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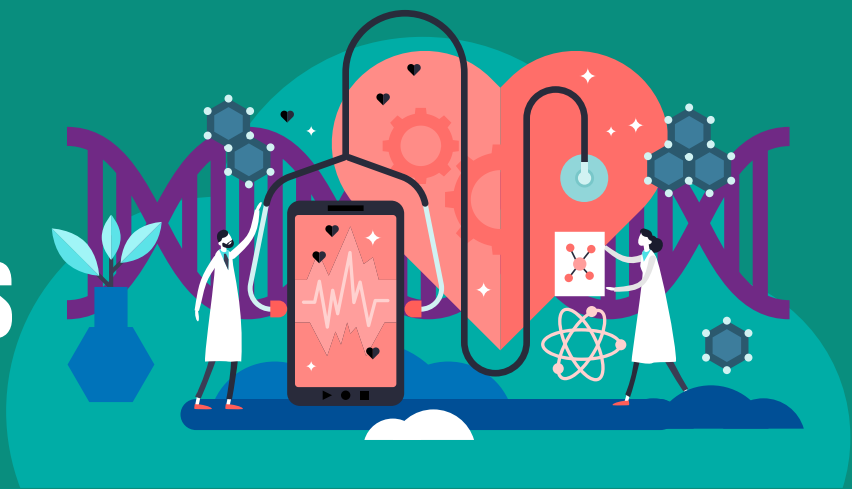
Life Sciences

Tax Newsletter



About the newsletter

Life Sciences Tax newsletter is our initiative to share informative tax insights, important developments and interesting interviews with business leaders focusing on the ever-evolving field of life sciences.

Foreword by Santosh Dalvi

Our aim with the tax newsletter is to give a holistic and in trend perspective on the life science and pharma sector. With this in mind we are glad to release our second edition of the newsletter which entails insights from our sector experts on global developments, recent mergers and acquisitions in the pharma sector, cost on expired goods and many more such relevant topics.

Track and Trace – Global Developments

Background

Circulation of counterfeit or substandard drugs are a serious threat in the pharmaceutical and healthcare industry. The effects of such substandard drugs may fail to treat an intended diseases causing adverse health consequences. As per the World Health Organisation (WHO) , anti-malarial and antibiotics are amongst the most reported substandard and falsified medical products.

In 2012, Turkey became the first country in the world to implement the end-to-end pharmaceutical track and trace system in order to secure the domestic pharmaceutical supply chain . After this successful implementation, countries such as United States, China, European Union member countries and Russia are making efforts to implement the end-to-end pharmaceutical track and trace system.

Globally, various organisations and government agencies are collaborating to ensure medications are safe, efficacious and are produced using the highest quality ingredients. To maintain the integrity of the supply chain and eliminate the usage of counterfeit medication, track and trace model can help the industry to combat counterfeit drugs.

Track and Trace model essentially involves 'tracking' a forward view which can track a product/drug in the supply chain as it moves through the supply chain. Tracing is more of a historical view i.e., tracing the ownership of product/drug.

1. Substandard and falsified medical products, World Health Organisation Website, January 2018
2. Open Access

Track and Trace – US[3]

On 27 November 2013, the Drug Supply Chain Security Act (DSCSA) was signed into U.S. law, which outlines critical steps to build an electronic platform so that a particular drug can be viewed and traced right from initial manufacturing to dispensation. This model could also be useful to send an alert amongst the trading partners if a product/drug is recalled. In this model, the members of the pharmaceutical supply chain are required to verify, track and trace prescription drugs as they are distributed within the United States[4].

There are key requirements underpinning the implementation of track and trace in the US pharma industry:

Authorized trading partner: The trading partners in the supply chain will be required to have a valid FDA registration or license (state or central/federal), as applicable

Product identification (serialization): DSCSA's regulations prescribed specific requirements of serialization of drugs wherein the Market Authorisation Holder (MAH) are required to encode unique serial numbers

Product tracing: Receiving and providing transactional documentation for each package through a serial number

Verification: Checking at any single point in the supply chain that the unique identifier printed on the item is assigned by the product manufacturer.

