

Pharma & Life Sciences Hot Topics 2020

June 2020



Pharma & Life Sciences – Hot Topics 2020

Equal Salary

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Customs / Brexit / Trade Activator

Responsible Business/
Moderate Immigration Initiatives

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Tax, Regulatory & Digitalization

EU GMP Annex 21

Revised Law on Gender Pay and Equal Salary Certification



What it is about?

- The revised Swiss Gender Equality Act featuring new regulations on equal pay has come into force on 1 July 2020.
- In general, the new rules apply to organizations (including branches of foreign companies) with >100 employees located in Switzerland, if the employment contracts are subject to Swiss law.
- Employers are required to conduct an internal analysis every four years. The analysis will have to be audited by an external expert.
- The government has developed a “snapshot” tool to conduct the analysis. Other scientific methods may be used if they are legally compliant.
- The results of the analysis must be shared with employees and with shareholders if the company is listed.
- PwC works with the independent EQUAL-SALARY Foundation to conduct audits that provide deep insight in potential discrimination of staff throughout the talent life cycle.



Importance for your company

One of the most basic ways to value and recognise people is how we pay them. Research shows that when it comes to compensation, people value pay fairness the most, meaning when compared to their colleagues, do they receive equal pay for equal work? Fairness is fundamental in creating an engaged and high performing workforce. How can people feel valued knowing or believing that someone else is paid differently for doing the same work?



Actions

- Perform an Impact assessment.
- Check or audit compliance with existing laws.
- Become EQUAL-SALARY certified.

EU ATAD



What it is about?

- The EU Anti-Tax Avoidance Directives (ATAD I & II "ATAD") form part of a larger anti-tax avoidance package adopted by the European Union in response to OECD's BEPS action plan.
- ATAD lays down minimum standards for EU Member States, requiring them to change their corporate tax laws in certain areas and within specific timelines in order to tackle tax avoidance practices.



Importance for your company

- ATAD will apply to all taxpayers (including EU permanent establishments of non-EU companies) that are subject to corporate tax in the EU.
- Most of the new rules apply as of 1 January 2019 (e.g. interest limitation rules, general anti-abuse rules, CFC rules, etc.). Additional rules regarding Exit tax and anti-hybrid mismatch rules have been implemented as of 1 January 2020. The rules may have a potential impact in particular on cross-border transactions involving an EU entity.



Actions

- Assess whether ATAD has an impact on your group companies in the EU.
- Country-specific analysis is required since some countries may impose stricter rules or decide on earlier implementation.

Customs/Brexit / Trade Activator



What it is about?

Customs / Brexit:

With the UK leaving the EU, the UK is no longer considered to be an EU country from a VAT and customs perspective, i.e.

- Introduction of new customs border
- Supplies from/to UK
- Check VAT registration obligation in the UK
- EU free trade agreements and potentially regulatory licences are no longer applicable for the UK
- Import / export control

Trade Activator:

- 90% of internationally companies struggle with their customs operations
- On average, internationally companies lose 10% of their total duty spend in overpayments, regulatory fines and inefficiencies



Importance for your company

Customs / Brexit:

All PLS clients doing business in the UK must assess the consequences of Brexit on their business

Trade Activator:

- It is crucial to know how much money the business is spending on international trade (duties, logistic fees etc.)
- Especially for pharma businesses it is important to know if they are compliant with the trade regulations
- Strategic decision can only be made with an accurate knowledge of the supply chain
- Validate the growth strategy based on the current and future customs & trade landscape



Actions

Customs / Brexit:

- Analyze whether you are prepared for Brexit.
- Our “PwC BREXIT Analyzer” tool helps you to assess the impact of Brexit on your business and helps to mitigate risk.
- Analyze in a post Brexit scenario whether new regulatory licenses are required (clinical trial and commercial phase)

Trade Activator:

- The “Trade Activator” Tool helps you to analyze the global trade operations via advanced analytic capabilities

The Responsible Business Initiative / The Initiative for moderate Immigration



What it is about?

The responsible business initiative

(*Konzernverantwortungsinitiative*):

- requests Swiss based companies to respect internationally recognized human rights and environmental standards domestically and abroad.
- stipulates direct liability of Swiss based companies for the behaviour of foreign subsidiaries and suppliers.
- The Swiss parliament agreed upon a (moderate) indirect counter-proposal without a liability but with a reporting obligation and a auditing duty of care (Conflict Minerals, Child Labour).

The initiative for moderate Immigration

(*Begrenzungsinitiative*):

- Requests of a limitation of the free movement of persons between Switzerland and the EU.



