Digital Passport Solutions

Pharma Passport Solution

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Agenda

1. Introduction to Context & Problem
2. Key Pharmaceutical Regulations
3. Market & Competitor Analysis
4. Atos' TruCycle Ecosystem
5. Pharma Passport Solution Overview
6. Conclusion & Way Forward

Context & Problem Statement

Exactly what are fake drugs or counterfeit medicines?

Counterfeit medicines enter the market through complex supply chains

Solution: Authentication Tools

Solution: Authentication Tools

What is Fake Medicine?	Risks and Impacts of Fake Medicines:	Types of Medicines Commonly Counterfeited:	How Fake Medicines Enter the Market:
Incorrect or Missing Ingredients: • Wrong or incorrect amounts of active ingredients. **Harmful Substances:** • Can include contaminants. **False Labeling:** • Packaging misrepresents brand, manufacturer **Incorrect Dosages:** • Contains too little or too much of the active ingredient. **Poor Quality:** • Fails to dissolve or made in unhygienic conditions.	**Health Risks:** • Treatment failure, worsening of illness, adverse reactions, and even death. **Economic Impact:** • Revenue loss for legitimate pharmaceutical companies and additional healthcare costs due to ineffective treatment. **Public Trust:** • Undermines confidence in healthcare systems and pharmaceutical brands.	**High-demand Drugs:** • Painkillers, antibiotics, antivirals, and treatments for chronic diseases (e.g., diabetes, cancer, heart conditions). **Vaccines and Biological Products:** • Particularly during pandemics or health crises (e.g., COVID-19 vaccines). **Lifestyle Medicines:** • Erectile dysfunction drugs, weight-loss supplements, and anabolic steroids.	**Weak Regulatory Oversight:** • In countries with limited resources for drug monitoring and enforcement. **Complex Supply Chains:** • Multiple intermediaries increase the risk of substitution or infiltration. **Online Pharmacies:** • Unregulated websites often serve as major distributors of counterfeit medicines.

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Global Problem: WHO highlights the need for harmonized strategies & tools and innovations like digitalization and traceability systems

- **Scale of the Problem:** Up to 10% of medicines in low- and middle-income countries are counterfeit, with higher prevalence in regions with weak healthcare systems.
- **Threat to Public Health:** Counterfeit medicines lead to treatment failure, harmful effects, or death, especially in critical treatments like antibiotics, vaccines, and cancer drugs.
- **Financial and Economic Impact:** Substandard and Falsified (SF) medicines **burden healthcare systems with extra costs and harm pharmaceutical companies through revenue losses and reputational damage.**
- **Regulatory and Operational Challenges:** Insufficient regulatory frameworks and supply chain vulnerabilities (e.g., unsecured transportation, inadequate distributor oversight) exacerbate the issue.
- **Online Risks:** 50–90% of medicines sold via unregulated online platforms are counterfeit, increasing risks for consumers.
- **Lack of Global Collaboration:** The absence of harmonized global strategies and tools hinders progress; WHO highlights the need for innovations like digitalization and traceability systems.
- **Vulnerable Populations:** Poor and remote communities disproportionately rely on unsafe sources, deepening health and social inequalities.

Source: A study on the public health and socioeconomic impact of substandard and falsified medical products 2020; 2024/11/19

Global Problem: fake drugs or counterfeit medicines impact

WHO issues warning on falsified medicines used for diabetes treatment and weight loss

WHO, 2024

Counterfeit prescription medicines have become a $200 billion illicit global business annually. The types of drugs being peddled range from chronic medications for diabetes and heart disease to cancer drugs and antiretrovirals for HIV. At the same time, counterfeit prescription medications laced with fentanyl are being sold on the internet and social media, causing an uptick in fatal overdoses across the US.

Pfizer, 2024

„Since 2017, they [Novartis] ascertained that **over 90% of the falsified medicines tested would have caused serious harm,** which could have potentially killed patients.“

Novartis, 2020

HEALTH

Warning about fake medicines

The global association of scientific academies warns of the increasing trade in counterfeit vaccines and medical products. Such fake medicines could cause up to a million deaths per year.

ORF, 2020

Stop counterfeit medicines

There have not yet been any deaths in Germany caused by counterfeit medicines. However, every counterfeit medicine endangers health - and the danger from online pharmacies is growing, warn manufacturers, the police and the Ministry of Health. Counterfeit medicines are no longer limited to developing countries - globalization and online trading have made them a worldwide problem. Every second product bought over the Internet is counterfeit. Counterfeit medicines generate at least as much profit as the drug trade.

Deaths are often difficult to trace back to counterfeit medicines; however, in developing countries it is estimated that around 1 million people die each year.

German Doctors, 2024

Bayer // Global

This is Bayer · Health · Agriculture · Products · Innovation · Sustainability

Home › Health › Medical Counterfeits

Beware of Counterfeits

Medical Counterfeits

Counterfeit drugs are a global threat. Patients who buy online or abroad increasingly fall prey to counterfeit drug scams. Worst case, such fakes can endanger the health of unsuspecting users or even be life-threatening.

Bayer, 2024

Some 95% of websites offering prescription drugs operate illegally, according to the National Association of Boards of Pharmacy.

How serious of a problem is the counterfeiting of prescription medicine?

- Counterfeit Pfizer medicines have breached supply chains in 60 countries.
- In countries generally considered "safe," such as Canada, the United States, and many of the European Union, counterfeit medicines have entered the supply chain, including, but not limited to counterfeit Lipitor®(atorvastatin calcium), Norvasc® (amlodipine), Viagra® (sildenafil citrate) , Zithromax® (azithromycin) and Celebrex® (celecoxib).
- During 2017, authorities from 49 countries seized more than 12 million dosages of counterfeit Pfizer medicines. Many of the raids resulted from leads developed by Pfizer Global Security.
- However, it is not just Pfizer whose medicines are being counterfeited. Based on Pharmaceutical Security Institute (PSI) data, counterfeit medicines were confirmed in 153 countries.