The US Food and Drug Administration (FDA) has undertaken critical measures by building a roadmap to implement an interoperable and electronic tracing of product. A particular drug can be viewed and traced right from initial manufacturing to dispensation. This model could also be useful to send an alert amongst the trading partners if a product/drug is recalled.

Track and Trace – European Union

The European Council and European Parliament has published Falsified Medicines Directive (FMD) to tackle the circulation and distribution of falsified medicines in the european union jurisdiction[5]. The measures inter alia include:

- Obligatory safety features – a unique identifier and an anti-tampering device - on the outer packaging of medicines
- Common, logo (EU-wide) to identify legal online pharmacies
- Tougher rules on import of active pharmaceutical ingredients
- Strengthened record-keeping requirements for wholesale distributors

EU stakeholders from across the medicines supply chain are working together to implement a national system to ensure compliance with the FMD i.e., rules to protect from fake medicines in the European Union (EU). Accordingly, various toolkits are developed as guidance for healthcare providers to help them prepare for the implementation of FMD.

3. FDA DSCSA Blockchain Interoperability Pilot Project Report, IBM-KPMG-Merck-Walmart, February 2020
4. Counterfeit Medicine, US Food and Drug Administration website, 2 March 2022
5. Falsified medicines, European Commission website

Track and trace – Russia

Russia's track and trace model known as Chestny ZNAK (operated by Centre for Research in Perspective Technologies or 'CRPT') is in pilot process of testing and implementation phase and is set to be fully operational in 2024. The Chestny ZNAK requires products to be marked with 2D data matrix codes with an 85-character alphanumeric sequence. In addition, the owner of the goods will also be required to create a Universal Transfer Documents at the moment of ownership. In addition to the US DSCSA's and EU FMD requirements, Chestny ZNAK requires over-the-counter drugs to be labeled, scanned, and recorded in the system. Chestny ZNAK track and trace requirements have a possibility to cover all types of products (including pharma products).

Track and trace – India

The Directorate General of Foreign Trade (DGFT) has incorporated implementation process for track and trace system for export of pharma and drug consignments. The Government of India has developed an online portal – DAVA (Drugs Authentication and Verification Application) which follows a GS1 standard traceability system.

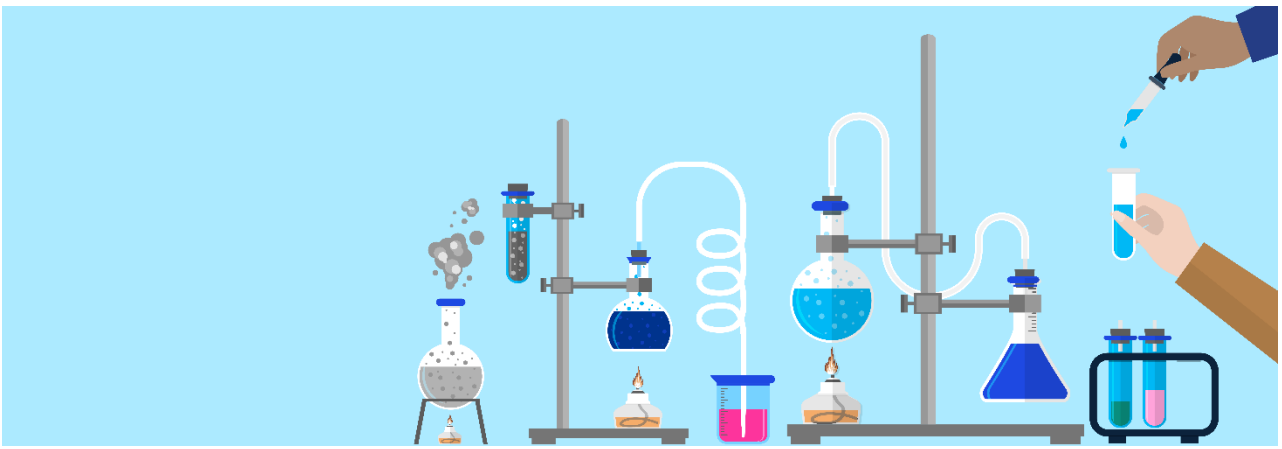
The manufacturers and exporters are required to barcode their products using GS1 standards along with the batch number, expiry date to facilitate authentication of exported drugs. They are also required to upload data of barcodes on secondary and tertiary packaging of exported drugs on the iVEDA portal[7]. Considering the technical glitches on DAVA portal, DGFT had extended the implementation of track and trace system for export of drugs till 1 April 2023.