Importance for your company

The responsible business initiative

(*Konzernverantwortungsinitiative*):

- Nowadays it is inevitable to address corporate governance issues. It is critical for businesses to comply with these upcoming transparency obligations.
- The popular vote will take place on November 29, 2020 (both councils recommended to reject the initiative, in which case the indirect counter-proposal will enter into force).

The initiative for moderate Immigration

(*Begrenzungsinitiative*):

- May affect access to markets, employment of foreign professionals, etc.
- The popular vote will take place on September 27, 2020 (both councils recommended rejecting the initiative)



Actions

- Impact assessment necessary in the foreseeable future to understand risks and required next steps.

VAT and Clinical Trials / Commercial



What it is about?

Clinical Trials:

Clinical Trials in Europe and VAT - a complex topic with 28 different local VAT regulations:

- Clinical Trials lead to VAT registration and numerous reporting obligations
- Increased complexity in the field of precision medicines

Commercial:

- CJEU's decision on Boehringer case* ("BC") has had broad impact throughout the EU, especially in EU Member States where statutory rebates are imposed for the sale of pharmaceuticals compensated both by public and private health insurers.
- We were directly involved in the BC and happy to leverage the experience on VAT amount successfully reclaimed for pharma companies (up to EUR 1 Mio.)



Importance for your company

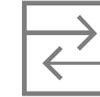
Clinical Trials:

The VAT topics around Clinical Trials are of relevance for all pharma & life sciences companies that perform clinical trials at hospitals / clinics with own investigational medical product ("IMP").

Commercial:

Your pharma company has the opportunity to achieve VAT savings by:

- Correcting the taxable basis taking into account the discounts granted to both public and private health insurers for the sale of drugs
- Filing for VAT refund to reclaim the VAT paid in past periods in relation to discounts on the sale of drugs provided to private insurance companies



Actions

Clinical Trials:

Immediate impact assessment necessary to assess the required next steps, e.g.

- Risk assessment and mitigation
- Implementation of the transactions in the ERP system
- Cash flow optimization
- Value base considerations for imports and intra-community supplies

Commercial:

- Assess the potential for VAT optimization
- Reclaiming "lost" VAT amounts
- Implement changes in your ERP system

Taxation of the Digitalized Economy (BEPS 2.0)



What it is about?

- The OECD/G20 Inclusive Framework (group of 130+ countries) is currently working on BEPS 2.0, a package that has the potential to radically change the current international tax system. In summary: The likely outcome is that more taxes will be levied and/or will be paid in highly populated countries
- In brief, the plan focuses on the creation of a new taxing right and the introduction of a global formulaic profit allocation approach not directly linked to physical presence (Pillar 1) and a mechanism to ensure a minimum level of taxation (Pillar 2)



Importance for your company

- The proposals of the OECD on Pillar 1 specifically target «consumer-oriented» enterprises with B2C sales, however it can not be assumed that PLS companies will not be impacted
- Pillar 2 is expected to impact all international businesses
- The major rules of the project shall be agreed by mid/end 2020 with implementation starting the following year
- Adjustments to current transfer pricing models may be required following the implementation of the new rules
- Additional compliance aspects will need to be considered



Actions

- Assess whether your company is within the scope of the expected regulations
- Perform an impact analysis on your company's effective tax rate
- Brief C-suite on the upcoming changes.
- Stay on top of the further developments

COVID-19 Measures



What it is about?

- The COVID-19 outbreak has been declared a public health emergency of international concern by the World Health Organization causing huge impact on people's lives, families and organizations
- As the national response continues to develop, we know that organisations are facing several risks to which they need to respond rapidly. We are working closely with firms and other organisations in Switzerland and internationally to help them prepare and respond to the different scenarios emerging from the coronavirus-crisis



Importance for your company

All PLS companies should consider:

- Securing their supply chain (clinical & commercial phase)
- Impact on research activities
- Liquidity health check (tax measures also available)



Actions

- Stay on top of the further developments and implement them accordingly (including tax relief/incentives from different countries)
- Review the original signed proof of VAT exemption certificates in general and in particular for your clinical trials (in practice during the COVID-19 lockdown the required original signature on the documents were missing leading to respective tax risks)

SAP S/4HANA



What it is about?

