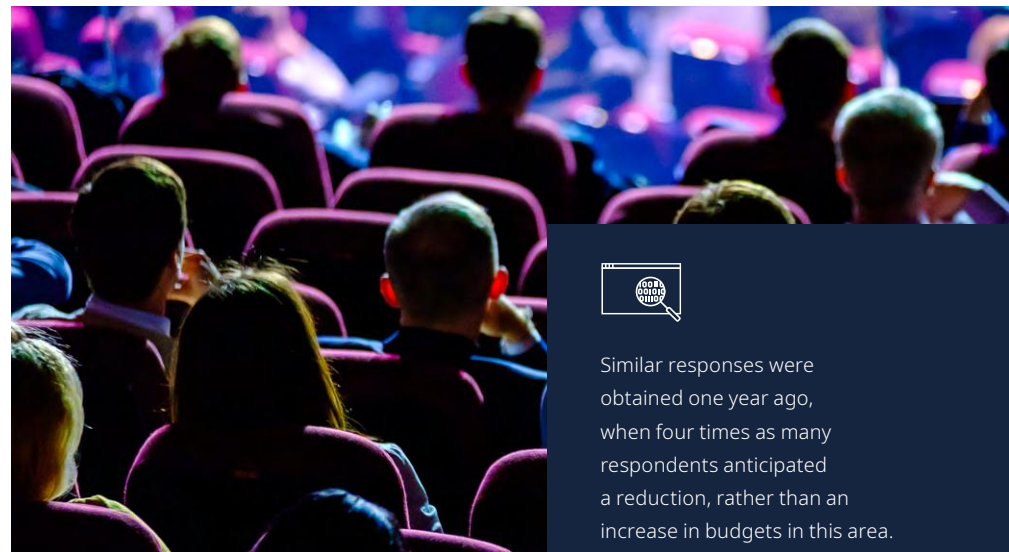
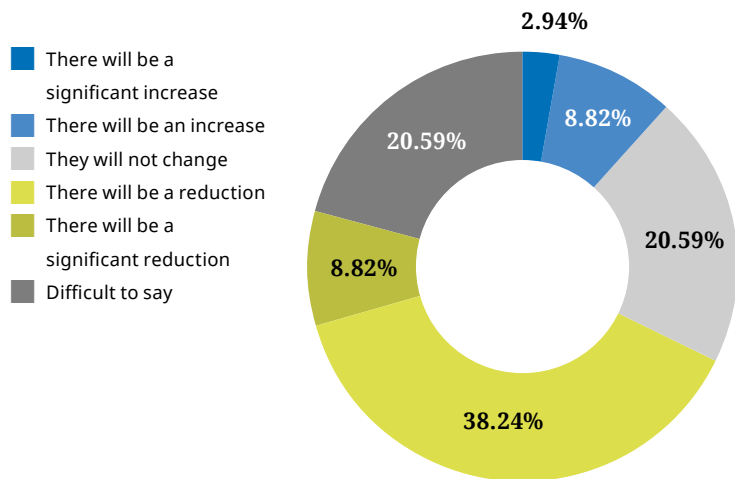


Nearly half of respondents (over 47%) anticipate a reduction in marketing budgets.

According to one fifth of respondents, there will be no change, and only one in seven predicts an increase in such budgets.

MARKETING AND RELATIONS WITH MEDICAL PROFESSIONALS

2.3 How will the budgets of pharmaceutical companies in Poland related to the sponsorship of participation in scientific conferences in 2023 and beyond compared to the current situation?



Similar responses were obtained one year ago, when four times as many respondents anticipated a reduction, rather than an increase in budgets in this area.

As in the previous question, nearly half of respondents (over 47%) anticipate a reduction in budgets related to the sponsorship of participation in scientific conferences.

According to a fifth of respondents, there will be no change and only one in nine respondents anticipates an increase in such budgets.

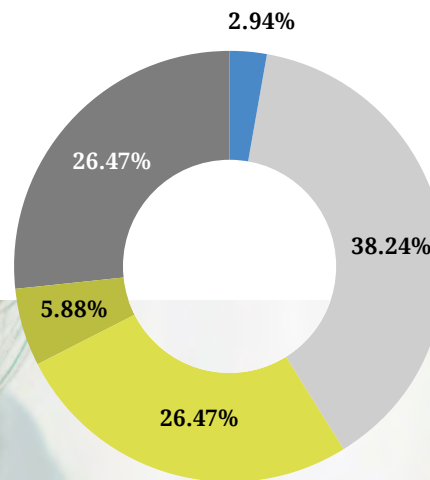
MARKETING AND RELATIONS WITH MEDICAL PROFESSIONALS

2.4 How will the number of sales representatives change in Poland in 2023 and beyond compared to the current situation?



In 2021, as many as half of the respondents anticipated a reduction in employment, indicating a weakening of the negative trend.

- There will be a significant increase
- There will be an increase
- They will not change
- There will be a reduction
- There will be a significant reduction
- Difficult to say



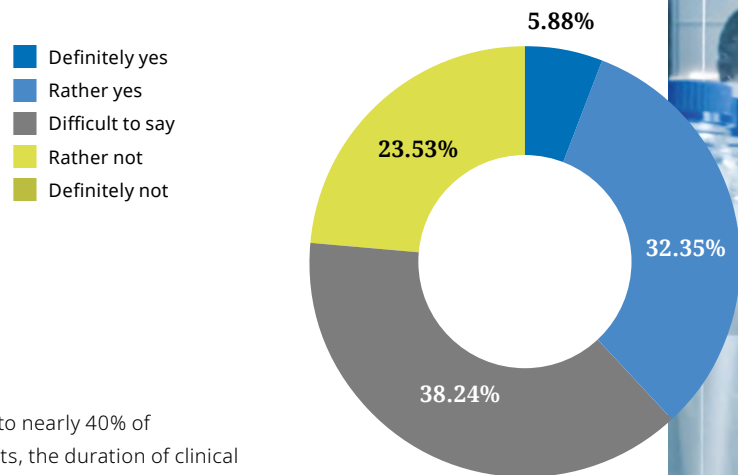
The largest group of respondents (nearly 40%) expect to maintain their current employment of sales representatives, up from 30% a year earlier. A reduction in employment is anticipated by a third of respondents.

