

Accompanying you in a healthy future

Pharmaceuticals & Life Sciences (P&LS) Capabilities



Gateway to the future

Growth markets

PwC Global Pharmaceuticals & Life Sciences Group has identified Turkey as one of the 6 strategic territories. Thanks to their specific qualities, these countries offer possibilities for the growth of pharmaceutical sector.

Mexico

Mexico offers one of the most favourable intellectual property (IP) environments in Latin America

Macroeconomic stability in Mexico is notorious, budget balance and inflation have been kept under control. Mexico offers one of the most favourable intellectual property (IP) environments in Latin America.

Russia

Plans to ramp up local drug production dramatically by 2020...

If things going according to plan, by 2020 around half of the medicines used in Russia will also be made there. The government wants to see export levels rise too.

China

The biggest of the growth markets and still growing fast...

GDP is expected to reach around \$25 trillion by 2025 and the government is working to increase access to healthcare, so there's little doubt that the market in China will continue to grow dramatically.

Brazil

It's time to take a serious look at Brazil's pharmaceutical and life sciences market...

Global pharmaceutical and life sciences companies have already increased their presence in Brazil, but there's still a lot of potential for global and national companies to work together.

Turkey

Regulations in Turkey make partnering locally more important than ever...

With its growing economy and increasing and aging population, Turkey is a significant market. The geopolitical location creates a potential for Turkey to be the regional hub. It is estimated that the pharmaceutical market will double by 2020. However, toll manufacturing regulation makes importing tough. And in Turkey, the government sets the prices. Partnering with companies that know the local market can help global players compete.

India

India's pharmaceuticals and life sciences companies are already having an impact globally...

With undisputed strength in generics, vaccines and API production, some top Indian pharma companies are already earning more than half of their revenues overseas.

PwC Turkey

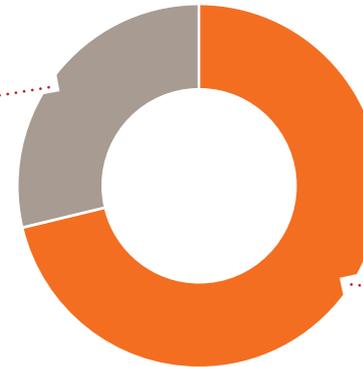
PwC helps organisations and individuals create the value they're looking for. We're a network of firms, committed to delivering quality in assurance, tax and advisory services.

PwC operating in Turkey since 1981, consists of 5 offices; in İstanbul (2), in Ankara, in Bursa and in İzmir, with 1,300 professional staff.

We are the market leader in pharmaceuticals industry with near 100 specialists.

Non clients

29%



PwC clients

71%

PwC Turkey market share of assurance, tax and advisory services in the IMS 2012 company list.

Our priorities in the P&LS industry

Pricing and operational issues

Issues

- Regulated pricing mechanism
- Pressure on margins
- Transfer pricing challenges
- Working capital management
- Cost management
- VAT refund issues
- Supply chain management
- Receivables collection risk from pharmacies and warehouses
- Operational financing
- Foreign currency risk

How PwC can help?

- Performance improvement
- Supply chain management
- Sales force effectiveness
- Portfolio management
- Indirect tax services
- TP documentation /consultancy
- Tax consultancy
- Budgeting
- Risk assesment

Compliance with laws & regulations

Issues

- Ministry of Health's regulations on GMP
- Ministry of Finance Reimbursement list
- Ministry of Environment-distruction of expired goods
- Budgetary concerns; government's intention to reduce pharma spending
- Incentives
- Turkish Commercial Code (TCC)
- Tax matters (TP, VAT Refund, R&D incentives)
- Ethic codes communique
- Ongoing lawsuits
- Copy rights
- e-invoice and e-book keeping

How PwC can help?

- TCC services
- Transfer pricing
- VAT refund
- R&D services
- General tax and legal consulting
- Litigation services
- Social Security services
- ERP implementation
- Internal control services
- Internal audit
- IT data security
- Ethic code compliance
- Other compliance services

Reputation

Issues

- Public relations
- Brand management
- Sustainability reporting
- Forged prescription
- Parallel trading

How PwC can help?

- Sustainability services
- Strategy allignment
- Setting KPIs
- Support on CSR reporting
- Assurance of CSR reporting
- Other
- Forensic services
- Turququality services

Competition

Issues

- Increasing competition
- Increased penetration of license holders
- Market consolidation
- International expansion
- Government opposition to aligning 'patent law' fully with international norms
- Discount requests of pharma warehouses
- Ban on advertisement
- Scarcity of talent

How PwC can help?

- Due diligence services
- Strategy advisory services
- Talent management
- Market entry services
- M&A services
- Turququality services

How can PwC help you?

We are ready to help you to solve your issues with over 100 industry specialists.

Electronic invoicing and electronic ledgers

The Turkish revenue authorities have made, for a certain group of tax payers, electronic invoicing and electronic ledgers obligatory. Electronic invoicing practices became obligatory in 2013 and electronic ledgers will be obligatory as of 2014.