- **Necessary migration:** SAP requires users to migrate their current ERP system to SAP S/4HANA by 2025
- **Tax disruption:** Digital transformation of tax authorities around the world
- **Future of tax functions:** It is recommended to prepare a tax road map to upgrade to SAP S/4HANA. This is also an opportunity to plan for tax automation and compliance in business processes
- Tax is one of the most important stakeholders in terms of ERP data and key in the SAP S/4HANA migration; opportunity for cost reduction, increased efficiency and complying with the digital requirements of tax authorities



Importance for your company

- All PLS companies using currently SAP need to migrate by 2025 at the latest
- Relevant for all PLS clients working in an international environment that have to deal with the digital transformation of tax authorities around the world



Actions

- Analyze the current status of S/4HANA migration
- Identify opportunities for compliance cost reduction and potential areas for increased efficiency

DAC-6



What it is about?

- The amendment to Directive 2011/16/EU on mandatory automatic exchange of information in the field of taxation in relation to reportable cross-border arrangements (DAC-6 for short) imposes mandatory disclosure requirements for certain arrangements with an EU cross-border element
- Disclosure is required where the arrangements fall within certain "hallmarks" mentioned in the directive and in certain instances where the main or expected benefit of the arrangement is a tax advantage



Importance for your company

- DAC-6 will have far-reaching consequences for tax advisors, service providers and taxpayers – including organisations and individuals in Switzerland and Liechtenstein
- PLS companies are particularly affected due to their specific characteristics that are often prone to fulfil one of the defined "hallmarks" triggering reporting requirements (e.g. in the case of transfers of intangibles between group companies)



Actions

- Develop a systematic approach to capture, identify and monitor cross-border arrangements as of 25 June 2018 (effective date of directive)
- Get ready for initial reporting by 1 July 2020
- Introduce appropriate processes to ensure compliance and avoid penalties on an ongoing basis
- Our DAC-6 technology might help you in the information gathering and reporting process

Swiss Tax Reform and AHV Financing (STAF)



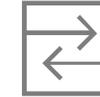
What it is about?

- The reform entered into force on 1 January 2020 and includes the abolition of cantonal tax privileges (Mixed company and Holding company regime), principal taxation (according to Circular 8) and the tax rules for Swiss finance branches (and entities) and also introduces new measures such as the patent box, special deduction for R&D costs, notional interest deduction (ZH only) and a step-up transition mechanism
- In addition to the reform measures, most of the Cantons decreased the corporate income tax rate substantially as per 1.1.2020



Importance for your company

- The Swiss Tax Reform measures can trigger a profound change in the tax burden of a company in Switzerland
- In particular, many multinational companies in the PLS industry with a Swiss footprint are affected by the reform as those companies benefitted from tax privileges, principal allocation or finance branch taxation



Actions

- Analyze which of the reform measures are relevant for your company
- Impact analysis of individual elements of the tax reform on the effective tax rate, including:
 - Modelling of potential patent box and special deduction for R&D costs
 - Modelling of transition rules (step-up)
 - Modelling of potential notional interest deduction on equity (ZH only)
 - Modelling of effects on annual capital tax
- Depending on the outcome of the analysis file and negotiate tax rulings

Pension 1e



What it is about?

- Possible pension offering for salaries above CHF 127'980 (limit according to Swiss pension law)
- Employees choose up to 10 different investment strategies for their pension assets, including a “low-risk” strategy. Risk and reward of investment process fully with the employee
- Defined contribution (DC) accounting according to IAS 19 possible if some key criteria are fulfilled



Importance for your company

- While not being industry-specific, a clear trend towards these pension funds (a recent report of a 3rd party advisor showed that 25% of SMI companies have already migrated into a 1e setup). A PwC survey shows significant growth of these plans
- 1e pension plans offer many pro's from both an employer and employee perspective. Employer: no risk of underfunding, classification as Defined Contribution (DC) plan under IFRS possible, increased employee engagements in plans – value for money on corporate spend, fewer subsidies between the insured members than traditional plans



Actions

- Check if your company has the right ‘ingredients’ to implement a 1e plan, which usually **(but not necessarily)** are:
- a significant number of higher earners
 - account under IFRS or US GAAP

Business Travellers



What it is about?

- Mobile employees now include all types of mobility, from assignments to relocations, from transfers to commuters, travellers and virtual workers impacting as much as 80% of the company's global employee workforce
- BEPS, growing protectionism trends and digitalization are fundamentally changing the mobility regulatory landscape. Tax and immigration authorities are becoming more assertive by leveraging technology and obtaining greater oversight
- Mistakes and non-compliance may result in penalties, delays, or refused travel, as well as reputational damage and negative scrutiny



Importance for your company

- Mobile employees pose risks across a multitude of areas including Corporate Tax, Employment Tax, Immigration and Social Security. Regulatory changes like the BEPS project and increasing scrutiny from national tax and immigration/border authorities mean that the time is right to ensure that compliance obligations are met and risks are managed
- Keeping a larger traveller population compliant across a wide array of jurisdictions can be incredibly difficult and time-consuming



Actions

- Establish a process with roles and responsibilities
- Perform a "health check"

Revision of the Company / Stock Corporation Law



What it is about?