3.0 Clinical trials



CLINICAL TRIALS

3.1 Is the current duration of clinical trials in Poland longer than before the COVID-19 pandemic?

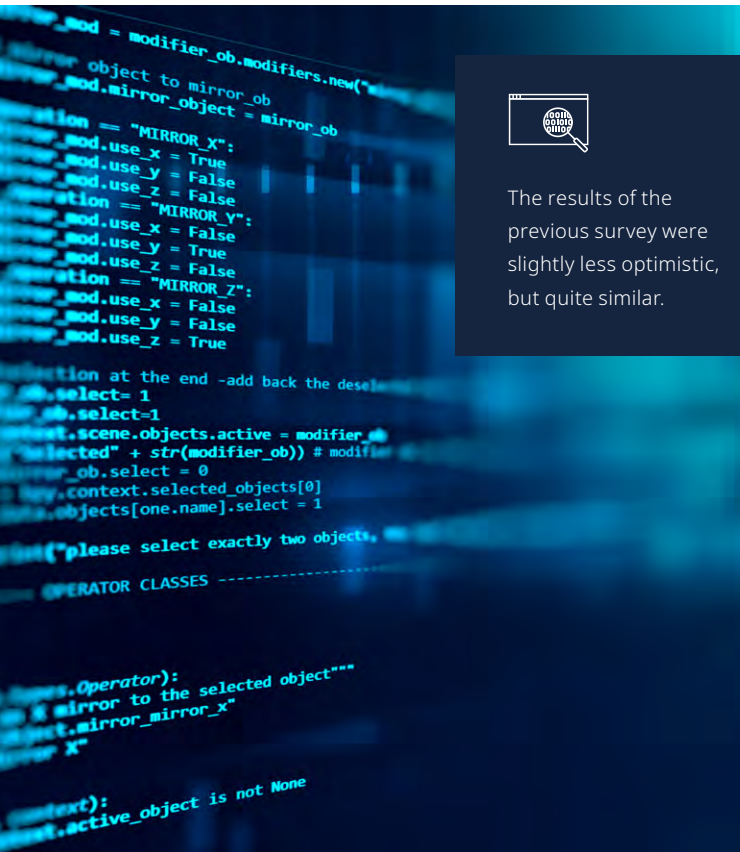



According to nearly 40% of respondents, the duration of clinical trials in Poland has lengthened compared to the period before the COVID-19 pandemic.



One year ago, the lengthening of the duration of clinical trials was noted by as many as two-thirds of respondents, indicating a significant stabilisation of the situation.





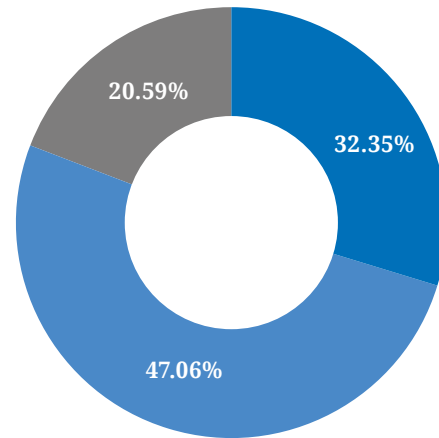


The results of the previous survey were slightly less optimistic, but quite similar.

CLINICAL TRIALS

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

- Definitely yes
- Rather yes
- Difficult to say
- Rather not
- Definitely not



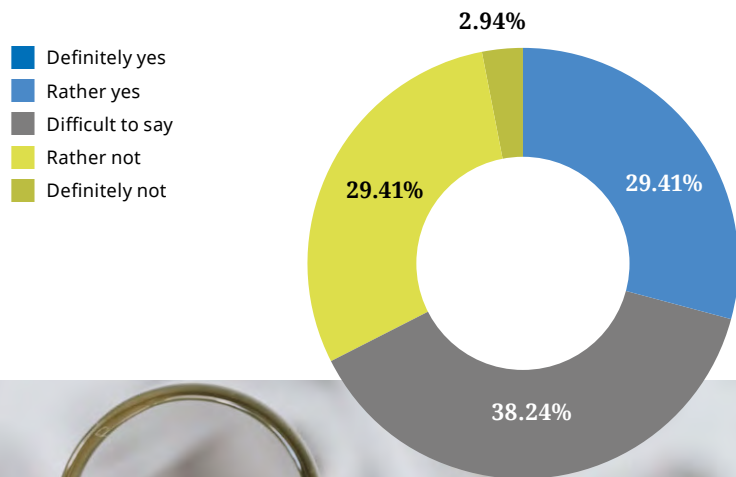
The majority of respondents is optimistic about the future use of digital technology in clinical trials. Nearly 80% believe it will bring greater efficiency in the conduct of such trials in the long term.

4.0 Reimbursement and purchasing procedures



REIMBURSEMENT AND PURCHASING PROCEDURES

4.1 Is there currently a greater emphasis on developing innovative reimbursement mechanisms in Poland than in previous years?



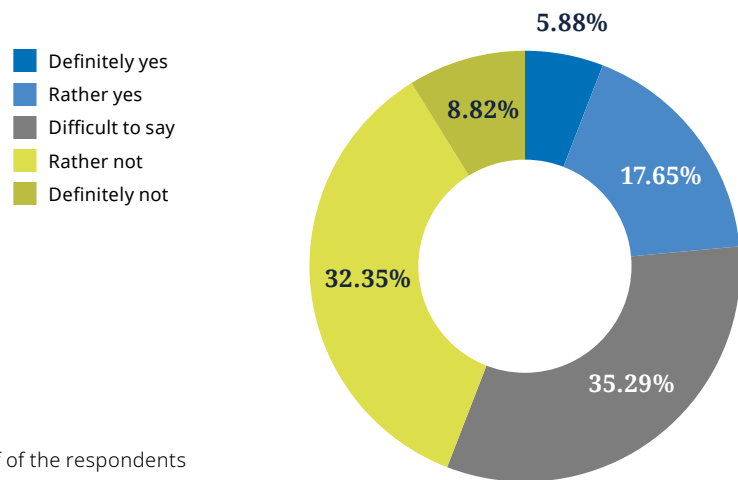
Respondents' answers fell into three groups, with around a third indicating "yes"; a slightly higher percentage indicating "no", and almost 40% had no opinion.



