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Facilitating Standardization through Living Labs – The Example of Drug Counterfeiting

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Abstract

The increasing threat inherent to counterfeited drugs requires coordinated effort among multiple actors with diverging interests. Although multiple initiatives exist, no comprehensive and promising development and diffusion of a commonly applicable and interoperable solution has taken place so far. Agreeing on standards is an essential step on the road to a successful initiative on drug counterfeiting. To facilitate standardization, especially the initiation of a standardization process, we propose the concept of Living Labs as an innovative developing and testing environment serving multiple purposes. Testing solutions in real-life-contexts, aligning multiple interests and resulting in a pre-standard and a proof-of-concept are the advantages of this concept which facilitate the participation and coordinated action among a broad set of different stakeholders.

Keywords: Collective Action, Living Labs, Standardization

1 Introduction

The infiltration of counterfeited pharmaceuticals into the pharmaceutical supply chain is an increasing, international problem, in developing countries but also increasingly in developed countries. The large volumes for pharmaceuticals, high margins for counterfeited drugs and the low penalties in conjunction with low risk of detection resemble an appealing field of activity for criminal minds.

Whereas a large number of anti-counterfeiting initiatives account for the acknowledgement of the problem among industry members, governmental agencies, and patient associations (OECD, 2007a), most of these initiatives focus on particular solutions: Technology for enabling tracking and tracing, new packaging materials, regulation for good manufacturing practices etc. The international cross-linking of the pharmaceutical supply-chain, including multiple manufacturing phases across different countries, cross-boundary trade of ingredients, semi-finished and packaged drugs, emphasizes the need for a coordinated action among multiple stakeholders to face and limit this problem sustainable. In light of this threat and the number of existing

initiatives, the question can be raised, why no coordinated and transparency increasing system has been established?
The example of developing and testing technical standards for this purpose is used in this paper to propose a research design that may facilitate this kind of collective action among multiple stakeholders.[1] Interoperability with legacy systems of the stakeholders as well as the integration into different regulative environments pose challenges for the prospective technology enabled anticounterfeiting systems.
By drawing on standardization process models in the literature and identified requirements we theorize that the concept of "Living Labs" can be used as an enabler of collective action, establishing an environment among a group of core stakeholders to identify and test pilot systems in real-life scenarios. Our argumentation is based on the literature and experiences from current research projects in the pharmaceutical industry.
In the next section of this paper we will introduce the threat of counterfeited pharmaceuticals as well as characteristics of current anti-counterfeiting initiatives to the reader. Furthermore we motivate the need for standards as prerequisites for increasing transparency in the supply chain. In the third section we propose to conceive standard development as a threefold problem of collective action and Living Labs as a possible enabler of Collective action. In the last section we will discuss whether a Living Lab can serve as an incubator of collective action or not. This is followed by a brief conclusion.

2 Facing counterfeiting of pharmaceuticals

In this section we will introduce the reader to the increasing threat of counterfeited drugs. A large number of initiatives on different national and international levels, including governmental, intergovernmental, nongovernmental and private stakeholders were established in the recent years. We will provide some propositions about challenges faced by these initiatives that may explain the lack of observable improvements in terms of secure pharmaceuticals.

2.1 Counterfeited drugs an increasing problem

Counterfeiting in general is an increasing problem concerning almost all consumer goods. (OECD, 1998) In addition to the economic impact and the infringement of intellectual property rights, counterfeit pharmaceuticals[2] pose severe dangers for human health or patient safety.
Potential counterfeits could harm the pharmaceutical supply-chain at multiple levels, starting with the active ingredient over the finished pharmaceutical product and the packaging. These levels also comprise the shipment and distribution activities. (OECD, 2007b) Figures according to the WHO state that 10% of the overall pharmaceuticals sold were faked, ranging up 30% in the developing countries with a total volume of U$ 75 billion globally. (WHO, 2006-11-14)

[1] In order to ensure the integrity of the whole supply chain we argue that a set of standards has to be developed that may be used to set up a trackingtracing system (TTS) on an interorganizational level. In this sense we conceive standards as multilateral agreements to ensure technical, organizational and procedural interoperability and compatibility.

[2] The Word Health Organization defines counterfeited pharmaceuticals as follows: "A product that is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients." WHO, 2006-11-14

Several factors can be identified that facilitate the market entry of counterfeit medicines, e.g. in Europe (Harper & Bertrand, 2006). As a result of the single EU market can products that have illicitly entered one member state easily be disseminated throughout the entire EU. In this regard the practice of parallel trade and re-import further aggravates the complexity of the pharmaceutical supply chain. After being granted the authorization by any EU national regulatory authority pharmaceutical distributors may import any drug from any other member country to capitalize e.g. on substantial price differences among different countries. Furthermore several member states (e.g. Germany, Netherlands, Norway, Sweden, UK) stimulate dispensing of parallel imported pharmaceuticals in order to reduce ever increasing healthcare costs (Kanavos et al., 2005). In UK the parallel import accounted for 20 percent of total brand name prescription drug sales in 2002 (Kanavos et al., 2005).

