Research paper

Patients’ access to drugs with rebates in Switzerland — Empirical analysis and policy implications for drug pricing in Europe

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ABSTRACT

Background: Many European countries introduced (confidential) rebates in the past years. Authorities and manufacturers argue that this strategy allows reduction of spending on high-cost drugs, and quick access of innovative drugs. We evaluated these arguments using Switzerland as an example, one of the last countries with transparent rebates.

Methods: We identified all drugs granted rebates in Switzerland and all new drugs without rebates between January 2012 and October 2020. We assessed the amount of introduced drugs with and without rebates over time, clinical benefit of drugs with rebates, and duration between approval and price determination.

Findings: Our study cohort included 51 drugs with rebates, the majority were cancer drugs (32; 63%). 15/51 (29%) had high clinical benefit, 25/51 (49%) low benefit and for 11/51 (22%) benefit could not be assessed. The number of drugs with rebates increased in recent years. Time duration between approval and price determination was 302 days in median for drugs with and 106 days for drugs without rebates.

Interpretation: Drugs with rebates may hamper access to drugs and lead to overpayment. Improving transparency on actual drug prices and stronger cooperation between countries could help national authorities to make better informed pricing decisions, and improve access of innovative drugs to patients.

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1. Introduction

Health care costs have increased in Europe, with drug costs serving as a contributor to this increase [1, 2]. In proportion to the total health care costs, key European countries, such as Germany, France, England, and Switzerland, spent more on drugs than the US [3]. The European Commission highlighted that health systems and patients have difficulty to cover the costs for drug expenditures, thus, ensuring access to affordable drugs for patients in Europe is highly crucial and at stake [4].

In Europe, drug prices are regulated on a national level [5, 6]. The goal of such pharmaceutical pricing policies and regulations is to ensure affordable access to drugs [6, 7]. A frequently applied pricing policy is, for example, external reference pricing [6]. The World Health Organization (WHO) describes this policy as a tool to allow a government to compare the price of a drug to one or several other countries to derive a benchmark or reference price for the purpose of setting or negotiating the price of the drug in the own country [8]. It shall ensure that the price paid for a drug in a specific country does not exceed unreasonably the price paid in the comparator countries [8, 9].

Official drug prices, also referred to as “publicly available prices” or “list prices”, should reflect the actual ex-factory drug prices [10, 11]. However, in the past years so-called “rebates” or “discounts” were introduced in many European countries (e.g., Germany, France and England) [12, 13], i.e., the national authority and the manufacturer agree that the actual price for a specific drug differ from and is lower than the official drug price. For simplicity we use “rebates” to refer to these practices.

Manufacturers and national authorities argue that (confidential) rebates allow to reduce spending on high-cost drugs and enable quicker access of drugs to patients by allowing more flexibility when negotiating the drug prices with manufacturers [8]. However, drugs that are granted rebates and the specific rebate amounts are confidential in most European countries [12, 14]. This approach masks actual drug prices and may lead to the obstruction of market transparency as well as distortion and overpayment of drug prices [12, 14].
2. Methods

2.1. Data sources and extraction

We used the public database (“special list”) by the Federal Office for Public Health (FOPH) to identify all drugs that were granted rebates as of 1 October 2020 [20]. We extracted the following information for our study cohort: active ingredient, indication, inclusion date on the special list (i.e., date of price determination and coverage by the social health insurance), price of the drug when included in the special list (list price and, if available, specific rebate amount). In cases where a rebate was granted after inclusion of the drug on the special list, we also extracted the date of the first introduction of the rebate. We used the public database by Swissmedic (Swiss drug approval agency) to extract the approval dates of all included drugs with a rebate [21].

Since Switzerland does not have a publicly established health technology assessment value tool, we assessed the clinical benefit of the cancer drugs in our study cohort based on the publicly available and established therapeutic value ratings of Germany (Federal Joint Committee) [22]. We considered the clinical benefit only for those indications for which a rebate was applied when first introduced on the special list. In cases in which drugs with rebates had more than one indication and different clinical benefit values, we focused on the indication with the highest benefit value. Consistent with a previous study, we defined ratings of moderate or greater benefit as “high benefit” and the rest (that is, low benefit, no benefit, not quantifiable benefit) as “low” [23].