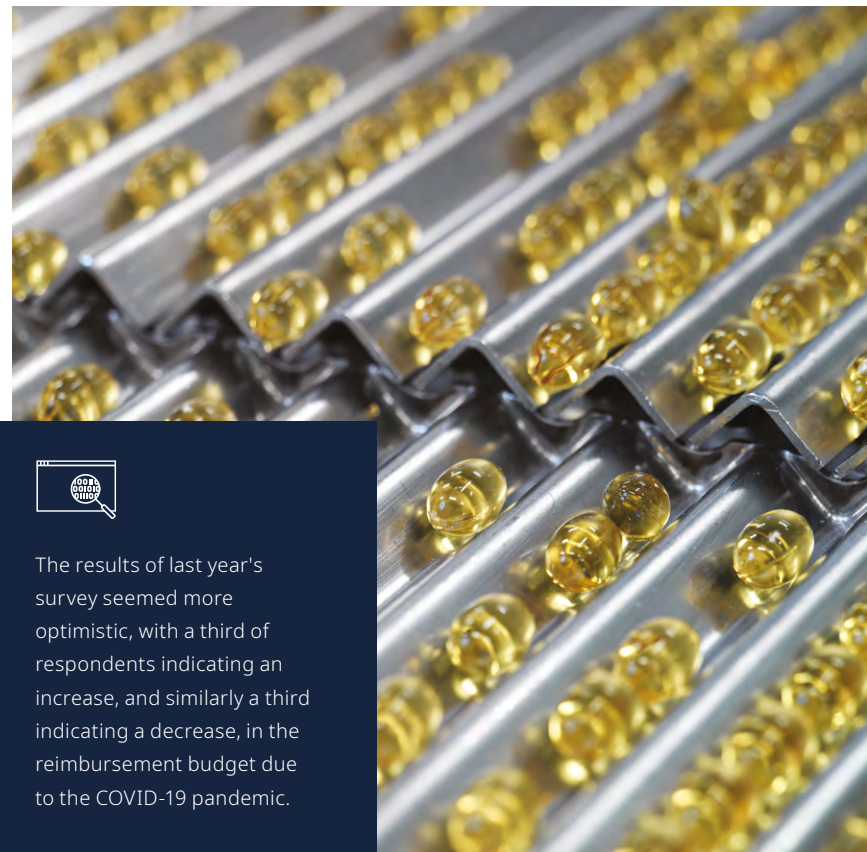
The current responses present a much more optimistic picture compared to last year's survey, in which only around 15% of respondents mentioned the development of innovative mechanisms, while as many as one in two saw no such development.

REIMBURSEMENT AND PURCHASING PROCEDURES

4.2 In your opinion, will the reimbursement budget in Poland be increased in 2023 and beyond compared to the current situation?



Nearly half of the respondents (around 45%) anticipate a reduction in the reimbursement budget, while only one in four believe it will be increased.

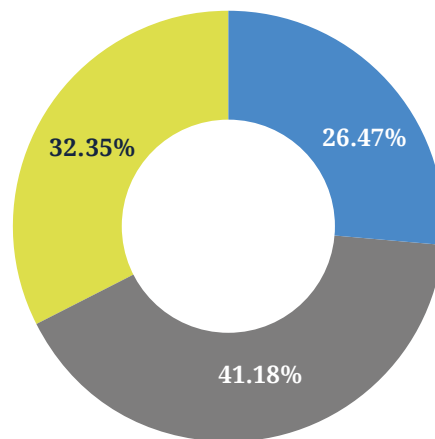


The results of last year's survey seemed more optimistic, with a third of respondents indicating an increase, and similarly a third indicating a decrease, in the reimbursement budget due to the COVID-19 pandemic.

REIMBURSEMENT AND PURCHASING PROCEDURES

4.3 In your opinion, will the COVID-19 pandemic affect the long-term funding of the most common so-called comorbidities compared to other diseases in Poland?

- Definitely yes
- Rather yes
- Difficult to say
- Rather not
- Definitely not



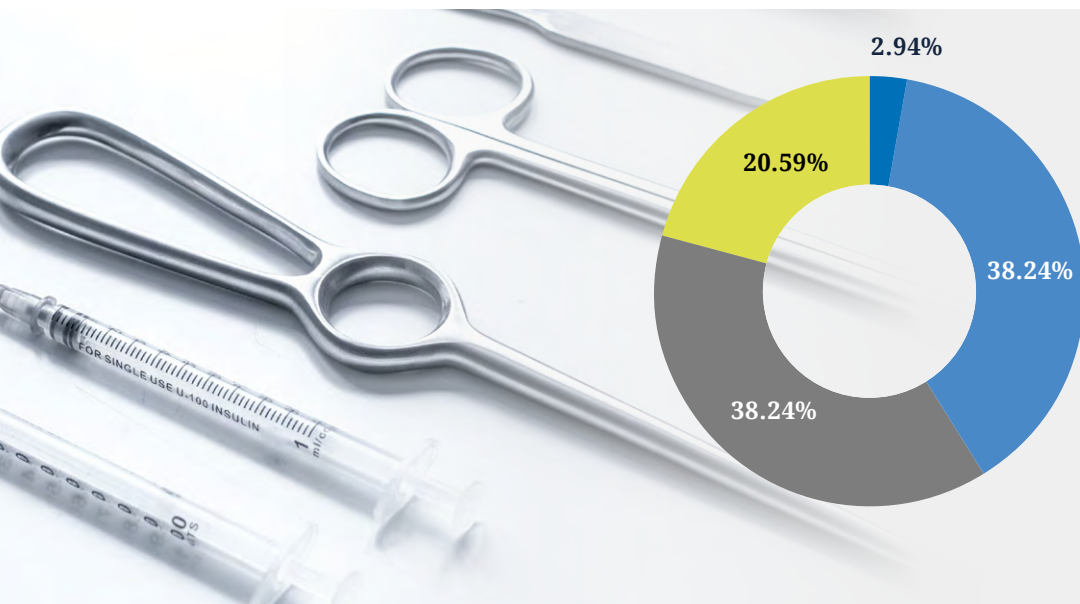
A quarter of respondents believe that the pandemic will affect the increasing funding for so-called comorbidities, while one third are of the opposite opinion.



The results of last year's survey were far more optimistic, with as many as half of the respondents anticipating an increase in funding, and only one in four were of the opposite opinion.

REIMBURSEMENT AND PURCHASING PROCEDURES

4.4 In your opinion, will central purchasing procedures for medicines and medical equipment be introduced in Poland in the coming years?



- Definitely yes
- Rather yes
- Difficult to say
- Rather not
- Definitely not

Twice as many respondents believe that in the coming years central purchasing procedures for medicines and medical equipment will be introduced (41% "yes" responses, compared to 21% "no" responses).



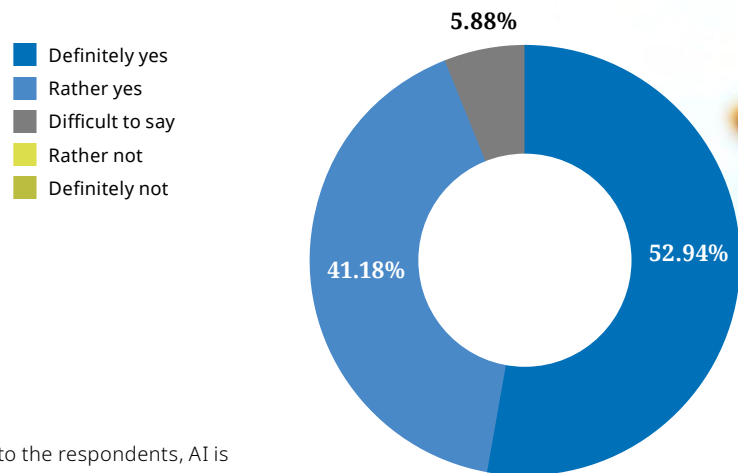
Responses to last year's edition research has moved in a similar direction, albeit were a little more forceful: 55% "yes" answers and 20% "no".