Implications – Tax and beyond

The movement and tracking of free goods, expired goods and returned goods are critical and have an implication on compliances mandated under both the direct tax and indirect tax legislations. The Track and trace mechanism would provide useful data points to manufacturers and distributors to cross verify their accounting records and various tax filings.

However, solving this interoperable solution of track and trace for pharmaceutical products will require a fundamental consideration for governance between the trading partners. To foster industry adoption, an inclusive and open-sourced commercial solution could help to launch a blockchain/any other network intended for information exchange of the pharmaceutical product transactions. However, uniting the industry around this concept will be a challenge.

Implementing a track and trace model will enhance patients' safety and eliminate circulation of counterfeit or substandard drugs, through efficient end-to-end product traceability and visibility for all supply chain participants. Highlighted above are key jurisdictions over the globe which are stepping up towards implementing the track and trace model to combat the counterfeit drugs regulations. Pharma companies, especially for Indian headquartered groups, will face new information needs, operational process changes, and network orchestration.



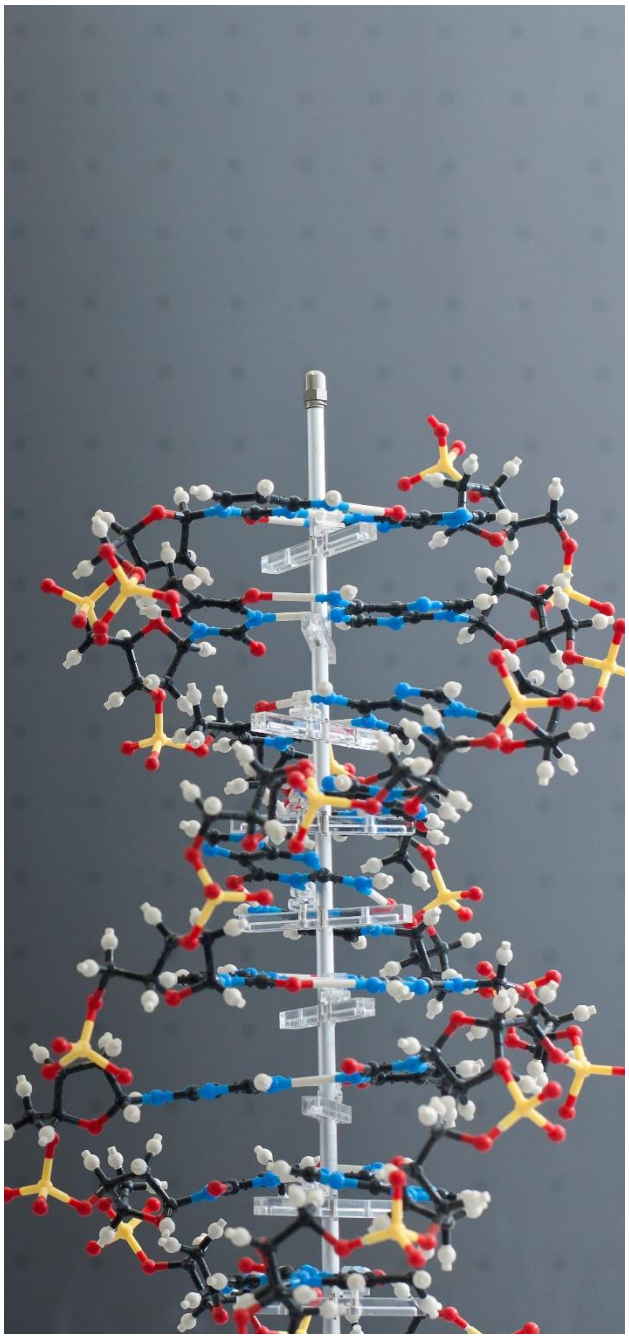
6. What you need to know about russia's pharma serialization regulations, Blog – OPTEL,