2.2 Challenges for anti-counterfeiting initiatives

The primary goal of measures to tackle counterfeited pharmaceuticals is to ensure integrity of the package, meaning for the patient to receive the unaltered medicine from the manufactures. In this regard "securing the supply chain" means that at least the point-of-sale (pharmacy) can verify that the medicine or package is uncorrupted. This however implies that both manufacturer and pharmacy have to collaborate and agree on verification technologies and standards.

The different regulations have a strong impact on a coordinated effort of standardization as well. The market for pharmaceuticals and their distribution is highly regulated throughout the EU. While at the same time the free movement of goods is proclaimed and legally enforced, slightly different legal frameworks can be observed in the EU. These differences among particular regulations are also barriers for standardization efforts, which should (especially) incorporate cross-boundary trade.

Lack of market incentives for the particular players might therefore impede coordinated action amongst them. Neither the manufactures, nor wholesalers or pharmacies have a strong incentive or position to enable a coordinated action, which affects even international regulation.

Manufacturers for example might have an economic interest. But they might face the dilemma of loss of reputation, when they prominently start action against the counterfeiting threat (e.g. might the patients assume, that especially the drugs of this manufacturer are counterfeited) having no solution at hand (because they just starting the effort). Also other stages of the pharmaceutical supply chain (wholesale, retail) lack either of power, economic incentives or both to implement more security in the supply chain.

Governmental action can be assumed to overcome at least the lack of economic incentives forcing the market actors to comply. Although protection of public health is deemed to be a sovereign task such action is still missing. Various factors contribute to this lack of governmental action. Rising mistrust by patients in politicians announcing the requirement of a system (but at the same time having no system, not even a proof-of-concept in sight) might impede here the government to tackle this issue prominently. Missing detailed and industry specific knowledge, the challenge of aligning national and international interests, and solving the problem of internationally distributed supply chains might be additional reasons for the absence of governmental action.

In the previous paragraphs we have shown that neither the market nor the government alone can provide the necessary standards and proof-of-concept to establish a viable

solution. We conclude that a multi-stakeholder approach is needed to overcome the individual rationalities that prevent the sufficient provision of the public good "patient safety".

A large number of initiatives on different national and international level, including governmental, intergovernmental, non-governmental and private stakeholders (for a detailed overview of initiatives see OECD, 2007a) have been established. They tackle a broad range of issues, regarding technological, organizational and also regulatory issues. Missing efforts to coordinate the single parts into common and comprehensive approaches prevent them from being successful and sustainable for a broad set of contexts.

The following table highlights potential shortcomings of existing initiatives or reasons of failure from the perspective of the particular driving party:

Actor group	**Potential shortcomings of existing initiatives**
Industry driven	⇨ Missing acceptance of competitors
	⇨ No public good as primary result
	⇨ Lack of regulative enforcement
	⇨ Emphasis on economic benefits
	⇨ Missing theoretical foundation
	⇨ Missing supply chain actors
	⇨ Power asymmetries
(Inter-)Government	⇨ Missing proof-of-concept
driven	⇨ Missing acceptance among industry
	⇨ Focused on national problems/regulations

Table 1. Actors and potential shortcomings of not-coordinated anti-counterfeiting initiatives

Although most people in the pharmaceutical distribution industry acknowledge the potential threat of counterfeited pharmaceuticals there is no industry-wide nor international consensus that this relates to the own business or industry. As we have shown the economic incentives will not lead industry-wide applicable solutions in the near future. It has become clear that to overcome the threat of counterfeited pharmaceuticals only a multi-stakeholder approach is feasible. Precedence in other industries (e.g. beef) has shown that such approaches are gaining momentum after the crisis broke out (e.g. BSE and CJD). Based on this unsatisfactorily observation the next chapter introduces the theoretical grounding for our suggested research design which may lead to feasible solutions before a crisis breaks out. Facing the problem of enabling a standardization process, we illustrate the phases of standardization and the
required collective action. By presenting the concept of Living Labs and applying it in our context we believe that it is possible to overcome or lower some of the barriers to coordinated action presented previously.

3 Theoretical Concepts

We want to conceive the formation of such a system as a problem of collective action which would be needed for the development and consequent diffusion of a system. We interpret this as a problem of standard development and distinguish several phases in which actors have to assume different roles.