5.0 New technologies

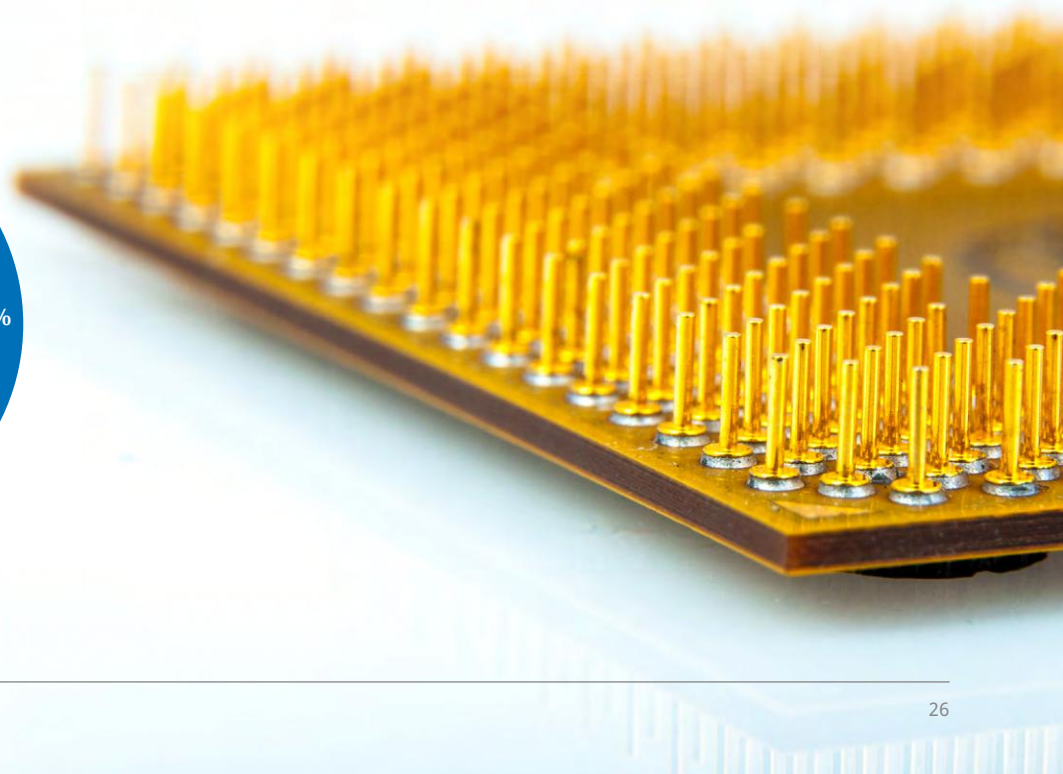


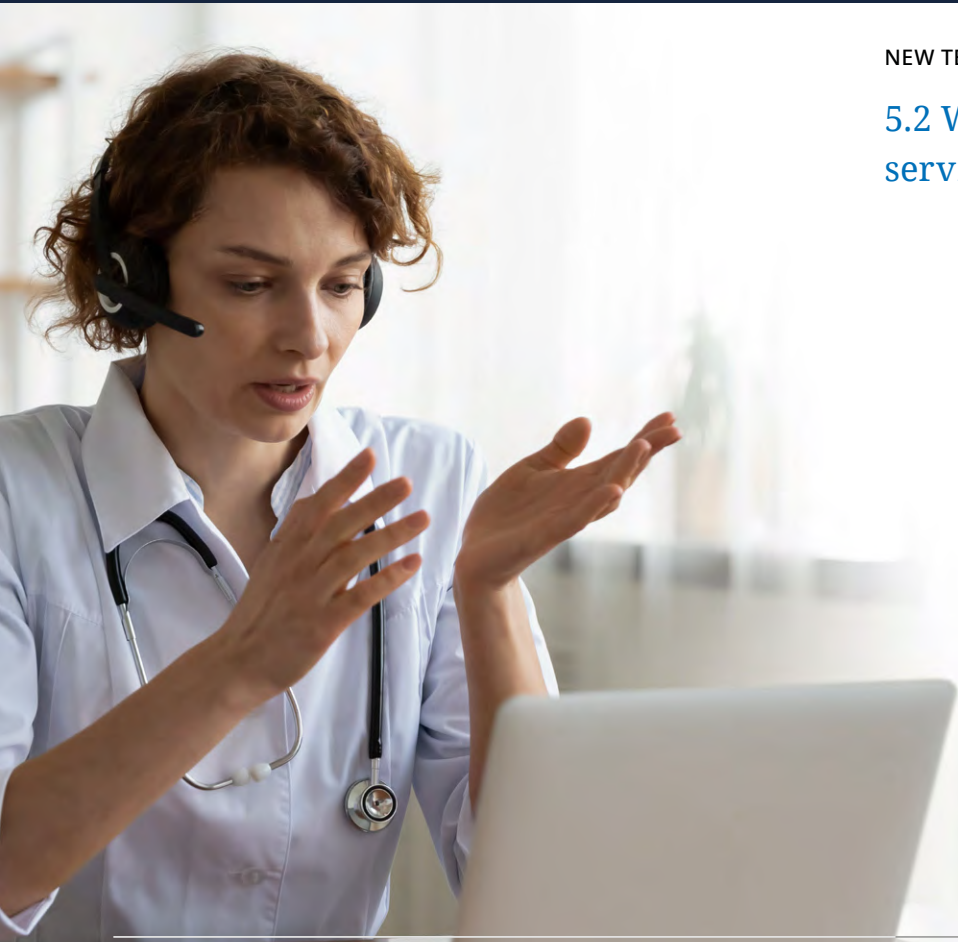
NEW TECHNOLOGIES

5.1 Will the use of AI-based solutions in the medical and pharmaceutical industries in Poland increase in the coming years?



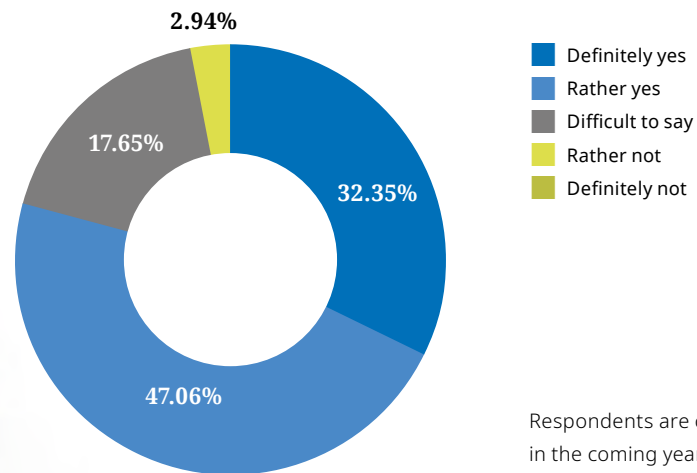
According to the respondents, AI is the future of the medical and pharmaceutical industry in Poland – nearly 95% of all responses were "yes".