To help companies with their e-invoicing and e-ledger practices, we provide the following consulting services :

- regulation compliance reviews,
- alignment of electronic invoice and electronic ledger practices,
- evaluate the compatibility between the process and control activities for system implementations

Litigation

Our litigation team provides consulting services to pharmaceutical companies during the inspection process to help our clients reduce risks and manage the painful process in the best way possible.

Once the inspection process is complete and you receive the official report, we will work with you to determine your defence points and provide consulting services throughout the reconciliation process.

In case of non-reconciliation, we assist you to prepare petitions that will be submitted to the court. We will follow up until the end of the court process and assist you in implementing the court decisions.

Internal Audit/Internal Control/SoX

With the latest developments around corporate governance both in Turkey; internal control structure, Sarbanes-Oxley (SoX) compliance and internal audit functions have gained more importance than ever before. For such areas, we provide the following services to our pharma and life sciences clients:

- Internal Audit Department establishment
- Internal audit out/co-sourcing support to provide additional resource and expertise to internal audit teams
- Quality Assessment Review (QAR)

of Internal Audit functions to be in line with International Standards of Internal Audit

- Internal controls assessment of business processes
- SoX structure establishment
- Internal controls assessment as part of SoX management testing / financial audit

VAT refund

Drugs VAT rate was reduced to 8%. This means that pharmaceutical companies now face a carried forward VAT burden.

The tax authorities have introduced a VAT refund mechanism, within the scope of exemption, in order to eliminate this burden.

To help our clients, our expert VAT refund team examines the accuracy of the refund amount to identify incorrect VAT practices at an early stage and correct them.

We support our clients with our deep knowledge and experience and help them with an easy and rapid completion of these processes.

Transfer Pricing

Transfer pricing inspections are most common to the pharmaceuticals sector. So, to make these inspections easier, pharmaceutical companies should review their pricing for the transactions with their group companies, determine any potentially risky areas and when necessary, rearrange them in accordance with legislation. Our specialised team is here to help you in determining your risks and the best way to manage these risks.

We work hand in hand with many domestic and foreign pharmaceutical companies.

We:

- assist with the transfer pricing issues you face during your operations,
- help you prepare your obligatory annual transfer pricing reports and
- provide you with benchmark studies.

Our team provides advisory services to many companies and is a thought leader in Advance Pricing Agreements- a huge opportunity to prevent inspection risks in transfer pricing.

ERP & GRC (Governance, Risk and Compliance) Services

Enterprise Resource Planning is the backbone of your company. Early detection of risks is crucial for effective decision making and a well designed ERP system should provide real-time and reliable access to information.

Within ERP&GRC Services, we provide the following services to our pharma and life sciences clients:

- ERP Post/Pre-Implementation Review
- ERP Controls/Security Assessment
- Selection Support of ERP and Implementation Partner
- ERP Conceptual and Logical Design and Quality Review
- ERP Localisation Support
- TFRS Conversion Support
- GRC Implementation Support

Research & Development

Institutions and bodies such as the Scientific and Technological Research Council of Turkey (TUBITAK), the Ministry of Science, Industry and Technology and the Ministry of Finance all provide R&D support to the pharmaceutical sector.

Our team provides R&D consulting services to companies operating in the pharmaceutical sector.

Within the scope of our services

- We prepare R&D incentive applications and we follow the process from beginning to end,
- We prepare financial and technical documents
- We provide consulting services for the R&D centre processes within the framework of compliance to relevant legislation.

We also offer financial and technical consulting services to companies that operate or plan to operate in Technological Development Zones.

We also provide financial and technical assistance with your applications for cash support made to institutions such as TUBITAK-TEYDEB, EU Funds, TTGV and KOSGEB.

Management reporting process design

Management reporting needs to be simple and clear with up-to-date information and a focus on accurate metrics. Companies should be able to access and review the necessary data in a timely manner.

Our Management Advisory team provides support to companies on "Process Design of Management Reporting".

We can help

- Determine corporate performance measurement targets
- Analyse the current situation
- Improve levels of content and detail
- Determine responsibilities and put in place the reporting calendar

Our thought leadership reports



Vision 2023 raporu

PwC Turkey report for the Association of Research-Based Pharmaceutical Companies “Turkey’s Pharmaceutical Sector Vision 2023” contains analyses of countries with successful pharmaceuticals industry as well as suggestions for a roadmap, basic strategies and policies alongside concrete, applicable steps for implementation. In whole, the report provides valuable insight into the potential high growth for the Turkish pharmaceutical sector in the decade ahead.



Pharma 2020 From vision to decision

In this report, we focus on how companies can reach 2020 in a position to benefit from more favourable conditions thereafter.

The pharmaceutical industry is at a critical juncture. The tools to develop remarkable new medicines are materialising, demand for its products is increasing and the barriers to free trade are falling. But pharma also faces major economic and operational challenges, if it’s to capitalise on these opportunities and create more value for healthcare payers, providers and patients.



Pharma 2020 Supplying the Future

Most pharma have complex supply chains that are under-utilised, inefficient and ill-equipped to cope with the sort of products coming down the pipeline. Our report predicts that in order to meet the demands of a fast evolving marketplace and the shift from patient to outcome, the pharma supply chain will need to undergo a radical overhaul.

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