We repeated our analysis in the subgroup of drugs with rebates for tumours using the European Society for Medical Oncology Magnitude of Clinical Benefit Scale version 1.1 (ESMO-MCBS) [24, 25]. Since the ESMO-MCBS tool cannot be applied to haematological cancers, the evaluation was restricted to drugs for solid tumours. For drugs with multiple pivotal clinical trials and different clinical benefit scores, we focused on the highest clinical benefit score. Our calculations were based on the pivotal trials relevant for approval by the European Medicines Agency (EMA) since Swissmedic did not publish such information. Consistent with the developers of the value framework as well as previous studies, high benefit was defined as a score of A-B (in adjuvant or neoadjuvant therapy settings) or 4–5 (in palliative setting) [7, 24, 25]. Low benefit was defined as any other score [7, 24, 25].

We calculated monthly treatment costs for each cancer drug in our study cohort and applied commonly used standard patient values (bodyweight of 70 kg and body surface area of 1.70 m²). The recommended dose for the relevant indication was used for calculation [26]. In cases of different dosages for the same indication, we used the dosage with the lowest associated monthly treatment costs. Rebates were calculated based on monthly treatment dosages. Drug prices are, in general, re-evaluated every financial resource [7].

One of the last transparent countries with regard to drugs that are granted rebates and the specific rebate amounts is Switzerland. However, also Switzerland introduced confidential rebates and the legislator is currently considering to revise the federal health insurance act in order to officially legitimate and promote confidential rebates [13].

To counter this development, the World Health Assembly adopted in May 2019 a resolution to support more transparency of drug prices [19]. The resolution urges member states to enhance public sharing, among other things, of information on actual prices paid by governments, and determinants of pricing. The goal is to help member states make better informed decisions when negotiating drug prices, and ultimately expand access to drugs for patients [19].

To assist the current discussions, we aimed to assess which drugs were granted rebates, the clinical value of these drugs, and whether such drugs may enable quicker access to patients in comparison to drugs without rebates, as suggested by national authorities and manufacturers. Our analyses are based on Switzerland since it is one of the last European countries with, in general, transparent rebates.
2.2. Statistical analysis

Descriptive statistics was performed to assess the amount of introduced drugs on the special list with and without a rebate over time, the amount of (cancer) drugs in the study cohort with high and low benefit, and the duration between approval date and inclusion date on the special list for the study cohort and comparison group. For the latter analysis, we only considered the drugs in our study cohort for which rebates were granted when first included in the special list.

All statistical analyses were done in R (version 3.6.2).

2.3. Role of the funding source

This study was funded by the Swiss Cancer Foundation (Krebsforschung Schweiz) and the Swiss National Foundation (SNF). Both funders did not have any role in study design, data collection, data analysis, interpretation or writing of the report.

3. Results

Our study cohort included 51 drugs with granted rebates between 1 January 2012 and 1 October 2020. The most drugs with rebates, 63% (32/51), were cancer drugs for solid and hematologic tumours (Table 1).

The number of drugs with newly granted rebates increased from 1 in 2012, 1 in 2013, 1 in 2014, 2 in 2015, 3 in 2016, 10 in 2017, 5 in 2018, 13 in 2019 to 15 in 2020 (Fig. 1). The time between drug approval and inclusion on the special list was 302 days in median for drugs with rebates and 106 days for drugs without rebates (Fig. 2). We applied Cox regression to model the duration between approval date and inclusion date. We fitted three different models. A simple model without additional covariates (hazard ratio, 0.52; 95% CI, 0.35 to 0.76), a model with approval year as an additional covariate in the model (hazard ratio, 0.49; 95% CI, 0.33 to 0.74), and a model for right-truncated data (hazard ratio, 0.43; 95% CI, 0.25 to 0.74). In each of the 3 cases, a significant difference between the 2 groups was found.

Based on the therapeutic value ratings of Germany (Federal Joint Committee), 15 (29%) of the 51 included drugs in our study cohort had a high benefit, 25 (49%) had a low benefit and for 11 (22%) no benefit score was available (Table 2).