NEW TECHNOLOGIES

5.2 Will there be more regulation of telemedicine services and their funding in the coming years in Poland?



Respondents are confident that in the coming years there will be increased regulation of telemedicine services and their funding – this is the view of nearly 80% of respondents.

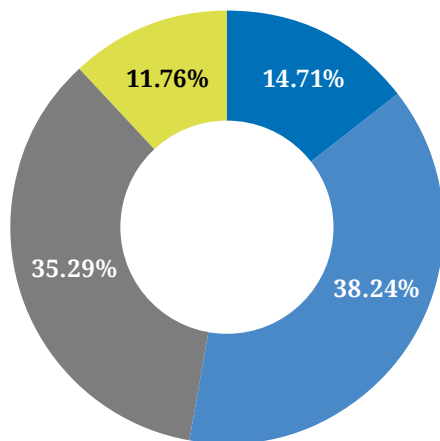
6.0 Health system and patient rights



HEALTH SYSTEM AND PATIENT RIGHTS

6.1 In your opinion, will the centralisation of the management of medical facilities increase in the coming years?

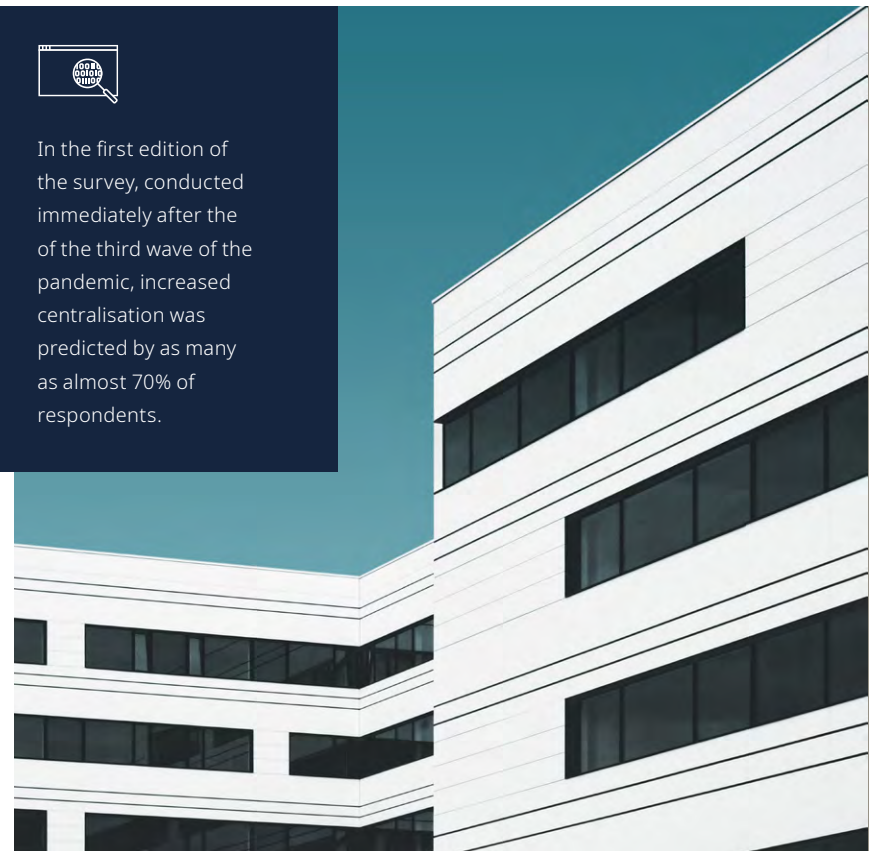
- Definitely yes
- Rather yes
- Difficult to say
- Rather not
- Definitely not



According to more than 50% of respondents, we will see the centralisation of the management of medical facilities in the near future. Only 12% were of the opposite view.

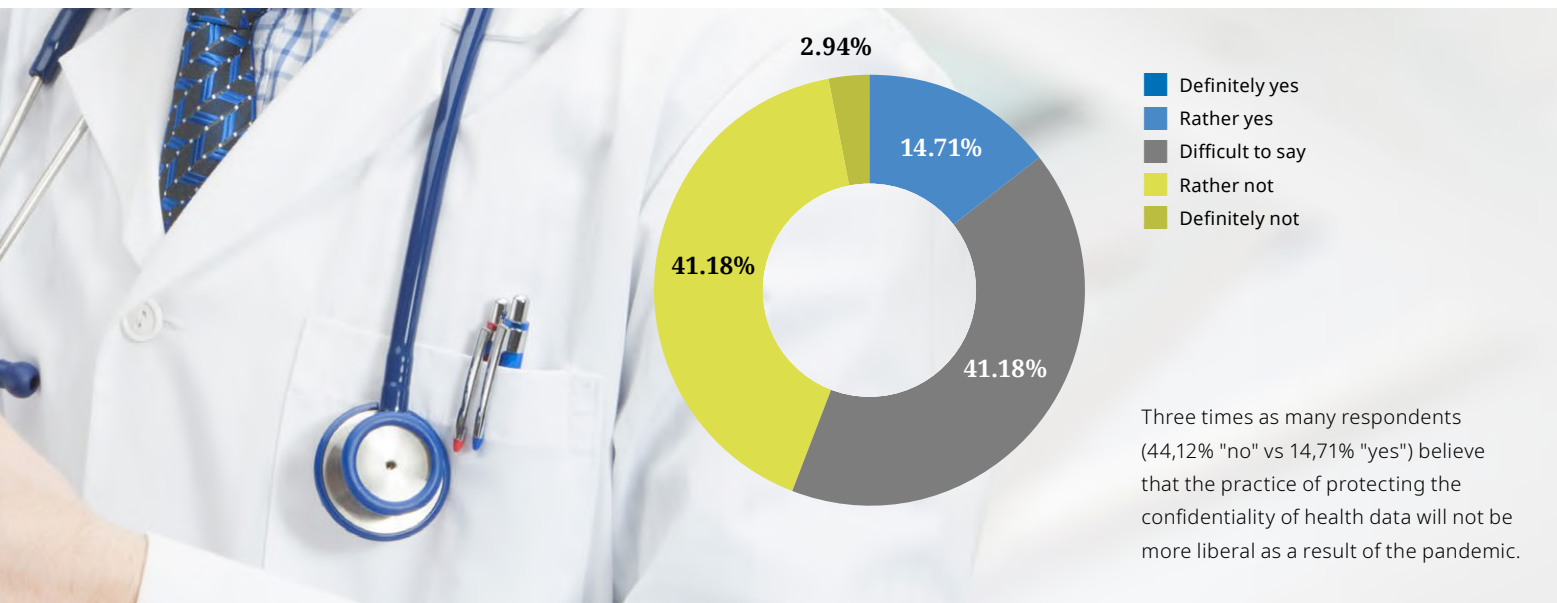


In the first edition of the survey, conducted immediately after the of the third wave of the pandemic, increased centralisation was predicted by as many as almost 70% of respondents.