3.1 Phases of Standardization and Collective Action

In the previous sections we pointed out that standards are needed to ensure a close cooperation between the actors along the supply chain and relevant governmental agencies. By conforming to these standards the actors would be able to establish a pharmaceutical security trade chain involving different stages of the supply chain from different sectors and from different countries. The standards put forward here exhibit the characteristics of collective goods (non-excludability, non-rivalry). Hence, Collective Action Theory or Public Choice Theory seems a promising analytical viewpoint.

Markus et al. have studied the consequences that collective good characteristics have on the development and diffusion process of standards. (Markus et al., 2006) By studying vertical information system standards they explored the linkage and differences between development and diffusion of standards as two distinct dilemmas. They come to the conclusion that for a successful standardization both need to be solved and addressed at the same time.

The development of a standard requires a close coordination of the actors. Farrell & Saloner (1988) discuss three mechanisms to achieve coordination in regard to compatibility standards. In this paper we want to focus on the first, which deals with standardization committees in which negotiations take place before unilateral irrevocable choices are made.

Before multilateral negotiations in such a context can take place the actors have to be persuaded to join the consortium. Reimers and Li argue for a transaction cost perspective to understand the individual firms' decision to join in (Reimers & Li, 2005). Following their argument each firm has to evaluate the costs of multilateral negotiations in a consortium and the costs it would incur by bilaterally negotiating with its business partners. In this model the costs depend largely on the number of competitors and intensity of competition among them. If several competing initiatives try to develop standard candidates uncertainty increases. This in return increases transaction costs. Therefore firms may prefer bilateral arrangements or simply adopt a free-rider position. This leads to two problems: First, no initiative will take off because of the free-rider problem. Second, the negotiating consortium might be too small to start a bandwagon effect in the diffusion phase.

The dilemma of standard development is concerned with success and failure of a standard negotiation process. By drawing on Reimers and Li we theorize that an explanation why the negotiation process started at all is needed in the first place.

Following Reimers and Li we distinguish between three phases instandardization processes (see Table 1): First, during the initiation phase the standard development consortium is formed. A nucleus of actors or at least one actor has to take the role of the initiative pusher by promoting or facilitating the formation of a forum to negotiate on standards. The outcome is a relatively stable consortium of actors that are willing to participate in the negotiation about a standard candidate. The standard is regarded as a "candidate" as it may or may not emerge as a de-facto standard in the third phase. In

Table 2 the phases of an abstract, consortium-driven standardization process and their outcomes are listed.

Phase		Outcome
I	Initiation	- consortium
II	Development	- standard candidate
III	Diffusion	- de-facto standard

Table 2. Phases of standardization processes

Despite its importance the initiation phase is rather disregarded by the literature on standardization. We therefore want to elaborate further on the challenges of the initiation phase.
As already pointed out the initiation phase is concerned with actors assuming two roles: the initiator and (passive) participants. One or more actors need to assume the role of an initiator (irrespective of their number hereby called initiator).
During the initiation phase the initiator tries to identify and persuade the relevant actors that need to participate in the consortium. The initiator may be motivated intrinsically (e.g. economic incentives), by an exogenous event (e.g. a crisis) or it may be part of a mission that has been entrusted to the initiator. In order to persuade actors to join the consortium the initiator employs means that rely on resources at disposal of the initiator. The persuasion of an actor has to be seen as a negotiation process in which the interests between the actor and the initiator are aligned.
Alignment means that both parties need to agree on the rules that will govern the consortium. Although they might have a diverging interest in the outcome of the activities of the consortium they need to find a common ground where their expectations are satisfied. In this regard the consortium needs to be interpretative flexible in order to accommodate the diverging interests. At this stage the addressed actor needs to evaluate the offer to participate in consortium. Despite a calculation of the (economic) costs and benefits to participate or not in this consortium the actors will evaluate the initiator and the other participants in terms of credibility, trustworthiness and past experiences.
During the standard development phase the decision making process exhibits several potential areas of conflict between the parties. These are conflicts of interest, conflicts of alignment and conflicts of appropriation. (Müller-Tengelmann, 1995) Conflicts of interest refer to the heterogeneity of interests among the actors. For example some might have preferred to develop a proprietary standard in order to lock-in their customers or shut-out competitors. Another reason for supporting particular standard might be the existing intra-organizational infrastructure (internal lock-in). This leads to the conflicts of alignment. The conflicts of appropriation result from different cost/ benefit structures of the actors. And even in case of a negative cost/benefit ratio, actors might still favor the standard development.[3]

[3] Müller-Tengelmann mentions three situations that would explain such behaviour. First there might be dependencies among the actors that force some of them to be compliant to the requirements of their (business) partner. Second the investment is justified by future expectations to sustain and strengthen the business relationship. Alternatively costs can be passed on to a third party like customers or suppliers (Müller-Tengelmann, 1995).