Pfizer, 2024

The newer WHO reports post-2020 expand on previous findings

Emphasis on new priorities and solutions like digital product passports

Specific problem: vulnerabilities in the Pharmaceutical industry Supply Chain

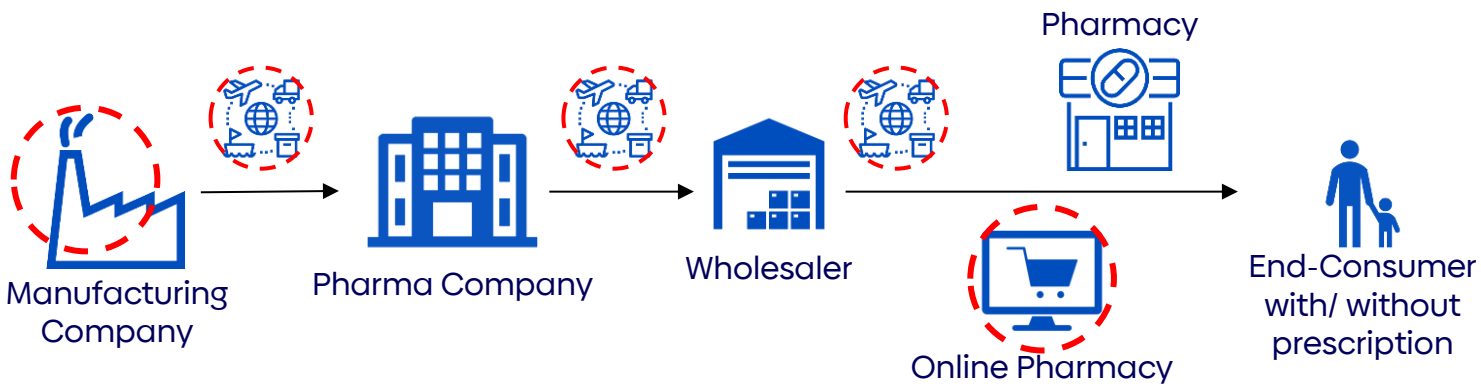
- **Urgency due to COVID-19:** Counterfeit COVID-19-related products have highlighted vulnerabilities in the supply chain.
- **Digitalization as a Solution:** The WHO published in its List of Prioritized Activities (2022–2023) greater emphasis on digital tools like **blockchain and digital product passports (DPPs)** as critical for securing the supply chain as a short-term goal (1-2 years).
- **Regional Adaptation:** There is increased focus on region-specific approaches to combating counterfeit medicines.
- These insights underscore the importance of modern technologies, such as **Digital Passport Solutions,** to close existing gaps and address emerging challenges effectively.

Source: WHO Global strategy on digital health 2020-2025 9789240020924-eng.pdf p.8ff; 2024/11/19

Where do fake drugs or counterfeit medicines join the Supply Chain?

Supply Chain efficiency and reliability directly impact the overall performance and success of the industry

Specific problem: vulnerabilities in the Pharmaceutical industry Supply Chain



Current implementation of controls and authentication:

- Raw material inspection before production
- Authentication features are applied and checked during production
- Random checks at wholesalers on incoming goods and onward transportation
- Authentication in the pharmacy via specific scanner
- Printing and labeling via specific printers in the production process

Source: Securpharm; BPI; Scanner

Companies that invest in supply chain innovation and optimization can gain a competitive edge by offering **faster delivery times, higher product quality, and enhanced customer service.**

A well functioning supply chain can contribute to:

- Improved patient outcomes
- Cost savings
- Regulatory compliance
- Competitive advantage

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Problem Statement and Context involving all Key Stakeholders

Vulnerabilities in the Pharmaceutical Industry Supply Chain

Who?

Who does the problem impact?

- End-Consumer
- Pharmaceutical Companies
- Pharmacies
- Distributors
- Government & Authorities

What?

What are the drivers of the problem?

- High profitability of counterfeit drugs[1]
- Complex Supply Chains
- Online Pharmacies
- Lack of Patient Awareness
- Technological Gaps for secure Tracking of Medicine
- Demand for cheap Medication
- Advanced Counterfeiting Techniques

Why?

Why is solving the problem important to stakeholders and the business?

- Consumer: Health Risk
- Pharmaceutical Companies: Liability and Reputational Risk
- Distributors: Liability
- Government & Authorities: Public Health Costs and Enforcing Regulations

Where?

Where does the problem have an impact?

- Healthcare and Patient Safety
- Pharmaceutical Industry (revenue losses and reputational damage)
- Law Enforcement

When?

When does the problem need to be solved?

- As soon as possible, mainly due to:
  - Ongoing Public Health Risks
  - Worldwide legal factors and regulations
  - Increasing end-consumer demand

How?

How was the problem created?

- Demand for affordable Medication
- Lack of Supervision
- Weak Regulatory Frameworks
- Unlicensed online Pharmacies

How can the problem be solved?

- Implementing Traceability Systems
- Strengthening Regulations
- Innovation in Digital Tools
- Raising Awareness

[1] Abda Faktenblatt Arzneimittelfaelschungen

Key Pharmaceutical Regulations

Legal Factors in the EU

Regulations in the Pharmaceutical Industry

1. **EU Directives and Regulations:**

- **Directive 2011/62/EU (Falsified Medicines Directive):** Requires safety features (e.g., unique identifiers and anti-tampering devices) on prescription medicines to prevent counterfeit drugs.
- **Delegated Regulation (EU) 2016/161:** Implements technical requirements for safety features, including integration with the EU Hub and verification systems.

2. **National Systems:**

- Member states must establish national verification systems to ensure compliance with EU regulations.
- These systems must connect to the EU Hub, which acts as the central data platform.

3. **Data Protection and GDPR:**

- Pharmaceutical companies must comply with the General Data Protection Regulation (GDPR) when handling patient or prescription data.
- Strict rules govern the collection, storage, and sharing of sensitive information.

4. **Market Authorization:**

- Medicines require approval from regulatory bodies such as the European Medicines Agency (EMA) or national agencies before they can be marketed.
- Ongoing compliance with Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) is required.

5. **Patent and IP Laws:**

- The EU protects pharmaceutical innovations through strict patent laws and data exclusivity periods, promoting R&D investments.
- Generic medicines can only be produced after patent expiration.