HEALTH SYSTEM AND PATIENT RIGHTS

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



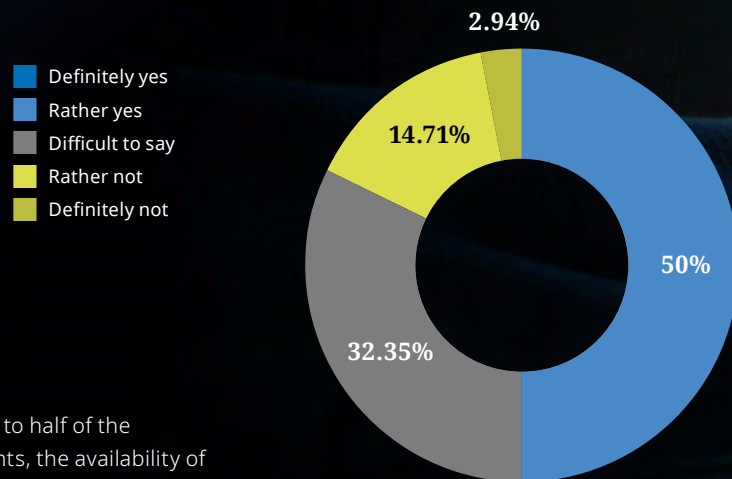
Three times as many respondents (44,12% "no" vs 14,71% "yes") believe that the practice of protecting the confidentiality of health data will not be more liberal as a result of the pandemic.



Respondents asked in last year's survey were of the opposite opinion – at that time three times as many respondents predicted that the practice of protecting the confidentiality of health data would be liberalised as a result of the pandemic.

HEALTH SYSTEM AND PATIENT RIGHTS

6.3 In your opinion, will there be an increase in the availability of treatment for rare diseases in the coming years in Poland?



According to half of the respondents, the availability of treatment for rare diseases will increase. Less than 20% are of the opposite view.

7.0 Market for medicines and medical equipment

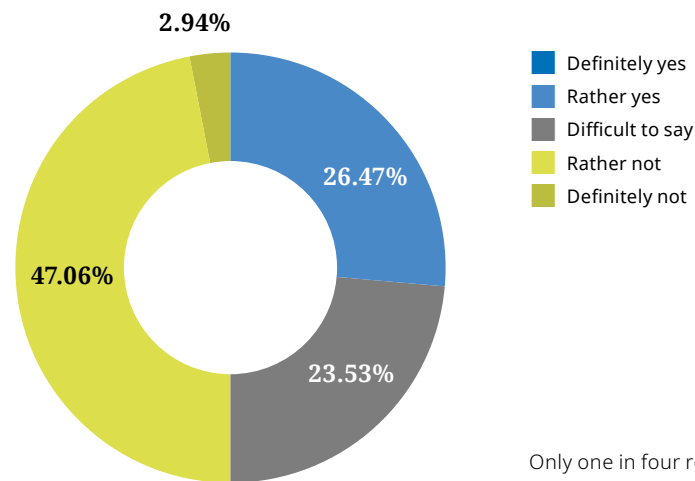




In the first edition of the survey, 30% of respondents predicted such an increase, while 40% held the opposite view.

MARKET FOR MEDICINES AND MEDICAL EQUIPMENT

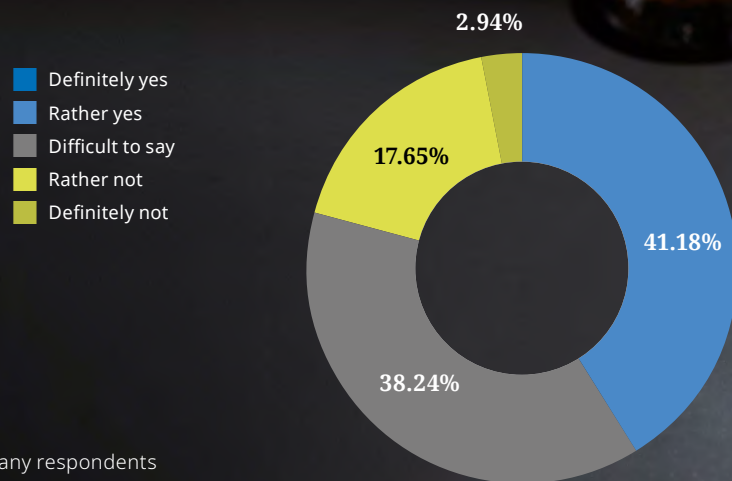
7.1 In your opinion, will there be an increase in the market share of innovative products in the coming years in relation to generic manufacturers?



Only one in four respondents anticipates an increase in the share of innovative products, as many as half hold the opposite view.

MARKET FOR MEDICINES AND MEDICAL EQUIPMENT

7.2 In your opinion, will there be an increase in the market share of locally produced products in the coming years?



Twice as many respondents (over 40%) believe that there will be an increase in the share of locally produced products.



In the first edition of the survey, this trend was even more pronounced, with over 55% of respondents predicting such an increase.

MARKET FOR MEDICINES AND MEDICAL EQUIPMENT

7.3 In your opinion, will there be an increase in the market share of over-the-counter products in the coming years?



- Definitely yes
- Rather yes
- Difficult to say
- Rather not
- Definitely not

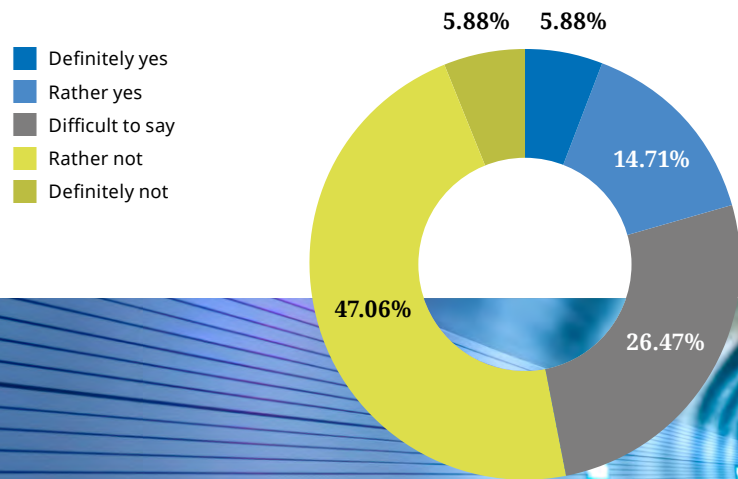
More than three quarters of respondents anticipate an increase in the market share of over-the-counter medicines.



In the first edition of the survey, such an increase was predicted by just over a third of respondents.