The ESMO-MCBS is limited to solid tumours (23 drugs in our study cohort). Applying the ESMO-MCBS, 12 (52%) cancer drugs with a rebate had a high benefit and 11 (48%) had a low benefit.

Monthly treatment costs for cancer drugs with rebates based on official list prices varied between EUR 3029 palbociclib (Ibrance) and EUR 34,577 blinatumomab (Blincyto), and had a median price of EUR 5053 (Table 2). Applied rebates (at monthly treatment cost level) varied between 4% (EUR 226) and 58% (EUR 3493), with a median reduction of 27% (EUR 1538) (Table 2).

4. Discussion

The amount of drugs with granted rebates has increased substantially in recent years in Switzerland, with a majority indicated for solid or haematologic tumours. However, less than a third of these drugs had a high clinical benefit and time duration until price determination was longer compared to drugs without rebates.

Using Switzerland as an example, the results demonstrate that the amount of drugs with newly granted rebates increased from 1 in 2012 to 15 drugs with a rebate 2020, with a total of 51 drugs by 1 October 2020. Publicly accessible rebates for cancer drugs ranged from 4% and EUR 226 for pembrolizumab (Keytruda) to 58% and EUR

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Table 1

| Therapeutic class | Total | Proportion (%) |
|------------------|-------|---------------|
| Oncology         | 32    | 63            |
| Gastroenterology | 3     | 6             |
| Hematology       | 3     | 6             |
| Nephrology       | 3     | 6             |
| Neurology        | 3     | 6             |
| Endocrinology    | 2     | 4             |
| Pneumology       | 2     | 4             |
| Infectology      | 1     | 2             |
| Psychiatry       | 1     | 2             |
| Rheumatology     | 1     | 2             |

Fig. 1. Number of drugs included on the special list (year of price determination) with rebates (left bar) and without rebates (right bar).
This could undermine the cost-containing drug pricing regulations in Europe, which have the goal to achieve affordable access of drugs to patients.

To enable timely access to patients, national authorities have the pressure to not only approve but also determine the drug prices for coverage by the social health insurances as quickly as possible. Therefore, the strategy of (confidential) rebates may seem at first glance a promising solution. However, the study results demonstrate—in line with the WHO’s resolution [19]—that time duration between approval and price determination was longer for drugs with rebates compared to those without rebates, thus, rebates may actually hamper timely access of patients to important drugs.

Our study results support the importance of the World Health Assembly’s resolution urging for transparency on actual drug prices paid by governments. Our results also indicate that the goal of the European Commission—to ensure access to affordable drugs for patients in Europe—may not be achieved with the strategy of drug rebates.

It is crucial that the limited resources are spent on innovative drugs that offer improved outcomes. To achieve this goal, one approach could be for countries to be more transparent about the actual prices and collaborate more closely. For example, the Benelux initiative on pharmaceutical policy—including Belgium, the Netherlands, Luxembourg, Austria, and Ireland—has the goal to ensure timely access and affordability of drugs by, among other things, exchanging expertise and joint pricing negotiations for specific drugs [37].

Another consideration could be to focus on transparent value-based pricing that enable informed, systematic, and carefully considered decisions about allocations of restricted resources [7, 38]. Previous studies criticized external reference pricing since differential drug pricing between countries may actually be justified due to factors, such as supply, demand, competition, risk, reimbursement policies, government subsidies, taxes, and regulatory constraints [38].

This study has limitations. We only assessed drugs with publicly available rebates in Switzerland since other countries, such as England or France, do not publish such data. Therefore, it remains unclear if these results are also valid for other European countries. We relied on the assumption that the manufacturers started the price negotiations with the Federal Office for Public Health (national authority in
Table 2