6. **Supply Chain Regulations:**

- The EU mandates stringent traceability requirements to prevent counterfeit products and ensure supply chain transparency.
- Regulations like the **Drug Supply Chain Security Act (DSCSA)** in global trade also impact EU exporters.

7. **Environmental Laws:**

- The pharmaceutical industry must comply with REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) and waste management directives.

8. **Pricing and Reimbursement Policies:**

- Pricing and reimbursement are often controlled by national governments, with many countries enforcing cost-effectiveness analyses.

9. **Public Health and Safety Standards:**

- Compliance with pharmacovigilance regulations, such as post-marketing surveillance, to monitor adverse drug reactions.

Key Pharmaceutical Regulations Outside the EU

Regulations in the Pharmaceutical Industry

United States:

- **FDA Regulations:** The U.S. Food and Drug Administration (FDA) oversees drug approval, manufacturing, and marketing under the Federal Food, Drug, and Cosmetic Act (FDCA).
- **Drug Supply Chain Security Act (DSCSA):** Mandates traceability of prescription drugs across the supply chain to combat counterfeit drugs.
- **Good Manufacturing Practices (GMP):** Enforced to ensure drug safety and quality.

Japan:

- **Pharmaceutical and Medical Device Act (PMDA):** Regulates drug approval, manufacturing, and post-marketing surveillance.
- Emphasis on compliance with ICH Guidelines (International Council for Harmonisation) for harmonized regulatory standards.

China:

- **National Medical Products Administration (NMPA):** Oversees drug registration and approval, formerly CFDA.
- **Drug Administration Law (DAL):** Strengthened regulations on clinical trials, production quality, and counterfeit medicine prevention.

India:

- **Drugs and Cosmetics Act (DCA):** Governs drug manufacture, sale, and distribution.
- Regulatory oversight by the Central Drugs Standard Control Organization (CDSCO).
- India is implementing stricter traceability laws for exports to combat counterfeit drugs.

Brazil:

- **ANVISA (National Health Surveillance Agency):** Manages drug approval, manufacturing, and market surveillance.
- Adheres to regional agreements under MERCOSUR to harmonize pharmaceutical standards.

Canada:

- **Health Canada:** Regulates drugs under the Food and Drugs Act.
- Emphasis on GMP compliance and post-market safety monitoring.

Australia:

- **Therapeutic Goods Administration (TGA):** Ensures the quality, safety, and efficacy of medicines.
- Requires adherence to GMP and pharmacovigilance standards.

Africa:

- Diverse national regulations, with harmonization efforts through the African Medicines Agency (AMA).
- Regional initiatives like ZAZIBONA in Southern Africa streamline drug approval across multiple countries.

Middle East:

- Countries like Saudi Arabia and UAE have independent regulatory bodies (e.g., Saudi Food and Drug Authority, SFDA).
- Many adopt international standards, such as ICH or WHO guidelines, for regulatory alignment.

Global Initiatives:

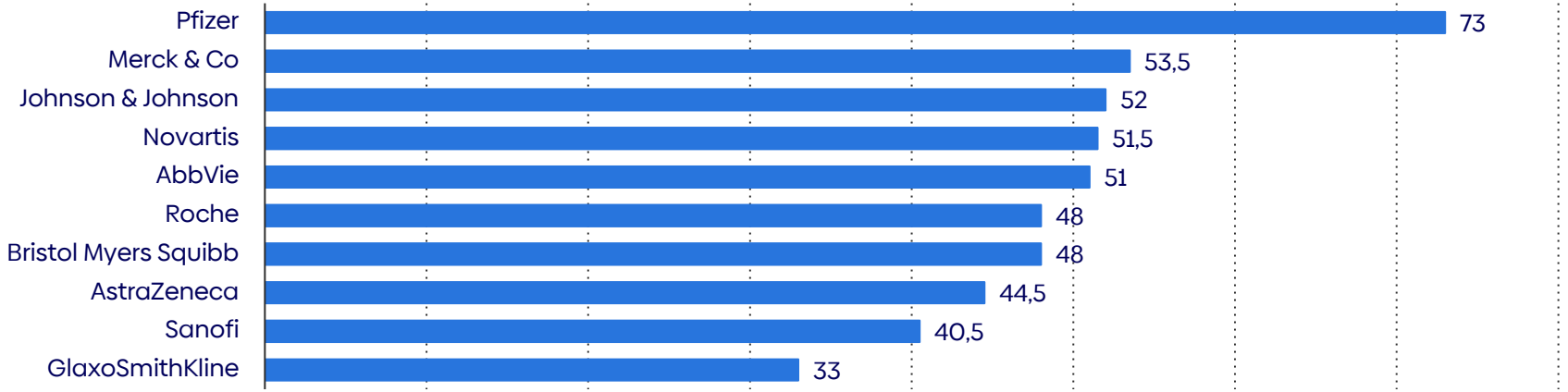
- **World Health Organization (WHO):** Sets international standards for drug quality and safety, including prequalification programs.
- **ICH Guidelines:** Harmonizes technical requirements for drug registration in key markets like the U.S., EU, and Japan.

Market & Competitor Analysis

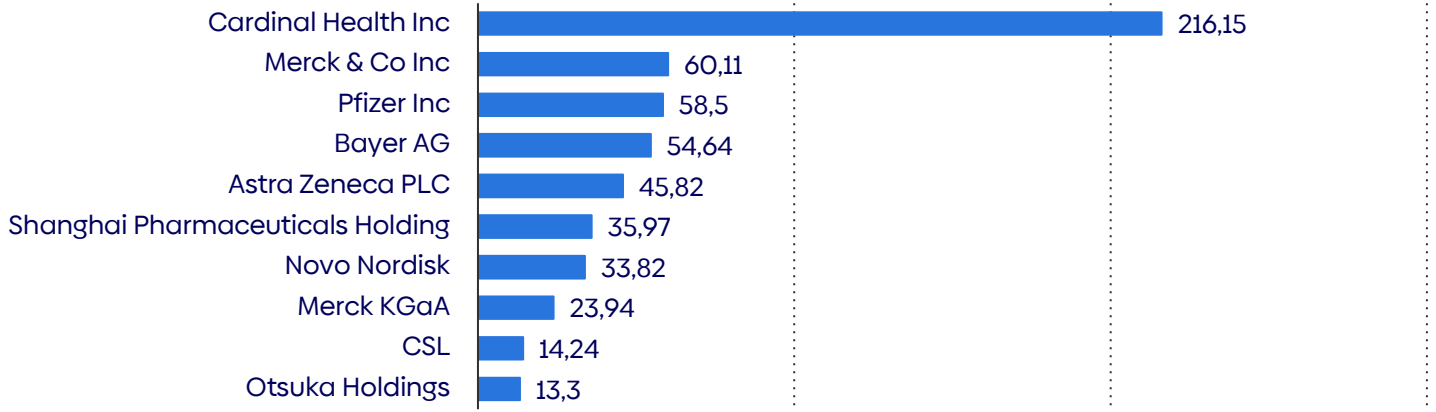
Market Potential: Top Biotech and Pharmaceutical Companies