7. Integrated Validation of Exports of Drugs from India and its Authentication (iVEDA) portal

Indian multi-generational family businesses – A rare phenomenon

Authored by Kalpesh Desai, Partner, M&A and PE Tax, KPMG in India and Akshika Harikrishnan, Director, Family Office and Private Enterprise, KPMG in India With inputs from Aditya Menon, Assistant Manager, Family Office and Private Enterprise, KPMG in India

Family business dynamics have evolved considerably. With several stakeholders and varied perspectives and expectations, conflicts in a family business are inevitable. Egos and misunderstandings, sometimes, lead to breakdown of relationships, long drawn court battles, reputational damage, erosion of value and eventually partition of the business. There are several instances of family business owners in India parting ways and reiterating statistics, only 12per cent of family businesses make it to the third generation and a mere 3per cent to the fourth generation[1]'



Some of the reasons for conflicts may be differences in points of view amongst a generation or between current and next generation, lack of alignment of strategy and vision, no governance and clarity, absence of a clear succession plan and accommodating non-competent family members in the business. In the Indian context, Professor John Davis of Harvard Business School who teaches an elective course on Managing the Family Business, has opined that "India has seen the decline of the joint family in business houses, which has been replaced by a loose system of living independently in proximity." This trend of moving from a joint family concept to a nuclear family concept may have also contributed to different experiences and growing complexities in working together in the family business.

Having said this, there are still several family businesses in India that have perpetuated for generations. But they are still a rarity in comparison to countries like Japan and Germany where family businesses have survived for well over 200 years and in case of some of the oldest family businesses have been passed down over 50 generations.

So, what is the secret to the survival and longevity of these multi-generational families?

While Japan follows an approach of single leadership and ownership, in Germany, founder families tend to retain majority shares and control. However, at the heart of multi-generational families are strong family values which are also translated into the business. There is a sense of shared purpose and to maintain the legacy of the founder. Late U.S. Senator Robert F Kennedy said, "Every generation inherits a world it never made; and, as it does so, it automatically becomes the trustee of that world for those who come after." In multi-generational families, members have a long-term mindset, a common stated vision and consider themselves as stewards of the family business.

Another key characteristic is putting the business first. While 'family' is the essence of a family business, it is important to balance the needs of the family with that of the business. Family members acknowledge that each of them plays different roles. However, it may not be necessary that everyone would be involved in the business. We have seen merit taking precedence over lineage. As the business grows, just family leadership may not suffice and there is a necessity to bring in external professionals not just in management but also by expanding the board with independent directors. We believe that as the business evolves, the leadership would also need to evolve in tandem.

We have also seen that despite different upbringings and varied experiences, members of multi-generational families consider themselves as one family organisation. A third-generation family explained that they departed from the mindset of family branch and adopted the philosophy of 'One Family' based on the founding value of meritocracy. They embrace differences of opinion, agree to disagree and strive for majority rather than consensus. To encourage family bonding, the members meet once every month over Sunday lunch and organise an annual retreat. They also recognised the need to build strong working relationships amongst cousins and formed a next generation committee which focused on the incoming generation collaborating and working together from an early stage.