| Approval date | Inclusion date | Active substance | Drug name | Indication | Monthly treatment costs (EUR) | Rebate total (EUR) | Rebate percentage (%) | FJC Germany | ESMO-MCBS |
|---------------|---------------|------------------|-----------|------------|-------------------------------|-------------------|----------------------|-------------|-----------|
| 05/2020       | 08/2020       | Bevacizumab      | Zirabev   | Renal cell carcinoma | 3353 | 768 | low |
| 12/2019       | 06/2020       | Talazoparib      | Talzezna  | Breast cancer    | 5437 | 1001 | high |
| 12/2019       | 07/2020       | Bevacizumab      | MVASI     | Renal cell carcinoma | 3400 | 1201 | low |
| 11/2019       | 12/2019       | Binimetinib      | Melitovia | Melanoma        | 5037 | 1944 | high |
| 06/2019       | 05/2020       | Celzakidim       | Zavicelta | Bacterial infection | – | – | – |
| 05/2019       | 07/2019\textsuperscript{a} | Alemacisib       | Verzenios | Breast cancer   | 3204 | – | low |
| 05/2019       | 05/2020       | Ivcacitor,       | Texacator  | Cystic fibrosis | – | – | – |
| 03/2019       | 05/2019       | Galkancemuzumab  | Emality   | Chronic migraine/Epidemic migraine | – | – | low |
| 11/2018       | 07/2019\textsuperscript{a} | Erinsizumib     | Nebilbra   | haemophilia a | – | – | low |
| 10/2018       | 08/2019       | Niraparib        | Zejula    | Ovarian cancer/Fallopian tube carcinoma/Pentosional carcinoma | 4962 | – | low |
| 09/2018       | 09/2019       | Olaparil         | Lynparza  | Ovarian cancer  | 4900 | – | low |
| 12/2017       | 08/2020       | Patromer         | Veltassa  | Hyperpotassiumia | – | – | low |
| 10/2017       | 06/2019       | Ribociclib       | Kiasqui   | Breast cancer   | 3160 | – | low |
| 09/2017       | 12/2017       | Glecaprevir,     | Pibrentavir | Chronic hepatitis C | – | – | low |
| 09/2017       | 03/2018\textsuperscript{b} | Ocrelizumab     | Ocrevus   | Multiple sclerosis | – | 9 | low |
| 09/2017       | 07/2020       | Nusinersen       | Spininzara | Spinal muscular atrophy | – | – | low |
| 09/2017       | 08/2018       | Guanfacin        | Intuniv   | Attention deficit hyperactivity disorder | – | – | low |
| 09/2017       | 12/2017       | Abirateronacetad | Zytiga    | Prostate cancer  | 3387 | – | low |
| 08/2017       | 10/2017       | Trifuridin       | Tipriazel | Colorectal carcinoma | 3427 | – | low |
| 07/2017       | 02/2018       | Inotuzumab       | Besponsa  | Acute lymphoblastic leukemia | 28,920 | – | low |
| 02/2017       | 09/2017\textsuperscript{c} | Pembrolizumab   | Keytruda  | Hodgkin lymphoma | 6286 | 226 | low |
| 02/2017       | 04/2018       | Ixazomib         | Nlaro     | Multiple myeloma | 6893 | 2617 | low |
| 01/2017       | 03/2017\textsuperscript{d} | Palboiclib      | Ibrance   | Breast cancer | 3029 | 5 | low |
| 12/2016       | 01/2017       | Tizikuzumab      | Taltz     | Plaque psoriasis | – | 7 | low |
| 12/2016       | 06/2017       | Daratumumab      | Darzalex  | Multiple myeloma | 10,311 | – | low |
| 09/2016       | 05/2020       | Lumacazfullor   | Orkambi   | Cystic fibrosis | – | – | low |
| 07/2016       | 08/2018\textsuperscript{e} | Osimertinib     | Tagrioso  | Lung cancer | 6027 | 1649 | high |
| 06/2016       | 08/2017       | Elotuzumab       | Emplisicti | Multiple myeloma | 6119 | 1649 | high |
| 04/2016       | 07/2017       | Alirocumib       | Praluent  | Hypercholesterolemia | – | – | low |
| 04/2016       | 11/2016       | Tolvaptan,       | Vladaptan | Autosomal dominant polycystic kidney disease | – | – | low |
| 04/2016       | 05/2016\textsuperscript{f} | Gropazprevi,    | Elebavir  | Chronic hepatitis C | – | – | low |
| 02/2017       | 10/2017       | Blinatumomab     | Blincyto  | Acute lymphoblastic leukemia | 34,577 | – | low |
| 02/2016       | 07/2016       | Trametinib       | Mekiniist | Melanoma | 6944 | 2750 | high |
| 02/2016       | 06/2016\textsuperscript{g} | Evolocumab      | Repathia  | Hypercholesterolemia | – | – | low |
| 11/2015       | 04/2016\textsuperscript{h} | Nivolumab       | Opdivo    | Renal cell carcinoma | 7429 | 1538 | high |
| 11/2015       | 06/2016\textsuperscript{i} | Carfilomizumab  | Kyroplis  | Multiple myeloma | 5724 | 309 | high |
| 10/2015       | 03/2016\textsuperscript{j} | Ramucizumab      | Cyramza   | Colorectal carcinoma | 4494 | – | low |
| 08/2015       | 05/2016\textsuperscript{k} | Cobilimetinib   | Cotelicul | Melanoma | 5993 | 3493 | high |
| 12/2014       | 02/2015\textsuperscript{l} | Sofosbuvir,     | Harveun   | Chronic hepatitis C | – | – | low |
| 06/2014       | 08/2014\textsuperscript{m} | Pomalidomiod    | Imnovid   | Multiple myeloma | 9839 | 1768 | high |
| 01/2014       | 02/2014\textsuperscript{n} | Dabrafenib     | Tafinlar  | Melanoma | 4716 | 1489 | high |
| 12/2013       | 03/2014       | Enzalutamid      | Xlantex   | Prostate cancer | 3581 | – | high |
| 05/2013       | 01/2014\textsuperscript{o} | Tratuzumab      | Kadcyla   | Breast cancer | 5069 | – | high |
| 02/2013       | 06/2013\textsuperscript{p} | Regorafenib     | Stivarga  | Colorectal carcinoma | 4726 | – | low |
| 12/2012       | 03/2020       | Hydrocractusin  | Plenadren | Primary adrenal insufficiency | – | – | low |
| 08/2012       | 07/2015       | Pertuzumab       | Perjera   | Breast cancer | 4957 | 1065 | high |
| 04/2011       | 10/2012       | Cabacitaxel      | Jevityna  | Hormone refractory prostate cancer | 4322 | – | low |
| 01/2010       | 02/2012\textsuperscript{q} | Eculizumab       | Soliris   | Paroxysmal nocturnal hemoglobinuria | – | 5 | low |
| 08/2007       | 07/2008\textsuperscript{r} | Lenalidomiod    | Revlimid  | Multiple myeloma | 6050 | 1248 | low |
| 12/2004       | 01/2005       | Bevacizumab      | Avatin    | Renal cell carcinoma | 5607 | 2346 | high |
| 09/2002       | 11/2002\textsuperscript{s} | Darbeportin alfa | Acanestp | Myelodysplastic syndrome | – | – | low |

