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IMPACT OF REGULATION AND ELEMENTS FOR THE SOLUTION OF THE REVISION OF ARTICLE 33 THERAPEUTIC PRODUCTS ACT

A report by Infras by order of the Swiss Federal Office of Public Health

SUMMARY

Background and aim of the revision of Article 33 Therapeutic Products Act

Article 33 of the Therapeutic Products Act (TPA) prohibits material benefits to be offered to persons who prescribe or supply medicinal products. These persons shall also neither solicit nor accept material benefits. Material benefits could encourage persons who prescribe or supply medicinal products to sell or prescribe more or more expensive medicinal products. This can endanger the safety of medicinal products, impair the optimal supply of medicinal products and also increase health costs.

Since the entry into force of the TPA on 1.1.2002, Article 33 has repeatedly been the subject of controversial discussions. The central points of criticism are the enforcement by Swissmedic and the fact that, in spite of Article 33 TPA, material benefits are still being accorded. As a result of the repeatedly voiced criticism, the Commission for Social Security and Health mandated the Federal Council to develop a solution.

Against this background, the Federal Office for Public Health (FOPH) commissioned a study to analyse the consequences of Article 33 TPA and to examine alternative regulations. Based on documentary analyses and discussions with experts, the study is intended to clarify today's facts,

gather proposals for change from politicians, the administration, experts and the legal profession and submit proposals to amend the regulation.

Understanding medicinal product safety

The Therapeutic Products Act (TPA) is intended to ensure the safety of medicinal products. The investigation showed that those involved understand the term, “medicinal product safety” in different ways and that this is decisive for the assessment of the problem of Article 33 TPA and for the proposed solutions. Medicinal product safety can be defined in a narrow or broad sense:

Medicinal product safety in the narrowest sense refers to the product level. It is intended to ensure that the appropriate optimal medicinal product is dispensed according to the approved indication and dosage.

Medicinal product safety in a broader sense includes the product level and the use level. An additional aim is that the patient does not receive any unnecessary medicinal product, none in too high an amount and none for another use than the approved use (off-label use). In this additional understanding, Article 33 TPA also refers to material advantages that service providers[1] (SP) could influence, prescribing/supplying too many medicinal products or introducing a medicinal product for use outside the approved field.

Today, Swissmedic implements Article 33 TPA based on the definition of medicinal product safety in the narrowest sense (product level) and consequently does not pursue possible broader issues on the medicinal products. The investigation revealed clear indications that the increase in sales can also be significant for medicinal product safety, so that it appears advisable to comprehend medicinal product safety in the context of Article 33 TPA in the wider sense and to also take into consideration the level of use.

Importance of material benefits from the point of view of the market participants

The analysis concluded that from the point of view of the market participants, since the introduction of the TPA the extent of the material benefits has declined, principally in the field of further and continuous training. Although they are still relevant in this field, they no longer constitute the central issue. In regard to the rebates, the widely held consensus of the interviewed experts was that pharmaceutical companies, after an initial reticence, are now once more awarding hospitals and medical doctors, who have the right to self dispensation (SD-doctors), substantial rebates or

[1] Pursuant to Art. 35 HIA, care providers are:

- persons, who provide services ordered or requested by a doctor, and organizations that employ such persons,
- places for supplying means and articles that are used for the examination or treatment,
- nursing homes.

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contributions to scientific funds, illicit accounts or subsidiaries. Rebates on medicinal products in favour of care providers represent today's central issue of Article 133 TPA, in that it principally highlights where the prescription of medicinal products is linked to the supply of medicinal products. The rebates also concern, in addition to the medicinal products, the medical devices, the latter not yet falling under Article 33 TPA.

If the objective of Article 33 TPA on medicinal product safety solely focuses on the product level (in the narrowest sense), then the problem of material benefits is indeed still relevant and there is room for improvement. However the problems appear much more significant, if in the wider sense the incentives for increased sales and off-label use (use of a medicinal product outside the approved area) are taken into account. Although the extent of the problem cannot be quantified exactly, there are clear indications, however that the issue is important. Firstly, the analysis of the current incentive structures for the care provider in the area of the obligatory health insurance (OHI) shows that incentives for undesirable behaviour do exist. This does not mean that all or many participants actually behave in this way, but it would be unrealistic to assume that no one is influenced by the incentives. As in many other areas of the law, it is a matter firstly of preventing incentives that can lead to an (often unconscious) undesirable behaviour. Secondly, experience from abroad also shows that similar arguments are made in regard to the effects of financial incentives: material benefits can offer incentives to increase quantities. The key problems arise when prescription and supply are not separated. The critical situations in the system are the SD-doctors (accepting material benefits with possible sub optimal substitution or increased quantities), hospitals (principally also through research financing, less problems with quantities) as well as resident physicians (free riders, increased quantities). In this context, the vertical integration of market participants throughout different parts of the value chain is also somewhat problematic, because incentives can also be offered that influence care providers in their prescription or supply behaviour.