MARKET FOR MEDICINES AND MEDICAL EQUIPMENT

7.4 In your opinion, will there be a reduction in parallel imports within the European Union in the coming years?



One in five respondents anticipates a reduction in parallel imports within the European Union and more than half hold the opposite view.

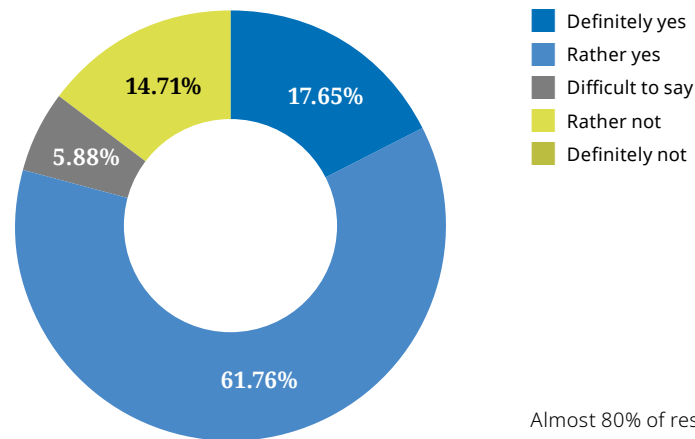


In last year's survey, the ratio of those predicting such a reduction to those with the opposite view was similar. However, there were more respondents indicating that it was difficult to say what the trend would be.



MARKET FOR MEDICINES AND MEDICAL EQUIPMENT

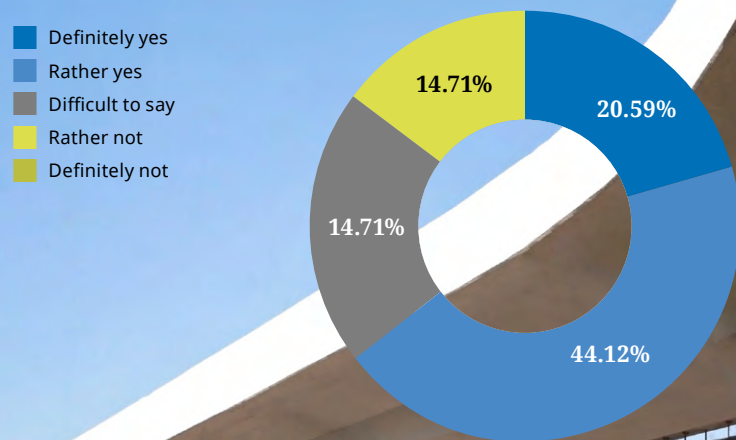
7.5 In your opinion, will there be a noticeable problem with the availability of medicines in Poland in the coming years?



Almost 80% of respondents foresee a problem with the availability of medicines, with less than 15% of respondents holding the opposite view.

MARKET FOR MEDICINES AND MEDICAL EQUIPMENT

7.6 In your opinion, will there be an increase in the importance of Poland as a drug 'hub' for other countries in the CEE region in the coming years?



Poland as a future drug 'hub' for other CEE countries is the vision of the vast majority of respondents (two-thirds). Only less than 15% of respondents foresee the opposite situation.

8.0 Other effects of the current situation. Suggested solutions



OTHER EFFECTS OF THE CURRENT SITUATION. SUGGESTED SOLUTIONS

8.1 In addition to those indicated above, what other effects, if any, will the current global and Polish situation (political, economic and medical, including the pandemic) have on the pharmaceutical, medical equipment and medical services sectors?

Medicines, supplements and medical devices



Patient accessibility – reduced availability of medicines and other devices to patients related to problems with production, supply chains and price levels.



Drug pricing – rising drug prices with increasing manufacturing costs.



Supply chains – risk of reduced availability of both medicines and active substances, especially those produced in China.



Transport and logistics – rising costs of transport and logistics for medicines and medical devices.



Reimbursement – reduction in reimbursement levels; undervaluation of medical services.



Access to capital – less availability of development capital, lower centrally-set budgets.



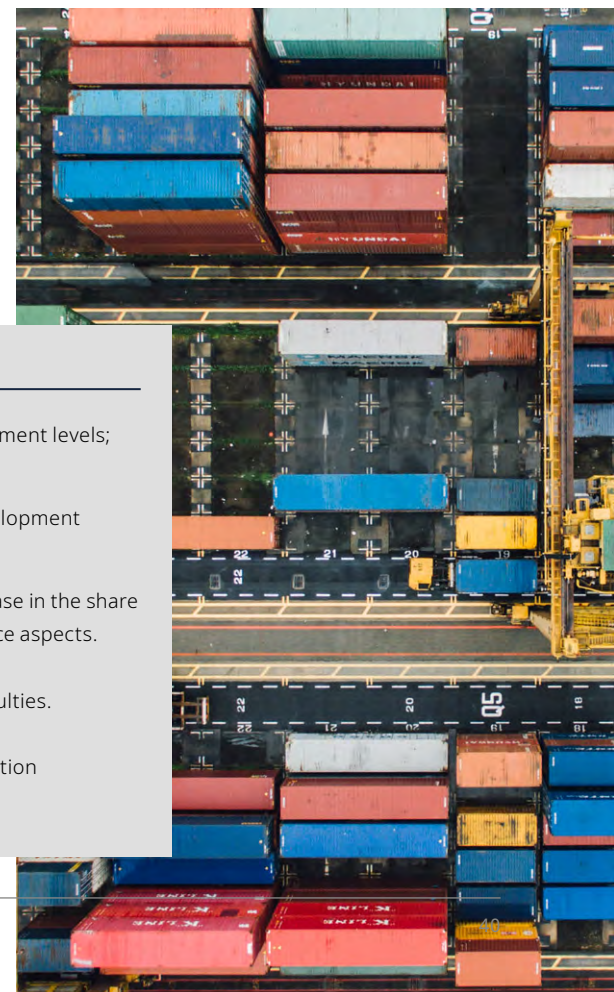
Innovative vs. generic medicines – increase in the share of generics due to, among other things, price aspects.