Global Industry and Customer overview and local example (Germany)

Top 10 pharmaceutical companies by forecast sales worldwide in 2023 (in billion US dollars)



Ranking of the top biotech and pharmaceutical companies in Germany by turnover in 2024 (in billion US dollars)



Source: Statista

Note: Cardinal Health to leave German market Q4 2024

Contract Development & Manufacturing Organizations:

- Lonza (EU)
- WuXi AppTec (Asia)
- Catalent (USA)
- Samsung Biologics (Asia)
- Recipharm (EU)
- Boehringer (EU)
- Famar (EU)

TruCycle Ecosystem

The TruCycle Ecosystem

Complete lifecycle management of any asset

Our Differentiators

- SaaS-based service delivery platform, combining blockchain with AI and cloud into a full solution stack with **own IPR** (+10 global Atos patents)
- Technology readiness level 9 (TRL-9) means full scale industrial strength, able to manage up to **millions of "passports"**
- Dedicated for industrial usage in B2B ecosystems, like **eBatteries** for manufacturers, or **supply-chain** optimizations, but also for **digital assets**
- **Interoperability** by using certified industry standards such as Catena-X, Asset Administration Shell (AAS), Eclipse Data Connector (EDC), etc.

Business Value

- Detailed tracking of production processes, materials, and distribution paths, **effectively reducing costs and risks** associated with supply disruptions, unethical sourcing, and regulatory compliance.
- A Passport/ID offers a tamper-proof record that spans each product's entire lifecycle. This unbreakable bond ensures a **verifiable proof of authenticity and origin,** bolstering trust among all stakeholders.
- Enhancement of **operations efficiency,** infield **surveillance capabilities** and **supply chain integrity,** guarantee the product's authenticity across the supply chain, protecting brands and consumers from fake goods.

The TruCycle Ecosystem

Ready-to-use, blockchain-based digital passport solutions

Our Comprehensive Approach

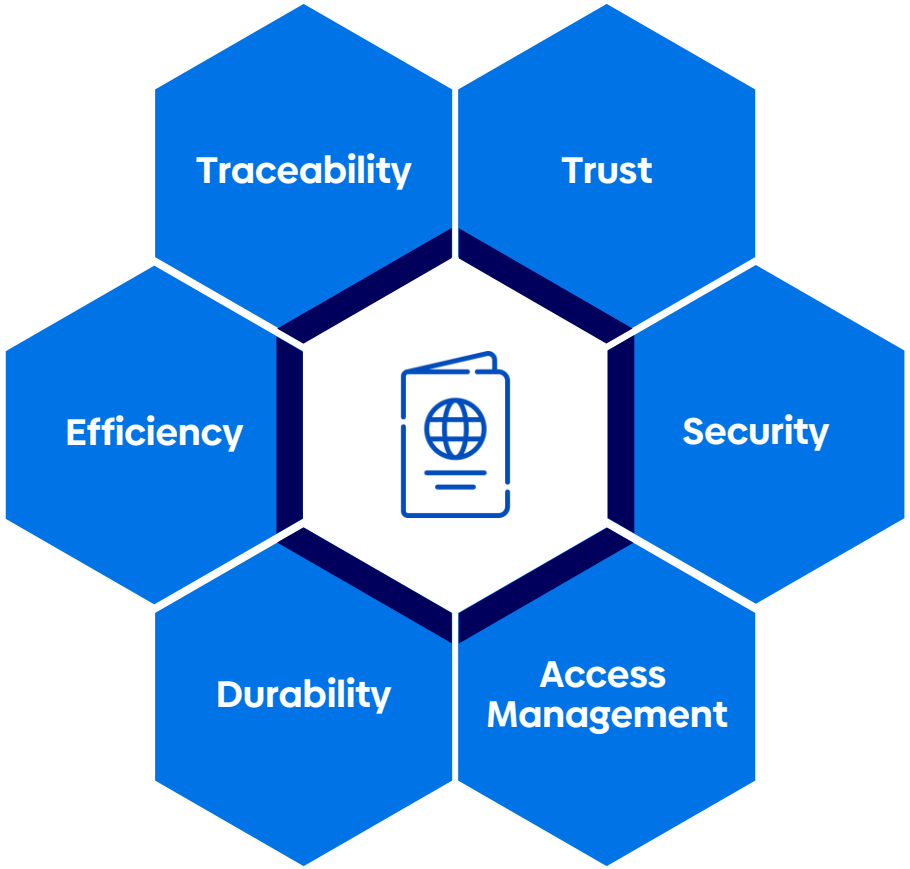
Passports are managed in the blockchain as non-fungible tokens (NFTs), **directly linked to resources, assets or products** without third party involvement (self-sovereign).

Data distribution takes place through **dedicated Apps and APIs** connecting to our platform, offering a gateway to other passport or regulation compliancy platforms.

Flexible data configuration possibilities to represent customer specific data and product series. Data consumers have dedicated Mobile Apps (e.g. via QR Code).

AI-based data analysis to monitor usage and prevent fraud, as well as to conduct performance outlier analysis.