Starting point for review

It is important to understand that Article 33 TPA represents a so-called secondary regulation, which was needed following the regulation on required prescriptions, speciality list[2] (SL) and SD. It also has, however, in the current formulation, a cross-reference to fixing the maximum price, which increases the need that the appropriate aspects concerning the material benefits be put in order in the Article 33 TPA. Accordingly, in a weakly competitive environment (as a consequence of the regulations), the manufacturers and distributors should be prevented from influencing the prescribing or dispensing doctors in their choice and quantity of specific products.

The analysis clearly shows the need for action for the revision of Article 33 TPA. Despite contrary proposals, it does not appear necessary to delete Article 33 TPA and to resolve the

[2] The list of specialities includes the pharmaceutical specialities and manufactured medicinal products, which are standard insurance benefits of the health insurer.

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problem in another article of law. Article 26 is not an alternative, as corruption is not regulated therein. Medicinal products that are not in the speciality list (SL) are not covered by Article 56 HIA. Article 4 (UCL) does not cover the independent care provider in the health sector, Article 40 MedPL does not regulate passive corruption and Article 322 quater (criminal code) only concerns persons who are public officials[3]. Article 33 TPA is more inclusive than the cited currently existing legal articles and therefore should fundamentally remain in place and be better implemented. Moreover, improvements should be aimed for at various levels.

Proposals for the solution

The literature, political discussion (including interviews) and foreign comparisons reveal many elements for approaching the problem. When drafting consistent proposals for the solution which tackle the different problem levels, then a combination of several elements of the solution is required, together with possible accompanying measures. Furthermore, depending on whether the medicinal product safety is defined as the target in the narrow or broad sense makes quite a difference to the proposals for a solution. The analyses clearly show that Article 33 TPA in regard to the material benefits and Article 56 para. 3 HIA are closely linked to one another. Material advantages that are not passed on or skimmed off constitute financial incentives that can tempt individual care providers to change the prescription behaviour or supply or use in such a way that the medicinal product safety at the product level (false medication) or even at the use level (increased quantities or off label use) can be endangered. Brief description:

Version 1 the proposals represent in practice a slightly improved version of the *status quo*. This version, focussing on the medicinal product safety in the narrowest sense ignores interdependence between the provision in the TPA and those in the HIA.

Version 2 is heavily based on the previous regulation and attempts to counteract the unwanted incentives by means of targeted supplementary elements and to tackle the regulation problem with the fundamentals of Article 33 TPA.

Version 3 also makes a link between TPA and HIA and has drug security in a broader sense as the general aim. It goes the furthest, in that it makes new market rules in various areas of the system of the medicinal product market. Variant 3 is based on a completely new market logic and thereby has the strongest impact on the current HIA.

Versions 2 and 3 make a link between TPA and HIA. Some regulations in the HIA lead to unwanted financial incentives in the handling of medicinal products by certain care providers (in hospitals, by SD-doctors) which exacerbate the problem of the material benefits comprised in Article 33 TPA and can lead to problems with medicinal product safety, principally also at the use level. This means that

[3] In this connection, it is also important to mention the provisions of the Swiss Criminal Code on the offences of granting and accepting advantages (Art 322quinquies und Art. 322sexies SCC).

version 2 also requires certain adjustments in the HIA which modify the unwanted incentives relative to medicinal product safety at the use level both for the prescription as well as for the supply of medicinal products by care providers.

Table 1 shows the elements comprised in each of the versions.