After the standard candidate is developed the actors in the market have the choice to adopt the standard (if it has not become a de-jure standard). Due to network effects actors have the incentive to delay their adoption in order to wait until a critical mass has been reached. Additionally dependencies and asymmetric power structures can also force or impede actors to adopt a standard. Intellectual property rights at non-open standards, missing practicability or incompleteness are further factors influencing the adoption and diffusion process.
This section demonstrates that a standardization process is precarious and characterized by a multiplicity of conflicts which have to be contained. The question arises how to set-up an environment that provides promising surrounding conditions for a successful initiation of a standardization process. We will elaborate on this question in the next section by analyzing Living Labs as providing such an appropriate environment.

3.2 Living Labs an appropriate incubator for CA?

"Living Labs are collaborations of public-private partnerships in which stakeholders co-create new products, services, businesses and technologies in real life environments and virtual networks in multi-contextual spheres."(Feuerstein et al., 2008)
This very broad definition of Living Labs is one indication for the typical characteristic of this construct. There co-exist multiple, not necessarily mutual exclusive understandings of what the concept "Living Lab" encompasses and how it could be utilized in practice.[4] For example, Mulder et al. (2008) emphasize the 'Living' part of the Living Lab. The integration and central meaning of the user in the research and design process in a real life-context facilitates the inclusion of experiences and dynamics among the technology, user and the social everyday context.
In addition to this conceptual work on Living Labs, empirical analyses of existing Living Labs in Europe show some common characteristics among this type of collaboration environment. They typically focus on the creation of innovative services featuring ICT and involve stakeholders both from the public and private domain. (Shamsi, 2008) In addition to governmental and commercial stakeholders, academia is another typical stakeholder in the a Living Lab. (Almirall & Wareham, 2008)
Based on the definition by Feuerstein (2008) and Almirall (2008) and the empirical findings from Shamsi (2008), we want to present our understanding of Living Labs in the context of multi-national and multi-stakeholder research projects. In contrast to Mulder et al. (2008), we focus not on the development of end-user technologies like ADSL or mobile applications, but analyze the issue of establishing standardization activities among a broad set of stakeholders with particular perspectives, interests and incentives. Especially in the context of standards development, the preservation of stakeholders' interests is seen as one opportunity to involve and endure the collaboration of industry members (David & Greenstein, 1990).

[4] e.g. being it "a research methodology for sensing, prototyping, validating and refining complex solutions in multiple and evolving real life contexts" [Prof. William Mitchell, MIT Boston; taken from http://www.sricbi. com/LoD/meetings/2005-06-08/VPNiitamo.ppt] and similar usage in Souminen, 2005, "an experimentation environment in which technology is given shape in real life contexts and in which (end) users are considered as ‚co-producers'" Pierson, Lievens & Ballon, 2005, or a test environment for different technologies and competing business models Niitamo, Kulkki & Hribernik, 2006.

Therefore we propose the concept of Living Labs being a research environment, bringing together a core group of stakeholders to explore potential solutions for a common problem and with each party having particular perspectives and interests.
As mentioned before, one stakeholder, not necessarily involved in typical Public-Private-Partnerships, is academia. Being an active part of a Living Lab, academia can at least compensate some of the shortcomings inherent to initiatives driven mainly by stakeholders from the public or private domain (as presented in Table 1). Being neutral (in terms of economic interest) and unbiased (e.g. in terms of usage of a specific technology) upfront and relying on scientific and theoretical knowledge, the credibility of the university might be used to moderate and design a Living Lab.
The outcome is not only the presentation of a proof-of-concept, but also the formulation of recommendations (in terms of legislation or organizational changes) and an assessment of impact (e.g. in terms of economic impact) for the stakeholders of this real-life case. (Shamsi, 2008) Hence, the Living Lab could serve not only as a technological testing environment, but also to evaluate future obstacles to a wider diffusion and adoption. Based on the barriers to standardization and collective action activities and also based on the very broad definition and current understanding of Living Labs presented in the paragraphs before, we propose for our context four stages of designing and running a Living Lab:

1. Funding and initiation

   Related to a concrete or upcoming challenge, a governmental or intergovernmental institution creates the opportunity to establish a Living Lab. This first stage mainly aims to reduce the barriers (both financial and political barriers) for the particular stakeholders to join this kind of research and development projects.