Key Features



The TruCycle Ecosystem

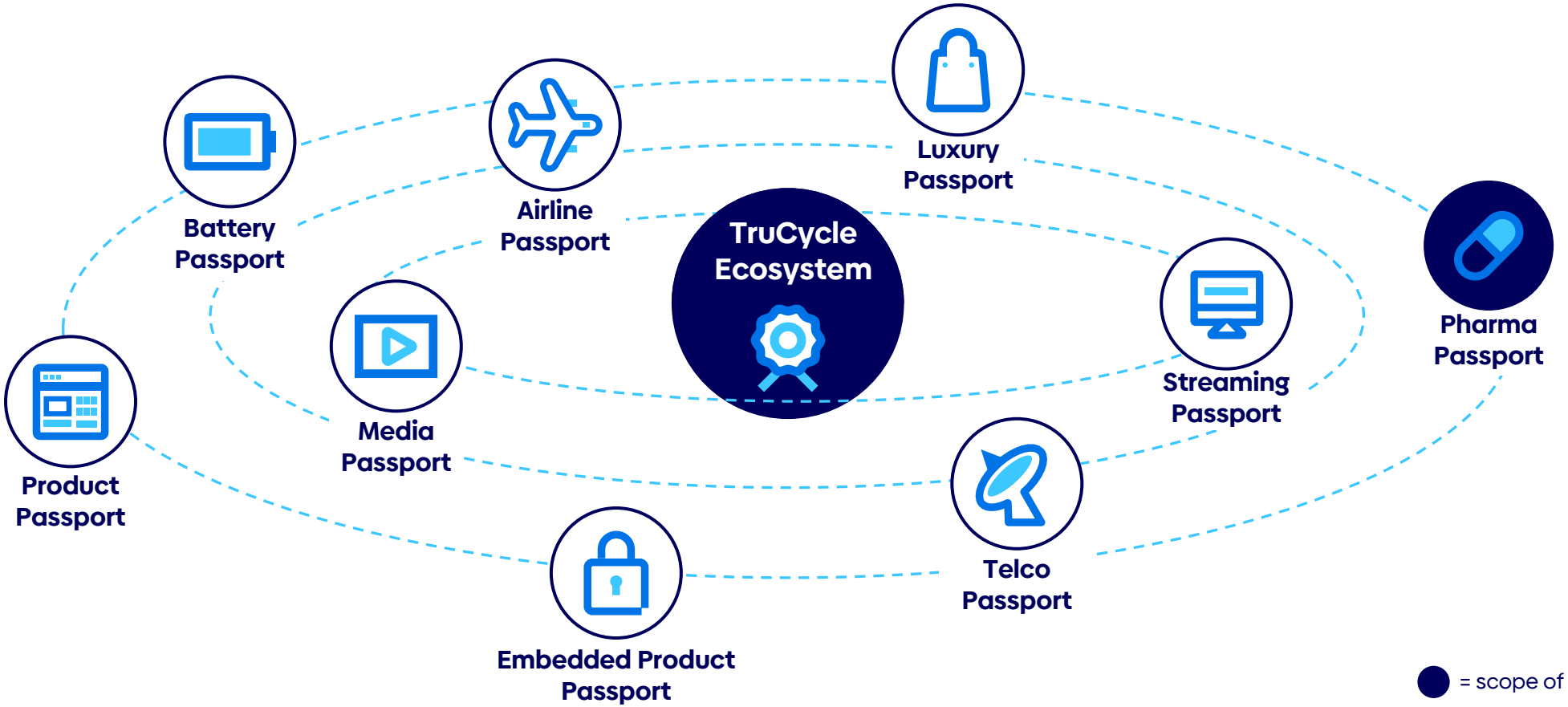
Energy-efficiency as a business value from implementing 's blockchain-based DPP solution

Overview	The TruCycle Ecosystem solution leverages Hyperledger Besu (an Ethereum client designed for enterprise use), utilizing a **Proof of Authority (PoA)** consensus mechanism, which allows a limited number of trusted actors to validate transactions, significantly enhancing energy efficiency. The solution is **transaction-based**, requiring computational power only when executing transactions. The unique **Blockchain Orchestrator** component supports REST API, enabling flexible and lightweight integration of applications, to manage for example the creation of 100 passports in a single transaction.
Energy Requirements	The PoA consensus mechanism drastically reduces energy consumption compared to Proof of Work (PoW) based systems like Bitcoin, which are known for their high energy consumption due to the need for extensive computational power to solve complex puzzles. In contrast, PoA systems rely on a few trusted validators, making the solution far more energy-efficient.
Performance	The solution achieves higher performance in terms of transactions per second (TPS) compared to PoW consensus. The use of PoA doesn't depend on a large, distributed network of nodes to reach consensus, which optimizes energy usage per transaction, allowing for faster transaction processing and reduced energy consumption.
Responsiveness	The TruCycle Ecosystem blockchain network supports adjusting the size of blocks (number of transactions), reducing calculations and storage space used. This adjustment minimizes the total number of blocks created, further enhancing energy efficiency per transaction.
Business Impact / Value	• **Operational Cost Reduction:** Implementing a low-energy consumption solution can significantly reduce operational costs for customers. • **Corporate Social Responsibility (CSR):** The energy-efficient blockchain technology aligns with companies' CSR goals, enhancing their commitment to sustainability. • **Regulatory Compliance:** Optimized energy usage supports customers in meeting regulatory requirements on energy consumption and carbon footprints. • **Return on Investment (ROI):** Despite higher initial setup costs due to the private and protected nature of the solution ecosystem, mid to long-term savings from reduced energy consumption provide a favourable ROI. • **Scalability and Performance:** The solution's scalability and performance can meet the needs for scaling without significantly impacting energy efficiency, provided the infrastructure can handle the requirements.

Real World Use Cases

The TruCycle Ecosystem is a set of innovative solutions for both physical and digital assets

Identified applications of the innovation based on the digital product passport solution



TruCycle Pharma Passport

TruCycle Pharma Passport

The problem

Counterfeit medicines endanger lives and mean considerable reputational and sales losses for the pharmaceutical industry.

Our solution

The TruCycle Pharma Passport provides end users with reliable traceability and control, thereby strengthening confidence in the medicines.

Functionality

Medicines can be uniquely labeled using existing identification systems and blockchain technology. Consumers can check the authenticity by scanning.