\* Rebate granted after first inclusion on the special list/price determination.
Switzerland responsible for the determination of the drug price) subsequently after drug approval. This assumption may not always hold. Furthermore, our cohort covered the drugs on the special list as of 1 October 2020. There are most likely drugs approved in recent years for which price negotiations are still in process. This leads to an underestimation of the time between approval and price determination.

Using Switzerland as an example, drugs with granted rebates have increased in the past years with a focus on cancer drugs. Rebates were not limited to high-cost drugs and the amount of granted rebates varied strongly. Furthermore, these drugs often did not have a high clinical value, and price determination (i.e., access to drugs) may be prolonged. The results demonstrate the importance of the WHO’s resolution urging for information on actual prices paid by governments, and indicate that the goal of the European Commission – to ensure access to affordable drugs for patients in Europe – may not be achieved with the strategy of drug rebates. Improving transparency on actual drug prices and stronger cooperation between countries could help to identify drugs that should be made readily available across countries, help national authorities to make better informed pricing decisions, and ultimately improve access of innovative drugs to patients.

Author Contributions

DLC contributed to study design, data collection, data interpretation, and revision of the manuscript. KNV contributed to study design, data interpretation, drafting and revision of the manuscript. All authors were involved at each stage of manuscript preparation and approved the final version.

Data sharing statement

All data used in this study are publicly available (see methods section).

Declaration of Interests

KNV reports grants from the Swiss Cancer Research Foundation and Swiss National Foundation (SNF) during the conduct of the study. DLC has nothing to disclose.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.lanepe.2021.100050.

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