Summing up, to sustain the family business for generations, it is vital to articulate and formalise the informal and unwritten understandings in a family constitution. This not only brings clarity of roles and level of involvement (as owner vis-à-vis board member vis-à-vis management) of the current generation but more importantly helps subsequent generations appreciate the family history and reinforce the responsibility of sustaining the legacy which was built on entrepreneurship and a strong foundation of values. A robust governance framework strengthens communication, builds trust, minimises potential conflicts and lays the foundation to perpetuating the family business.

A version of this article appeared in The Economic Times Online on 20 June 2022

Tax cost of expired pharmaceutical goods – An unresolved anomaly

Introduction

Our article on track and trace above covered DAVA (Drugs Authentication and Verification Application) system developed by Indian Government wherein the manufacturers and exporters are required to provide data to facilitate authentication of exported drugs including expiry of products which is a very important factor for pharmaceutical goods. Close to 1.5 per cent (USD 63 million) of medicines out of the $42 billion domestic pharma market either expire or have to be destroyed due to unfavorable conditions during manufacture, transit or storage, each year resulting in huge wastage and losses[8].

To add to this, on the regulatory front, the Drugs and Cosmetics Rules, 1945 provides that no drug shall be sold or stocked by the licensee after the date of expiration or in violation of any statement or direction recorded on its container, label or wrapper. Such goods are typically returned back to the manufacturers for disposal as per the manner prescribed in the Bio-Medical Waste Management Rules, 2016.

Further, on tax front, the said expiry/destruction/ wastage is a cost to the sector including its applicable indirect taxes both in the erstwhile indirect tax regimes as well as under the current GST regime. Adding fuel to the fire, the GST law[9] does not provide clarity in certain situations potentially leading to duplication of GST cost.

Treatment under GST law for expired goods

Under the GST law, GST Input Tax Credit ('ITC') is not available to the taxpayer in respect of the goods destroyed. Given the above, in this article, we seek to analyze ITC reversal for destruction of expired goods in various scenarios"

Types of expiry destruction and value to be considered for reversal

Major types of expiry destruction could be categorized as under:

A. Expiry and destruction of inputs at the factory of manufacture without being put to use
B. Expiry and destruction of finished goods at the factory of manufacture, warehouse or distribution locations
C. Expiry and destruction of finished goods sold to customers (distributors) and returned

GST law does not expressly provide for the value of reversal in the case of destruction of goods. Therefore, aid needs to be taken from the restriction provision itself which provides that the ITC 'in respect of' goods destroyed should not be available. That is, the GST paid on the procurements 'in respect of' goods destroyed needs to be reversed.

Various practical scenarios

1. **Expiry and destruction of goods without being put to use:**

Taking the above further, in case of inputs or other procurements expiring and being destructed at the factory or procurement locations without being used/further transferred, the value of ITC reversal may be taken as the ITC availed on purchase of these goods.

2. **Expiry and destruction of manufactured goods (before sale):**

   Further, in case of expiry and destruction of manufactured goods (finished/intermediate goods) at factory, the ITC in respect of such goods may be construed as the cost of manufacture of such goods. For this, reference may be taken of Bill of Material for manufacture or Cost Accounting Standard 4 or any other means to derive the cost of goods manufactured (including direct overheads/services). Also, in case the manufactured goods are transferred to other state locations, the ITC reversal may be considered basis the transfer value. If the transfer value is less than the cost of goods manufactured, reference may be taken of cost of goods manufactured as the ITC in respect of manufactured goods qua an entity is more coherent than qua a registration.

8. Blog of Lakshmi Ajay (Associate Editor, STAT Media Group)
9. Central Good and Services Act, 2017, Integrated Goods an Services Tax Act, 2017, respective State Goods and Services Tax Acts including rules, notifications, circulars, clarification etc. thereto.