Client benefits

By fostering confidence in high-quality medicines, pharmaceutical companies can enhance their reputation, deter counterfeiting, and ultimately save lives.

TruCycle Pharma Passport

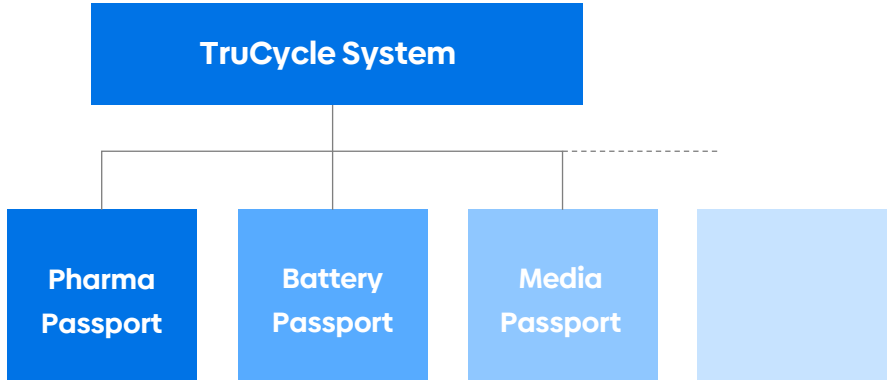
Current Track-and-Trace Solutions are Ideal for basic traceability and regulatory compliance, but limited in terms of security and transparency

A Unique Solution

Blockchain-based Digital Passport Solutions: Advanced, tamper-proof solutions offering comprehensive transparency, tailored to the challenges of modern global supply chains.

- Our **Digital Passport Solution** combines blockchain technology with data intelligence, providing a long-term, future-proof approach to ensuring product integrity and authenticity in the supply chain.
- **Integration with Anti-Counterfeit Features:**
  - Incorporating tamper-t seals, QR codes, and blockchain to provide an additional layer of security.
  - Possibility to track key elements such as location, time, and involved stakeholders
- **Data Security and Privacy:**
  - Enhanced measures to protect sensitive medical and supply chain data.

Key Benefits



- **Improved Patient Safety:** Minimizes exposure to counterfeit products.
- **Regulatory Efficiency:** Simplifies compliance and reporting for pharmaceutical companies.
- **Supply Chain Optimization:** Provides real-time visibility into the movement and status of medicines.
- **Brand Protection:** Helps manufacturers maintain trust by ensuring product authenticity.

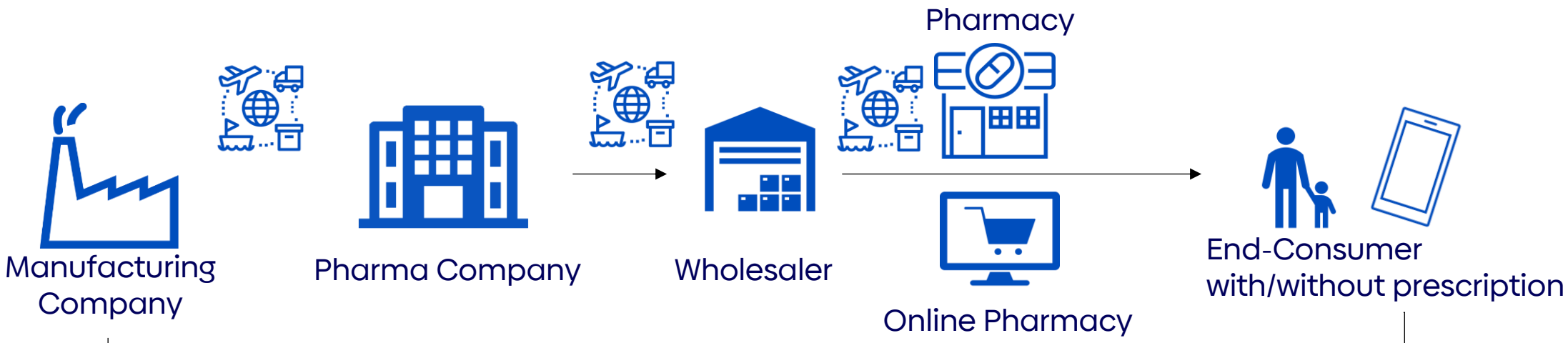
TruCycle Pharma Passport

Energy-efficiency as a business value from implementing 's blockchain-based DPP solution

Comparison	Status Quo Track-and-Trace Solutions	's Blockchain & AI-based Digital Passport Solutions
Underlying Technology	• **Technology:** Typically centralized databases or software systems that track the movement of a product along the supply chain. • Serialization (e.g., unique barcodes or QR codes) enables product tracking. Involvement of multiple administrations. • **Examples:** Systems like GS1 for serialization and traceability standards. Implemented under regulations such as the EU-FMD (Falsified Medicines Directive) or DSCSA (Drug Supply Chain Security Act).	• **Technology:** Decentralized, immutable ledgers (Distributed Ledger Technology, DLT) that record all transactions along the supply chain. • Each product receives a digital "passport" containing critical data (origin, production details, storage conditions, transport history). • **Examples :** Solutions like 's Digital Product Passport leverage blockchain for enhanced security and transparency.
System Architecture	• **Centralized:** Data is stored in a centralized database controlled by a single organization or consortium. • **Trust Model:** Participants must trust the central authority to maintain secure and unaltered data. • **Weaknesses:** Single point of failure (e.g., hacking or data manipulation). Limited transparency for other supply chain participants.	• **Decentralized:** Data is stored across multiple nodes that each have to verify transaction of data through comparison, making it nearly impossible to tamper with. • **Trust Model:** Trust is built into the blockchain itself—no central authority is required for manual verification. • **Strengths:** Transparent, tamper-proof, and resilient against cyberattacks.
Data Integrity and Security	• **Data Integrity:** Data can be altered, especially if the centralized authority lacks robust security. • **Security:** Depends on the IT infrastructure of the centralized system.	• **Data Integrity:** Data written to the blockchain is immutable. • **Security:** Secured by cryptographic methods, making data manipulation virtually impossible.
Transparency and Traceability	• **Limited Transparency:** Data access is often restricted, and only authorized participants can view relevant information. • **Traceability:** Tracks the flow of a product but offers limited visibility into details like production conditions or authenticity.	• **High Transparency:** All participants can access relevant data without compromising integrity or confidentiality based on levels of access (public, private, or consortium) • **Traceability:** Provides a complete product history, including origin, processing, and even environmental or sustainability data.
Scalability and Interoperability	• **Scalability:** May struggle with scalability in large or complex supply chains. • **Interoperability:** Integration with other systems can be challenging, especially in global supply chains.	• **Scalability:** Blockchain systems can efficiently support large, global networks. • **Interoperability:** Blockchain can integrate with existing track-and-trace systems to add an extra layer of security and transparency.
Specific Benefits of Blockchain (Digital Passport Solution)		• **Anti-Counterfeiting:** Blockchain prevents counterfeit products from entering the supply chain, as any alterations are transparent and traceable. • **Consumer Trust:** Patients and customers can easily verify product authenticity (e.g., scanning a QR code linked to the blockchain). • **Value-Added Data:** Blockchain can store additional information such as storage conditions, sustainability metrics, and certifications.