ELEMENTS OF THE THREE VERSIONS TO THE SOLUTION			
Elements	**Version 1: improving the enforcement**	**Version 2: no unwanted incentives**	**Version 3: new market logic with consensus on therapy**
Focus medicinal product safety	In the narrow sense: product level	In a broader sense: product and use	In a broader sense: product and use
Tighten criminal offence	X	X	X
Increase transparency	X	X	X
Decouple the income of doctors/hospitals from supply		X	X
"Adjustment problem" in hospitals		X	X
Regulating vertical integration		X	X
Independent Central Office		X	X
Include medical devices		X	X
Limit scope of the regulation to prescription medicines		X	X
Strengthen the buying power/ consensus on therapy			X

Table 1

Version 1: improving the enforcement

The first version originates from the medicinal product safety in the narrow sense (product level), which Swissmedic followed up to now. The proposal provides for the Article 33 TPA to remain in the Therapeutic Product Act and be slightly amended. Compared with today, enforcement should be simplified and become more effective, in that Swissmedic focuses on cases involving prescription (RX) medicinal products and cases of interactions of C/D medicinal products with RX medicinal products. In addition, the criminal offence should be tightened, i.e. be raised to the level of "misdemeanour", in order to emphasise the regulation and have available better means for investigation. Care providers, in particular hospitals and doctors, who are themselves allowed to supply medicinal products (SD doctors), shall be obligated to transparency and to disclose their accounts. This means that the care providers must indicate all rebates that they obtain in the invoice and must disclose them when requested by the management authority Swissmedic.

Version 2: no unwanted incentive structures

The objective of Version 2 is medicinal product safety in the broader sense (product level and use level, increased sales), and consequently also the problem of increased sales due to material advantages. It includes all the measures of version 1, but moreover strives to fundamentally improve all incentive structures of the medicinal product market which present problems in regard to

increased sales and off label use. The problems result when a care provider, by prescribing a medicinal product, generates direct or indirect income for himself or his organisation at the same time. For hospitals and self-dispensation doctors, problems arise that trace back to the principal-agent problem that figures several times in the medicinal product market. This problem arises because of an information asymmetry between doctor and patient due to the patient's lack of technical knowledge and experience. The agent (here the doctor) can exploit this in regard to the principal (patient) by prescribing or supplying the patient with that medicinal product, which generates the greatest income for himself, chosen from a line up of expedient medicinal products. In the hospital, material benefits from the manufacturer can be an incentive to provide a specific medicinal product to patients during their hospitalisation such that the patient once released from hospital will also continue to take the same medicinal product.

Version 2 aims to alleviate this interconnection at the following levels:

Self dispensation doctors (SD): The problem of material benefits for the medical fraternity can be largely removed at the cause, if SD doctors could not achieve any direct or indirect increase in earnings by selling medicinal products. This does not concern the self-dispensation or additional income *per se*, but rather concerns the false incentives that result from the connection between the additional income of the doctor on the amount and the price (and thereby the discount/rebate) of the supplied medicinal product. Rebates in kind above a (low) threshold value are absolutely forbidden.

Hospitals. In contrast to SD doctor practices, institutional reforms to resolve the unwanted connection between prescription and supply rights are more easily possible in hospitals. Version 2 makes transparency an obligation for hospitals by requiring them to disclose material benefits in the form of rebates or research grants in the invoice.

Vertical integration: Prescription and supply can not only be directly linked as is the case for the SD doctors and the hospital, but rather also indirectly through the participation of doctors in sales companies (e.g. mail-order companies) and manufacturers. This vertical integration is undesirable when doctors, as the owner of a sales company, can influence the profits of the company and consequently indirectly influence their own income by their actions. Therefore, care providers in the field of health should only be involved in upstream or downstream companies to the degree that there exists no perceptible connection between their actions or their prescription and the result of the upstream or downstream company, e.g. by limiting the maximum possible participation of doctors and a restriction of the profits from such participations to a specific amount/fraction of income of the doctor, e.g. less than 1% of the income.

Version 2 additionally comprises further recommendations for change:

With the constraints of transparency and the inclusion of the problem of quantities, Article 33 TPA involves new market supervision duties; the previous management authority Swissmedic is not suited to execute them because of its usual duties and due to the latent capture problem.

Swissmedic as the approval and prosecuting authority is co financed from the fees of the manufacturers, which would mean that the required independence in regard to the medicinal product safety is not adequately guaranteed. Consequently, the enforcement of Article 33 TPA should be transferred from Swissmedic to a new, independent enforcement agency.

The application field should primarily relate to the RX medicinal products: The medicinal product safety, both at the product level as well as use, primarily affects the list A/B of the SL and the list exemptions as well as C/D preparations with relevant interactions with A/B medicinal products.

The inclusion of medical devices into Article 33 TPA should be examined because the principal-agent problem arises in the same way and because the transition between medicinal products and medical devices is becoming more and more indistinct.