3. **Expiry and destruction of goods returned (sales returns before expiry):**

   In the cases where finished goods are sold to distributor / customers, returned before expiry (near expiry returns) and destroyed at the manufactured location, returns of goods may happen basis GST credit note or supply invoice (to ensure clear flow-back of ITC throughout the reverse chain of supply i.e. DEPOT – distributor - stockist / dealer. In such cases, reference may be taken of cost of goods sold or GST ITC availed on reverse supply invoice depending upon the mode of return.

   In case the said returns are routed back throughout the return supply chain (i.e. dealer / stockiest – distributor – company depot) basis commercial credit notes bearing value of goods and GST both, it may lead to duplication of GST tax cost similar to scenario 4 discussed below.

4. **Expiry and destruction of goods returned (sales returns after expiry):**

   The scenario complicates when the goods are sold to distributor / customer and are returned after expiry. In these situations, the distributor / stockiest / dealer cannot route the goods returns through a supply invoice due to regulatory constraints. Therefore, in the cases where GST credit note timelines have lapsed, the said returns are routed back throughout the return supply chain (i.e. dealer / stockiest – distributor – company depot) basis commercial credit notes bearing both the value of goods and GST thereon. The further transfer of return goods from company depot to factory/destruction location (in another state) can be explored basis delivery challan basis the argument that there can be no 'supply' of expired goods. This is also because already expired goods have no marketability owing to the above stated regulatory reasons and therefore, there is no market or any value for these expired goods. Now when these goods are incinerated / destroyed at the factory, the question of reversing the GST ITC towards such destruction should not arise as:

   1) there is no GST levied or ITC taken on return of these goods from the distributor / customer; and

   2) the company has already indirectly suffered reversal in terms of compensating the GST amount to distributor / customer and not being able to avail the GST ITC / adjustment of the same.

As the GST law does not provide required clarity on this, the industry currently is facing challenges where the tax authorities are demanding ITC reversal on expiry destruction at factory / destruction location in the above scenario leading to duplication of tax cost. This could be addressed by having strong standard operating procedures and appropriate documentation including documentation to substantiate that the commercial credit note issued to distributor / customer includes GST amount.

Further, the above scenario becomes more complex if the transfer of goods from company depot to factory/destruction location (in another state) is done basis tax invoice. In this case also there could be duplication of tax cost:

1) First - when commercial credit note is issued along with the GST to the distributor/ customer, the said GST amount becomes a tax cost as ITC or tax adjustment towards the said GST is not available to manufacturer.

2) Second - Reversal of ITC pertaining to GST charged by depot to factory/destruction location as the goods suffering tax & ITC are destructed.

The above situation can be avoided by the industry by ensuring that tax invoice is not issued for transfer from depot to factory/ destruction location in other state basis the argument that there can be no supply of expired goods. Also, it may be explored to route the returns throughout the reverse supply chain (i.e. dealer / stockist – distributor – company depot) through a tax invoice with a concurrence / clarification from the regulatory bodies that the said invoice is not for sales but return of expired goods.

Conclusion:

In view of the above discussions, manufacturers should set up a Standard Operating Procedure (SOP) in relation to return and destruction of expired goods, along with necessary supporting documents to substantiate the value of reversals.

Being an industry issue, industry representation should continue for issuing the necessary and express clarifications for not only removing potential duplication of tax cost but also for removal of tax cost altogether as expiry destruction is a normal business expense in the pharmaceutical industry. A simultaneous clarification from regulatory authorities on issuance of invoice for return of expiry goods should also be of umpteen help to the industry.

Did you know?

Did you know the famous author Agatha Christie was a pharmacy technician before becoming a writer. She used her pharmacy experience as inspiration for her mystery stories involving poisons.

Happy Reading!

KPMG in India contacts:

Santosh Dalvi
Partner & Deputy Head,
Indirect Tax
KPMG in India
T: +91 22 3090 2685
E: sdalvi@kpmg.com

home.kpmg/in

home.kpmg/in/socialmedia