TruCycle Pharma Passport

Strengthening the Supply Chain with a Self-Sovereign System for Tracking and Verification



QR Code connected to unique Blockchain node is printed on the package (possibly also on each pill(-pack) and on the charge)

Can scan and check medication independently

Unlocks the unique number combination (UUID)

Blockchain System
Data implementation, recording, and retrieval

Interaction of the two systems enables secure **verification of the product**

AI-based Data Analysis
Search and retrieve data in the digital landscape to monitor usage and prevent fraud

TruCycle Pharma Passport

Technical and Operational Details for a Potential Implementation

Ste-by-Step Implementation

1. **QR Code Creation** using existing printer/laser
2. **Enter Product Data** in the dashboard
3. **Data Sync** to QR code system
4. **Apply QR Code** to product packaging
5. **Integration Testing** to ensure functionality

Key Benefits:

- **Scalability:** Easily scalable for large production
- **Interoperability:** Compatible with existing systems

Financial Impact:

- Increased customer trust across all products
- Enhanced company reputation
- $200 billion of counterfeit drugs moved off the black market and redirected to legitimate pharmaceutical companies

Timeframe:

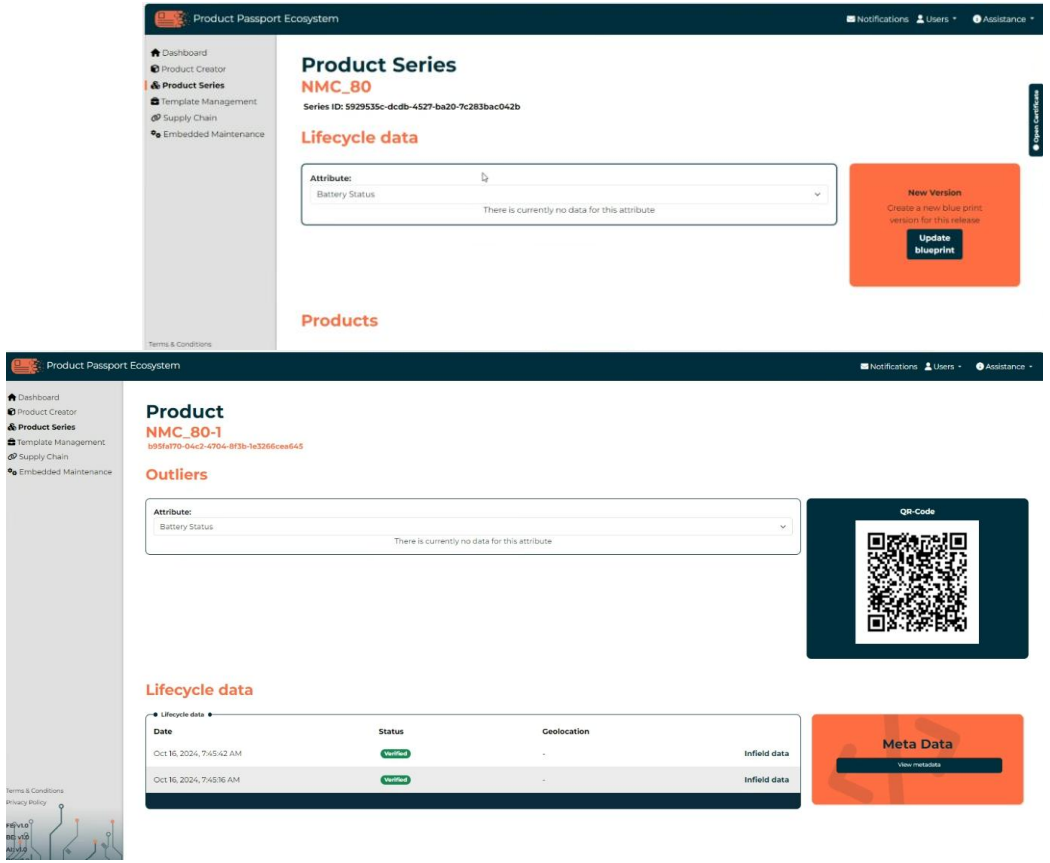
- **Begin Creator setup:** approx. 4 weeks per customer site
- **System Ready:** Following the Creator setup, the system will be fully operational

Cost Model:

- One-Time Implementation setup*
- Ongoing Costs per blister/tablet pack

*Dependent on the number of Customer's production facilities

Adaptation from the Battery Passport Solution (TRL-9)



TruCycle Pharma Passport

Why We Should Offer our Solution to Pharma Companies?

1. **Context & Problem Statement:** Counterfeit medicines jeopardize consumer safety, contribute to a $200 billion illicit market, and infiltrate the supply chain, complicating traceability and accountability.
2. **Product & Market:** Our solution provides superior traceability, meets global regulatory demands, ensures full transparency from production to consumer, offers enhanced data integrity and security, and outperforms competitors in integration and scalability.
3. **Market Potential:** The growing demand for secure supply chains and counterfeit prevention in the pharmaceutical sector makes our solution a key offering, enhancing trust, reputation, and ensuring regulatory compliance.
4. **Operational Details:** Our solution is easy to implement with minimal setup, scales across multiple sites and partners, and integrates seamlessly with existing pharmaceutical IT systems.
5. **Numbers:** The solution could cost approx. €50,000 for setup, with ongoing costs of €0.03 per blister, recaptures $200 billion in counterfeit drug revenue, and is fully operational within 4 weeks per site.