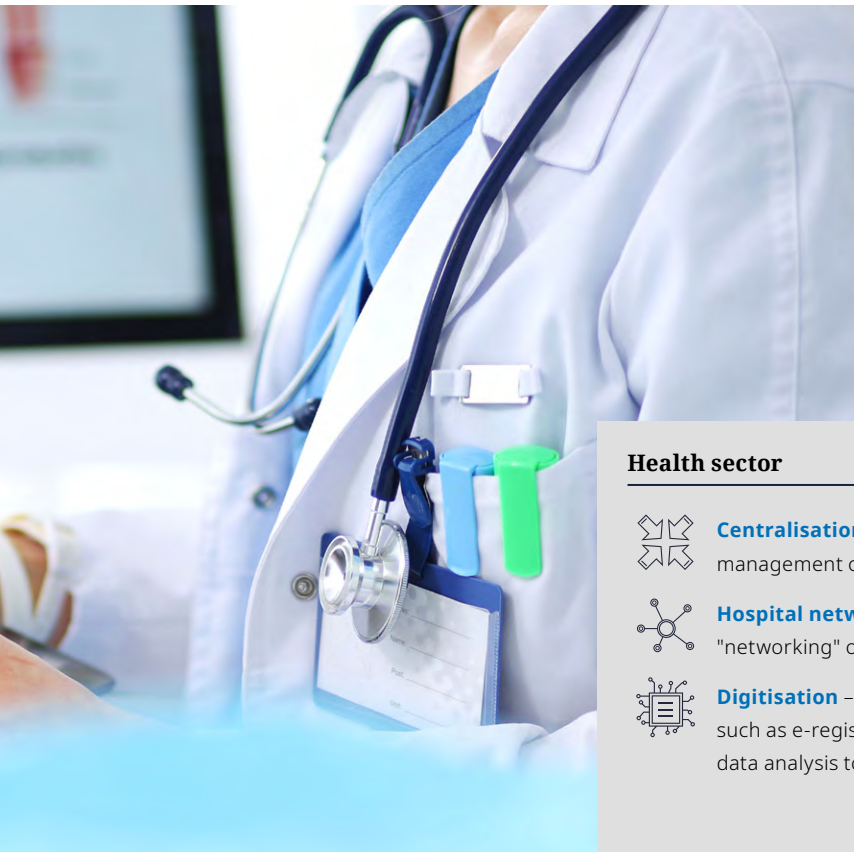


Smaller businesses – bankruptcy or difficulties.



Clinical trials – extending the implementation of clinical trials.





OTHER EFFECTS OF THE CURRENT SITUATION. SUGGESTED SOLUTIONS

8.1 In addition to those indicated above, what other effects, if any, will the current global and Polish situation (political, economic and medical, including the pandemic) have on the pharmaceutical, medical equipment and medical services sectors?

Health sector



Centralisation – increased emphasis on centralising the management of medical services and coordination of services.



Hospital network – reinforcing the trend towards "networking" of healthcare providers.



Digitisation – dissemination of central electronic tools such as e-registration; growth of medical registers and data analysis tools e.g. clinical and performance indicators.



Homecare – the rise of home care.



Migration of patients – increasing importance of patient migration.

OTHER EFFECTS OF THE CURRENT SITUATION. SUGGESTED SOLUTIONS

8.2 What are the biggest barriers for the pharmaceuticals, medical devices and medical services sectors in Poland today?



Lack of strategy – lack of appropriate policies, including economic/sectoral policies, in response to the current global crisis.



Economic situation – high inflation and unsustainable valuations.



Funding – too little public funding, lengthy reimbursement processes, lack of reimbursement for modern medical products and systems.



Know-how – limited local know-how in medicines and medical devices.



Qualified staff – difficulties in attracting and retaining valuable employees involved in manufacturing, logistics and distribution.



Scientific advice procedure – lack of a national scientific advisory procedure for very important areas such as the clinical trials process and certification required by the European Medicines Agency.



Manufacturing – no local manufacturing base for active substances.



Health system – shortages in medical staffing, undervalued services.



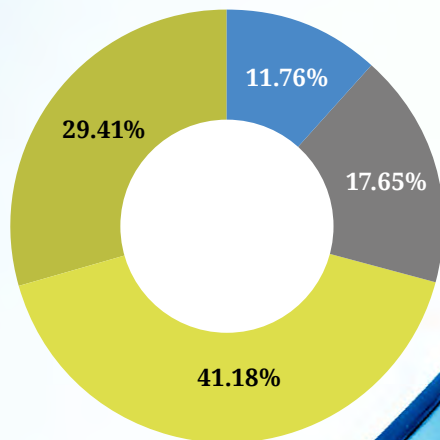
Regulation – complex and inconsistent legislation, unfavourable regulatory provisions; lack of predictability of change, lack of robust public consultation.



OTHER EFFECTS OF THE CURRENT SITUATION. SUGGESTED SOLUTIONS

8.3 State action to reduce barriers in the pharmaceuticals, medical devices and medical services sectors in Poland is:

- Definitely adequate
- Adequate
- Difficult to say
- Inadequate
- Definitely inadequate



More than 70% of respondents have a negative view of state action to reduce barriers in the sectors. Only just over 10% view such measures positively.



In last year's survey, negative ratings were 80% and positive ratings were less than 10%.

OTHER EFFECTS OF THE CURRENT SITUATION. SUGGESTED SOLUTIONS

8.4 What should the state do to remove barriers in the pharmaceuticals, medical devices and medical services sector in Poland?



FINANCING

increasing public funding for health care.



INVESTMENT INCENTIVES

increasing resources and incentives for innovation in the areas of medicines and medical technology.



TAXES

stabilising the tax and public finance system.



ACTION OF THE AUTHORITIES

streamlining the operation of sectoral bodies, increasing the staffing of qualified personnel, and increasing funding for their operation.



SOCIAL DIALOGUE

strengthening dialogue with the sector, promoting public consultation, publishing assumptions, taking into account industry comments, longer time to submit comments, implementing industry comments and solutions from other countries.



ANALYSIS OF THE SECTOR

better market analysis, hiring of specialists.



LEGISLATION

greater stability and predictability of the law.



HEALTH SYSTEM

increasing public funding, levelling the playing field between private and public actors.

Life Sciences | DLA Piper Poland

“Truly outstanding life sciences team.”
Legal 500 EMEA 2022

“Great understanding of the market combined with pragmatic approach.”

Legal 500 EMEA 2022

“Emphasis on diversity and the spirit of internal collaboration are clearly visible.”

Legal 500 EMEA 2022

The leading Life Sciences team in Poland.

We are one of the very few full-service, multi-jurisdictional law firms in Poland that offer life sciences clients a broad scope of expertise being also actively engaged in the work of professional associations in the life sciences sector and regularly participating in public affairs projects.

Our Warsaw Life Sciences team provides comprehensive services to all life sciences subsectors, including pharmaceutical, medical devices, food and healthcare.

The team specializes in advising on regulatory issues and product liability matters, as well as on manufacturing, marketing, distribution, advertising, clinical trials and public reimbursement issues.

Regulatory matters	Market access, reimbursement	Product recalls and falsified medicines
Standard Operating Procedures	Educational campaigns	Distribution issues
Advertising, marketing and promotion	Procurement matters	Product liability and contentious matters
Data protection: GDPR breaches	Transactional support	Permits, registrations, licences



**Tier 1:
Life Sciences
& Healthcare**
Legal 500 EMEA
since 2021



**Andrzej Balicki:
Leading Individual
in Life Sciences
& Healthcare**
Legal 500 EMEA
since 2020



**Jolanta Dąbrowicz:
Rising Star
in Life Sciences
& Healthcare**
Legal 500 EMEA
since 2021



Stay tuned and follow us on



www.dlapiper.com