2. Design and set-up

   Due to the complexity of the problem, the concrete design and set-up of the Living Lab could be done by an academic institution. Academia has multiple advantages in contrast to political or commercial parties. It could be assumed, that they are able to act neutrally, not being driven by financial or political interests and therefore being creditable. Also their theoretical funding sustains their credibility.

   Typical tasks are defining and detailing the description of the problem, considering potential technological solutions, establishing a network of stakeholders (being it technology providers and users of the technology) and also defining (in collaboration with the stakeholders) the outline of the following phase.

3. Test, assessment, improvement

   This phase has the most interrelations to the traditional innovation development process. The specific setting of a Living Lab, focusing not on the development of new technology, but the application, assessment and improvement of existing technology (e.g. provided by particular partners) in real-life contexts, enables an incorporation of multiple interests resulting in a proof-of-concept. Later diffusion activities among regulatory bodies but also among a wider set of industry stakeholders can be supported by conducting impact assessment.

4. Documentation and development of recommendation

   Deriving recommendations on the basis of former results is the main task in the last phase. The inclusion of scientific research, application to reallife- scenarios

and the assessment by users into these recommendations should therefore provide a basis for sustainable, well-proven and applicable solutions.

Figure 1 illustrates the phases with the particular results and also details the third phase, which could encompass multiple test, assessment and improvement cycles.