The aim of the revision of the stock corporation law is the following:

- to make the founding and capital regulations more flexible (e.g. interim dividends will be permissible),
- to strengthen shareholders' rights and
- to moderately regulate remuneration regulations and
- to introduce new director liabilities in situations of financial distress and
- to modernise company law and adapt it to the economic needs of the coming years.
- The draft also proposes gender related guidelines for large listed companies and provisions for regulating transparency in economically significant companies active in the commodity sector



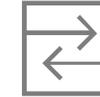
Importance for your company

In June 2020, the Parliament adopted the reform of the stock corporation law, which affects AG/Ltd and GmbH/LLC but also Genossenschaften/Cooperatives, Associations and Foundations.

The Reform is not supposed to come into force before the second half of 2021, but may soon thereafter.

Various topics from this revision could be relevant for your company in the foreseeable future, such as:

- Director liabilities re liquidity management
- Gender quotas
- Changes/flexibilization to nominal capital
- Improved shareholder rights
- Interim dividends possible
- Virtual general assembly
- Restructuring law



Actions

- Analysis of individual elements of the revision of the stock corporation law, regarding relevance and new possibilities for your company, and identify potential for improvement (e.g. more flexible capital base by creating flexible share capital within a certain range, virtual general meeting)
- Transition period:
 - Articles of Association: 2 years
 - Gender Quotas in the Board: 5 years
 - Gender Quotas in the Management: 10 years
 - Transparency for commodity companies: 1 year

Tax, Regulatory & Digitalization



What it is about?

- The digital transformation represents a new stage in the organization and control of the industrial value chain
- Also the tax and health authorities went digital:
 - The centralized European database for pharma (EU GMP Annex 6 & 16) and medtech products (revision of medical device regulation in the EU) heralds a new era of tighter control and surveillance
 - More and more European countries implement digital tools to control the VAT transactions of the tax payers (e.g. real time reporting and e-invoicing in Italy in 2019)



Importance for your company

- The digitalization of the tax and health authorities leads to an increased transparency of your PLS supply chain for tax and regulatory purposes
- Therefore it is important that digitalization approaches are considered for your company that help you complying with the new ways of electronic filing, staying up to date with the upcoming changes in legislation and bringing you to the next level
- PLS companies should be prepared for the next digital audit in tax & regulatory



Actions

- Our four cutting edge digital tax & regulatory solutions may add value to your business and help you to comply with the new mandatory disclosure rules and ensure compliance and transparency in a lean, time and cost effective way:
 1. The “PLS Regulatory Radar” keeps you up to date with regulatory developments
 2. Data analytic tools aggregate and reconcile your PLS data in order to be ready to be transmitted electronically
 3. PLS blockchain solutions empowers you to digitize the transaction workflow and reporting requirement by linking blockchain technology and business processes
 4. Legal document engines for clinical trials and commercial contracts digitize, automate and optimize your legal processes

EU GMP Annex 21



What it is about?

- The European Commission published the draft version of the new EU GMP Annex 21 on 20 March 2020. Apart from the main Chapters and Annexes of the EU GMP Guide, it has become necessary to establish specific guidelines for the activity of importing medicinal products
- The Annex summarizes the principles and guidelines of good practice requirements that apply to holders of a manufacturing and import authorisation (MIA) who import medicinal products (human and veterinary) from outside the EU/EEA borders and thus from third countries
- The issue of "fiscal import" is no longer addressed in the current draft
- The deadline for coming into operation still needs to be determined
- However, the EU Member States started implementing local regulation in a decentral approach



Importance for your company

- Since the "fiscal import" of drugs into the EU (e.g. flow of invoice from a non EU/EFTA established pharma company to another company established in the EU) is no longer addressed in the draft EU GMP Annex 21, local implementations of the rules in each of the 28 EU Member States have to be analysed
- Respective adaption in the supply chain are required:
 - Corporate tax (shift in taxation, permanent establishment risk)
 - Legal (agreement)
 - ERP (VAT Codes)
 - VAT (registration obligation and invoicing, fixed establishment risk)
 - QP release topics have to be considered



Actions

- Analysis on a country by country approach, whether your sale of drugs is affected from the local changes
- Identify potential improvement in the supply chain from a regulatory, tax and legal perspective
- Ensure compliance and mitigate stock out risks

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“Every brilliant experiment, like every great work, starts with an act of imagination.”

Jonah Lehrer

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