Version 3: new market logic with consensus on therapy

The objective of Version 3 is also medicinal product safety in the broader sense. However, version 3 does not build on the current market logic, but goes in the direction of pharmacy benefit management (PBM, medicinal product management). In the PBM the health insurance companies, respectively their duly authorised companies, negotiate rebate contracts with pharmaceutical manufacturers.[4] The model aims at the prescription and/or supply behaviour of the doctors and pharmacists. With generics for example, in this version the pharmacist can deliver preparations to the client for which his health insurance company has concluded a rebate contract. Only the active principle has to be identical with the doctor's prescription. This is less easy for branded products as mostly there are only similar active principles. If the health insurers want to realise rebates then they have to change the way the doctors prescribe, e.g. in the following way:

The FOPH and the insurer compile a therapy consensus for the most frequent diagnoses indicating the lists of SL medicinal products and medical devices, in which form and in which intensity (quantity, dose) are the most suitable. According to statements from care providers, a therapy consensus is possible for at least two thirds of the total turnover in basic health care.

After the possible medicinal products (therapies) have been determined for the therapy consensus, the manufacturers and insurers negotiate the prices for the medicinal products that are approved for the therapy consensus. The most suitable products shall be approved. When prescribing/supplying, the doctors, SD-doctors, pharmacists and hospitals may only choose among these.

In order that as many doctors and pharmacists join in the therapy consensus, the obligation to contract is abolished. The health insurers are then free to work with doctors, hospitals and pharmacists who support the therapy consensus.

4 http://gesundheitsnews.imedo.de/news/10713-us-arzneiriesen-kommen-nach-deutschland

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The therapy consensus improves the medicinal product safety at the product level and at the use level and significantly lessens the incentive for non-optimal medication (product and use) for the care providers. The incentive for manufacturers to award material benefits to hospitals, doctors and pharmacists declines sharply. Rebates/discounts will continue however, but differently from today, in that they will be negotiated between the insurers and the manufacturers, and the rebates will directly benefit the insurers and their policyholders. With this version, it can be expected that medicinal product costs will tend to fall.

Version 3 represents a major change from the current market regime and leaves behind open questions. Thus, for example, the manufacturers will search for possibilities to influence the therapy consensus. It also remains unclear how the therapy consensus impacts the incentive for research activities, as overall the number of medicinal products will be somewhat smaller and will be divided among fewer products (principally those of the therapy consensus).

Assessment

As discussed above, the three versions pursue different objectives and lines of attack. In contrast to the two other versions, version 1 is limited to the general aim of medicinal product safety in the narrow sense. On the other hand, important problem areas concerning Article 33 TPA such as the problem of quantities, off label use, medical devices and the independence of the enforcement agency are not covered. In contrast, the advantage of version 1 is that it requires relatively little effort for the legislative amendment and enforcement and provokes little political resistance.

Versions 2 and 3 cover similar objectives, but version 3 reaches significantly more into the current market regime. The advantages over version 2 are that the medicinal product costs in the obligatory health insurance (OHI) system can be curbed. However this does not represent a major objective of the revision of Article 33 TPA, but rather a positive side effect. In other respects, various disadvantages must be considered, such as open implementation issues, higher amendment and enforcement costs, lower political acceptance and a reduction in the choice of therapy. Version 2 achieves the objectives practically just as well, with significantly fewer disadvantages than version 3. Compared with version 1, higher amendment and enforcement costs and stronger political resistance has to be reckoned with, but it also offers a significantly more comprehensive solution to the problem.

Because of the close connection between the problems of Article 56 HIA and Article 33 TPA, the versions that focussed on medicinal product safety in the broader sense (variants 2 and 3) additionally have the desired side effect that through a lower income incentive from the medicinal product supply, they curb the sales of SL products and thereby an important part of the expenditure for medicinal products.

Version 3 offers a similar contribution to version 2 for the most important problems/objectives, but requires a significant change to the current market logic, in that the choice of therapy for the care provider is greatly restricted by the therapy consensus. Figure 1 summarises how the three

versions can be assessed on the basis of criteria (aims of the TPA, economic and political indicators).