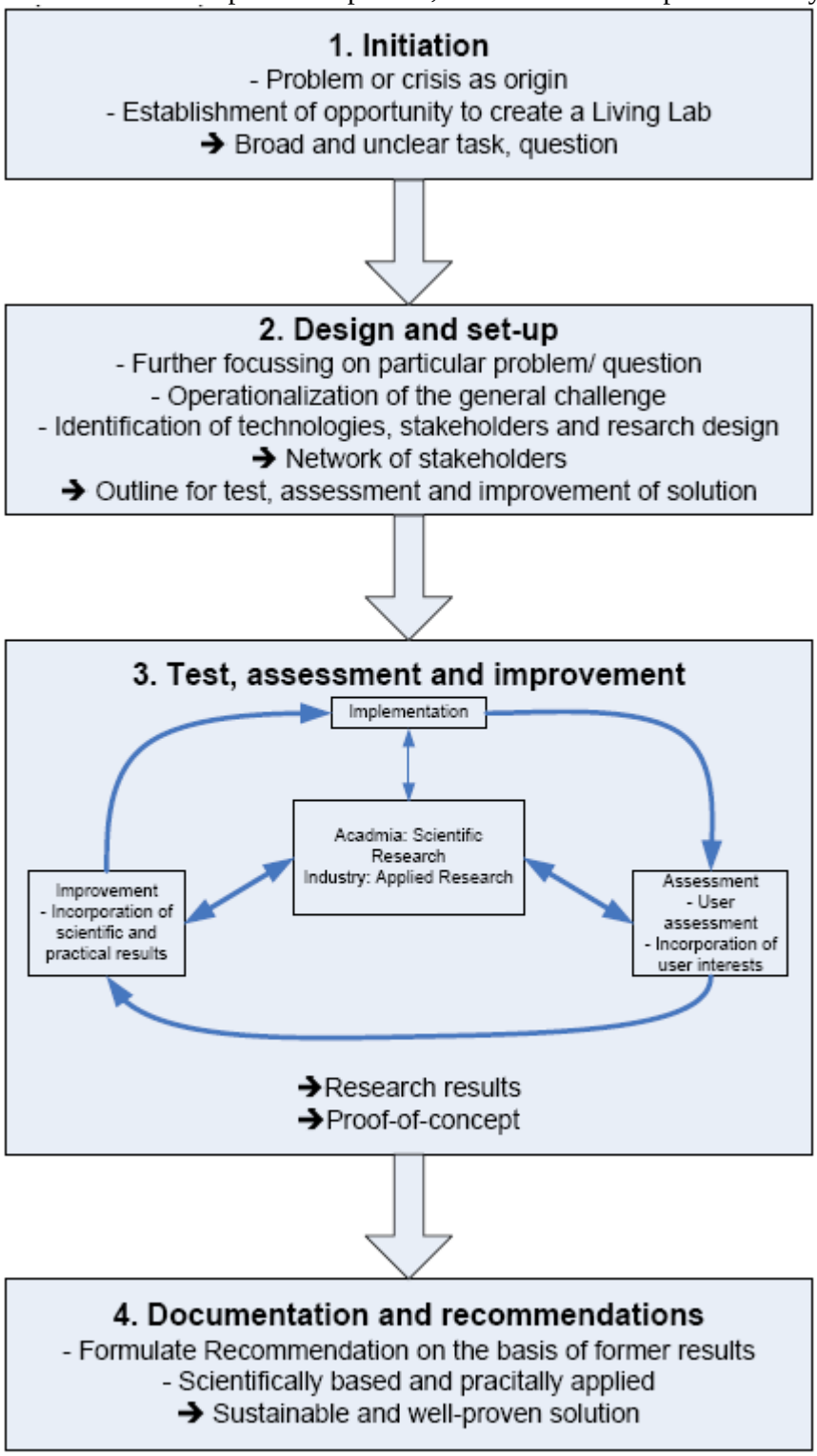

Figure 1. Phases of a Living Lab

The alignment of particular interests and contributions among the network of stakeholders has already been identified as being one important issue for enabling standardization before. The following table therefore highlights the stakeholders of the proposed Living Lab setting, each having particular interests and contributing competencies.

Name/ Institutional setting	Role	Contribution/ Competencies	(Primary) Interests
Governmental/ Intergovernmental institution	Initiator of project setting	- Financial funding - Organizational momentum	- Solution of the original problem - Recommendation, standard
Academia	Designer and Researcher	- Design and set-up of the concrete Living Lab - Scientifically based - Neutrality and credibility	- Research results
Industry	Technology Provider	- Existing technology	- Proof-of-concept - Influence on recommendation
Industry	User	- Real-life context - Application and assessment of solution	- Increased efficiency - Influence on recommendation
Governmental institution/ Administration	User	- Real-life context - Application and assessment of solution	- Fulfillment of sovereign task (security, control etc.)
Consumer/ End-User	User	- Real-life context	- Fulfillment of user-needs

Table 3. Stakeholders and their roles in Living Labs

Academia is one key actor in the Living Labs, with its neutral and scientific basis as competencies. Combined with the mandate by the international institution, we believe that the critical task of bringing together a key community and align its interest is one central opportunity for the concept of Living Labs.

4 Use of a Living Lab approach to generate CA

Especially the first phase has been identified to be critical for establishing the momentum for Collective Action. The following sections discuss the application of the Living Lab concept in the initiation phase and the implications for the remaining two phases.

4.1 Phase I: Initiation

The standardization process via the coordination mechanism of a consortium requires actors that bring together the participants of the consortium. This process previously termed “initiation phase” is a necessary prerequisite to set a standardization process on

track. As pointed out before this phase requires two roles which have to be assumed by the actors. However even though an initiator might be motivated the actors may restrain from joining the consortium and adopt a free-rider position. This seems to be likely in case of dubious benefits but clear costs of participation. Furthermore the composition and focus of the consortium may prevent actors from joining. In this regard the initiator (in terms of a governmental/ intergovernmental institution) and also the designer (in terms of academia) play a crucial role in convincing the respective actor of his neutrality and mediating qualities which account for the ability to balance different interests and power disequilibria among the participants.

In the case of anti-counterfeiting initiatives actors from all stages of the supply chain and different legal frameworks have to be brought together. This results in a high degree of heterogeneity among the actors. In such a consortium the multi-national, multi-billion manufacturer has to collaborate with the pharmacist from the next door. Thus we have to attribute this kind of consortium a high degree of heterogeneity not only in terms of money or power but in their interests regarding the outcome as well.

A Living Lab as we introduced in the previous section has several characteristics that may facilitate the initiation of a standardization process.

First of all a Living Lab is situated in the first phase of a standardization process and thus has also implications for the latter stages. Typical Living Labs are funded by the EU. This supranational governmental body provides financial funding for setting up Living Labs. The objectives of this funding authority are to foster the competitiveness of European research and industry. At the same time it expects recommendations for future legislative acts and the political agenda. Universities or academic institutions are competing on these funds by proposing projects. As projects are carried out under the aegis of the proposing academic institution we will focus on their role as an initiator in the standardization process. Despite being funded the academic institution

is interested in the research part in the Living Lab. By designing and settingup the concrete Living Lab it assumes the role of an initiator. Several means are at its disposal to persuade industry members to join the Living Lab. First and foremost, an academic institution is commonly perceived as being a neutral actor that is neither politically nor economically biased. This neutrality is especially helpful in case of power imbalances among the future participants. Second, through the involvement of an academic institution objective and scientifically grounded results are to be expected as an outcome.

The initiator of a Living Lab tries to bring technology providers, industrial users as well as users from governmental institutions together. The incentives for each of these may be different. The analysis and alignment of the particular interests is thus a critical task for the neutral academic initiator. The technology provider expects to achieve a proof-of-concept of his technology. Furthermore the LL may serve as a forum to raise attention for a particular technology and discuss and test needed improvements in situ. The industrial users can test the application of technology and cooperation mediated by technology with partners (e.g. customs, other companies). As this is done in a controlled environment with a limited scope it has only limited impact on regular business. In this regard it represents a low-risk test environment (laboratory) but with results that are close to reality (living).