Our TruCycle Pharma Passport Solution delivers a scalable, cost-effective, and secure solution that meets regulatory needs, reduces counterfeiting, and improves ROI. Sales teams should promote this solution to help pharmaceutical companies secure their supply chains and boost their market position.

Digital Product Passport (DPP)

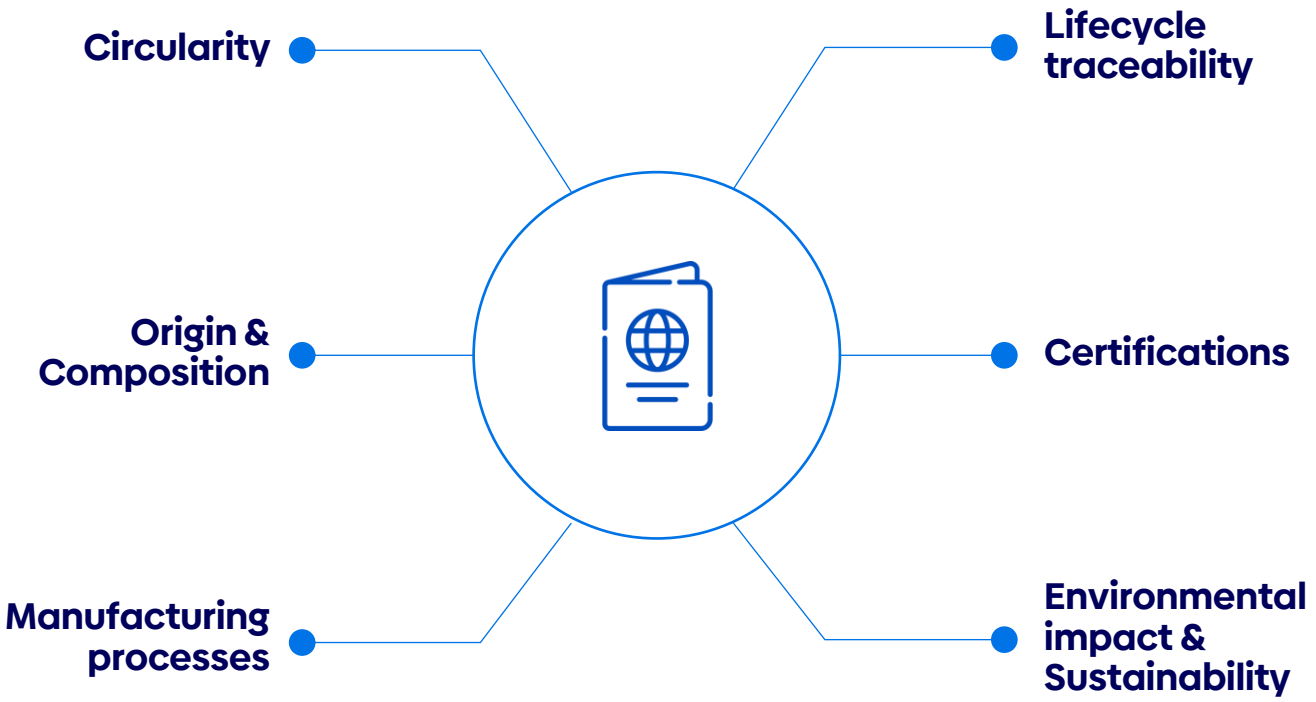
A digital record of essential data for products placed on the EU market

What is a DPP?

A structured collection of product related data with pre-defined scope and agreed data management with access rights conveyed through a unique product identifier and that is accessible via electronic means through a data carrier.

What are the DPP goals?

1. enhance sustainable production
2. extend product lifetimes, optimize product use, and provide new business opportunities to economic actors through circular value retention and extraction
3. support consumers in making sustainable choices
4. enable the transition to the circular economy by boosting materials and energy efficiency
5. support authorities (EC) to verify compliance



Digital Product Passport (DPP)

Mandatory for managing the information requirements based on product sustainability and circularity

Driver

Authorities & Sustainable Products Regulations

- The EC already announced in March 2022 its intention to make DPPs mandatory at least for all product categories regulated under the **Ecodesign for Sustainable Products Regulation (ESPR).**
- DPPs are a main component of the ESPR and one of the key actions under the Circular Economy Action Plan (CEAP). This means **anyone doing business with and within the EU will have to share product information.**
- The idea is to gain a deeper understanding about product's **sustainability and recyclability attributes across the supply chain,** including e.g. raw materials used in production and associated environmental impacts.

Impact

High Innovation Potential & Global DPP Market

- At first, the DPP will apply to product categories like **eBatteries, consumer electronics, construction materials and textiles.** More products will be included later.
- DPPs are also seen as an opportunity that can be a **gateway for innovation** and a door opener for potential new revenue streams.
- DPPs are expected to increase **transparency**, both for supply chains businesses and for the general public and to increase **efficiencies** in terms of information transfer.

Digital Product Passport (DPP)

Enabling transparency, compliance management and new low-carbon and circular business models

Enhanced Transparency

By providing detailed information about a product's lifecycle, consumers and businesses can make better choices.

Regulatory Compliance

Helping companies comply with environmental regulations by providing the necessary data for reporting and audits.

Sustainability Promotion

Encouraging companies to adopt more sustainable practices and support the circular economy, while aligning with their Corporate Social Responsibility (CSR) goals.

Innovation and New Opportunities

The data collected through DPPs can reveal new business opportunities and drive innovation in product design and manufacturing.

Supply Chain Management

Better tracking and management of products throughout the supply chain, leading to increased efficiency and reduced waste.

Waste Reduction

Giving clear instructions on recycling and disposal, DPPs help cut down on waste and recover valuable materials.

Thank you!

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