ASSESSMENT OF THE PROPOSALS ACCORDING TO SELECTED CRITERIA

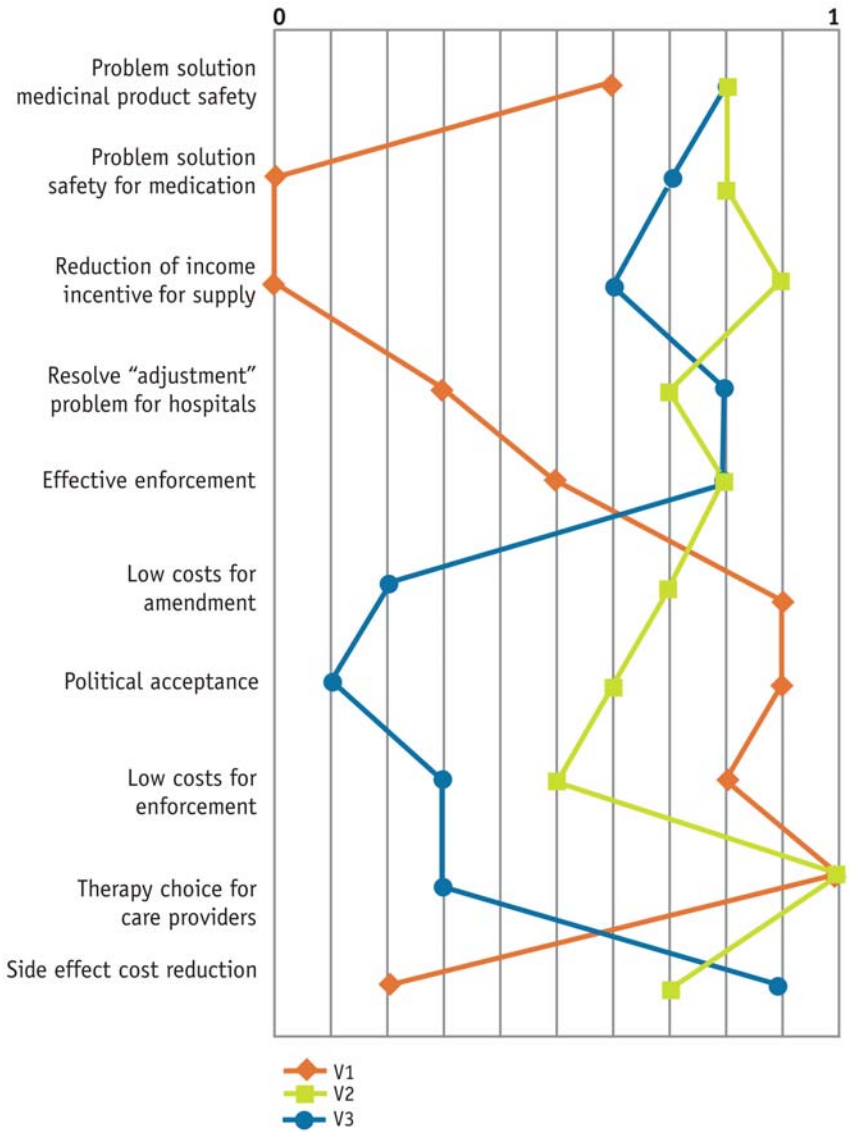

Figure 1: **1 = total fulfilment of the criterion, 0 = not fulfilled.**

The recommendation to the FOPH depends on which (political) objectives are given priority:

If in Article 33 TPA the medicinal product safety in the narrow sense (product level) is intended to be guaranteed, then the revision according to version 1 represents a pragmatic way with relatively low transition costs and high acceptance.

If the medicinal product safety in the wider sense (product level and use level), including problems of increased sales and off label use, is intended to be the general objective, then version 2 should be pursued further: bBased on the current market logic, it can reduce or avoid the fundamental weaknesses and unwanted incentives of the current regulation. A prerequisite is

certain amendments in the HIA. At the same time, version 2 represents a solution that allows it to be somewhat more easily realised than version 3 in the current political situation.

Version 3 demonstrates which total solution can be achieved with the objective of medicinal product safety in the wider sense when one is ready to partially relinquish the current market logic in the obligatory health insurance (OHI) system, thereby involving more fundamental changes. Partial aspects of this approach can be found in a few cases from other countries, also with inconsistent results, for example in regard to the therapy consensus. Version 3 reorganises the market situation so strongly that it can hardly be considered solely on the grounds of Article 33 TPA. Should the politicians decide on the basis of general considerations for a pharmacy benefit management, then it also offers a solution to the problem of material benefits.

The investigation clearly shows that a narrow interpretation of the medicinal product safety, as is the basis for version 1, is far too limited. According to the present information, the material benefit-driven incentives for increased sales and off label use represent at least such a relevant problem. Accordingly, we consider it advisable to choose the medicinal product safety in the broader sense as the objective and to continue with version 2 in order to solve the problem of the material benefits in Article 33 TPA.

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