The outcome of a Living Lab is a “pre-standard concept”. In most cases it cannot be directly transformed into an actual de-jure standard nor can it be marketed as a de-facto standard. This limitation is due to the limited scope in terms of involved stakeholders, products and processes that have been analyzed. This analysis and the results of the proof-of-concept are input for later phases of a standardization process. The major

achievement however is to bring actors together in order to experiment on grand-scale solutions in a comprehensive manner. Scale and comprehensiveness of such a proof-ofconcept are the major assets of Living Labs in contrast to market-driven initiatives. Furthermore Living Labs are a vehicle to enable the actors to engage in technologies and initiatives that may not provide direct economic benefits. Therefore they are a promising means for governments to address the scarcity of public goods deemed beneficial for society but which are not provided by the market.

4.2 Phase II-III: Development and Diffusion

Starting with a proof-of-concept, which has been tested in a real-life context and a pre-standard, which already involves multiple requirements and interests should facilitate phases II and III of the standardization process. The conflicts in the development phase are often based on missing interests of single stakeholders. By already integrating multiple stakeholders in the former phase and conducting impact assessment from multiple perspectives, we assume that this potential threat can be lowered significantly. In addition to the second phase, the proof-of-concept elaborated in the Living Lab can also enable the diffusion among the network. The decision, if an innovative technology or standard is adopted by one or respectively multiple parties relies, amongst other factors, on the applicability and sustainability of the standard. In contrast to a standard based on pure scientific and conceptual work, this standard has already proofed in a real-context. In terms of network externalities, there exists already the core group of adopters (the Living Lab community), which might serve as the required initial point or 'momentum' to facilitate the industry wide diffusion, e.g. by incorporating their suppliers/customers etc.

4.3 Standardization and Drug Counterfeiting

The inherent challenges of drug counterfeiting discussed in chapter 2 illustrated the complexity of the problem: Bringing multiple stakeholders together, facing a highly explosive issue both for industry and politics, developing standards among different stages of a highly branched supply chain, and incorporation of national and international regulatory contexts. At the same time, it makes sense to tackle the issue before the general necessity is discussed in the media, e.g. by creating a scandal as a consequence of (more) serious incidents of counterfeited drugs. Overcoming the inherent barriers of these challenges in the process of standardization using a Living Lab as a research environment seems to be a promising solution:

From the technological perspective, multiple solutions like RFID, barcodes, tracking and tracing systems etc. are available. Although they are often developed for different contexts or tackling only very specific problems, Living Labs can be used to integrate existing different solutions or apply them in new contexts. Also the test, application and improvement in real-life context are important parts of a Living Lab with the aim to present a proof-of-concept. Based on this proof-of-concept, recommendations for regulation can be derived, but also concrete impact assessments can be conducted as further steps of a successful introduction of standards.

From the organizational perspective, the multiplicity of stakeholders and the alignment of interests might be an obstacle for successful standardization efforts. Although awareness among public and private stakeholders exists, establishing an active collaboration often requires further efforts. In this sense Living Labs could be used as a framework to lower the financial and organizational barriers of collaboration. Being funded by a public

institution and designed/organized by an academic institution the formation of stakeholder group might be facilitated.
The third challenge for standardization activities regarding the problem of counterfeiting is the potential discussion in the media and the loose of trust in the industry (esp. when the problem is discussed but no solution or at least a potential solution is presented at the same time). Living Labs could be used as some kind of real-life testing and developing environment, but at the same time not being discussed that prominently in the media as they are still limited to this (project) context.
By assessing the impact of solutions, not only from a financial but also from an organizational perspective (e.g. in terms of social impact, strategic impact etc.) also the diffusion of standards might be facilitated. Facing at least some of the challenges of drug counterfeiting, we believe that concept of a Living Lab could facilitate the standardization process significantly.

5 Conclusions

The counterfeiting of pharmaceuticals presents a rising problem for several stakeholders. Ranging from being life-threatening for patients, over loss of trust against the medical system up to huge economic risks, the potential threat for multiple stakeholders is significant. Due to the nature of the problem, counterfeiting is not limited to a geographical region, does not end at national boundaries or is limited to certain types of pharmaceuticals. The complexity of the problem implies multiple challenges, e.g. how to enable coordinated action among different stakeholders with different interests, acting in different organizational and regulative environments etc. A number of initiatives are already in place, but none of them incorporates a coordinated and supply-chain-wide approach. The development of standards should therefore be the first step towards increased transparency along the supply chain to face the counterfeiting problem.
Standardization processes can be distinguished in three phases: Initiation, development and diffusion. Each of the phases contains particular challenges, which have to be overcome to enable the whole process. By presenting the concept of Living Labs, especially the conflicts of phase I (initiation) should be tackled in a structured way. Academia as an economically and politically neutral actor could play the role of a mediator between multiple stakeholders from different sectors to align their interests and also ease the collaboration. Also phases II and III benefit from the concept of Living Labs. As the typical result of a Living Lab is a proof-of-concept and first recommendations for a pre-standard, the development of the real standard is supported. Furthermore, the diffusion among the industry is facilitated: On the one hand, the technology has already proven in real-life context and it also has been assessed. On this basis the adoption decision among a wider community could be influenced. On the other hand, the existing Living Lab community could serve as a nucleus for network/ industry-wide diffusion.
The concept of Living Labs has been applied in multiple contexts, especially for driving technological innovation. Actively enabling standardization activities is an innovative application context and has therefore proven to work in real life. Future research in this field can therefore be related to case studies of particular Living Labs. Further detailed knowledge is needed concerning the concept of Living Labs entailing its roles and phases.

References

Almirall, E. and Wareham, J. (2008). The Role of Living Labs in Open Innovation. In: European Living Labs (Schumacher, J. and Niitamo, V. P., Eds.), Wissenschaftlicher Verlag Berlin, Berlin, pp. 147–157.

David, P. A. and Greenstein, S. (1990). The Economics of Compatibility Standards: An Introduction to Recent Research. Economic Innovation and New Technology, No. 1, pp. 3–41.

Farrell, J. and Saloner, G. (1988). Coordination Through Committees and Markets. The RAND Journal of Economics, 19, No. 2, pp. 235–252.

Feuerstein, K.; Hesmer, A.; Hribernik, K. A.; Thoben, K. D. and Schumacher, J. (2008). Living Labs: A New Development Strategy. In: European Living Labs (Schumacher, J. and Niitamo, V. P., Eds.), Wissenschaftlicher Verlag Berlin, Berlin, pp. 1–14.

Harper, J. and Bertrand, G. (2006). Counterfeit medicines.Council of Europe Publ., Strasbourg.

Kanavos, P.; Gross, D. J.; Taylor, D. and Public Policy Institute (2005). Parallel Trading in Medicines: Europe's Experience and Its Implications for Commercial Drug Importation in the United States.AARP Public Policy Institute.

Markus, L. M.; Steinfield, C. W.; Wigand, R. T. and Minton, G. (2006). Industry-wide Information Systems Standardization as Collective Action: The Case of the U.S. Residential Mortgage Industry. MIS Quarterly, 30, No. Special Issue, pp. 439–465.

Mulder, I.; Velthausz, D. and Kriens, M. (2008). Living Methodologies: Understanding the Dynamics of Innovation. In: European Living Labs (Schumacher, J. and Niitamo, V. P., Eds.), Wissenschaftlicher Verlag Berlin, Berlin, pp. 31–38.

Müller-Tengelmann, H. (1995). Kollektive Investitionsstrategien - Der elektronische Datenaustausch als überbetriebliche Infrastruktur.Lang, Frankfurt am Main; Berlin; Bern; New York; Paris; Wien.

Niitamo, V.-P.; Kulkki, M. E. and Hribernik, K. A. (2006). State-of-the-Art and Good Practice in the Field of Living Labs.

OECD (1998). The Economic Impact of Counterfeiting, Paris.

OECD (2007a). THE ECONOMIC IMPACT OF COUNTERFEITING AND PIRACY, Part II: Efforts to Combat Counterfeiting and Piracy.

OECD (2007b). THE ECONOMIC IMPACT OF COUNTERFEITING AND PIRACY, Part III: Industy and Sectors - Draft.

Pierson, J.; Lievens, B. and Ballon, P. (2005). Living labs for broadband innovation: Configuring user involvement. BBEurope, 12-15. December 2005, Bordeaux, France.

Reimers, K. and Li, M. (2005). Antecedents of a Transaction Cost Theory of Vertical IS Standardization Processes. Electronic Markets, 15, No. 4, pp. 301–312.

Shamsi, T. A. (2008). Living Labs: Good Practices in Europe. In: European Living Labs (Schumacher, J. and Niitamo, V. P., Eds.), Wissenschaftlicher Verlag Berlin, Berlin, pp. 15–30.

Souminen, J. (2005). Introducing Living Labs. Available from: http://www.kingston.ac.uk/~ku07009/LivingLabs/PapersAndSlides/Day1RichardEnnals.pdf.

WHO (2006). Counterfeit medicines. Available from: http://www.who.int/mediacentre/factsheets/fs275/en/index.html.