Drug launch timing and international reference pricing*

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Abstract

This paper analyzes the timing decisions of pharmaceutical firms to launch a new drug in countries involved in international reference pricing. We show three important features of launch timing when all countries refer to the prices in all other countries and in all previous periods of time. First, there is no withdrawal of drugs in any country and in any period of time. Second, whenever the drug is sold in a country, it is also sold in all countries with larger willingness to pay. Third, there is no strict incentive to delay the launch of a drug in any country. We then show that the first and third results continue to hold when the countries only refer to the prices of a subset of all countries in a transitive way and in any period of time. We also show that the second result continues to hold when the reference is on the last period prices only. Last, we show that the seller’s profits increase as the sets of reference countries decrease with respect to inclusion.

Key-Words: Drug launch timing, international reference pricing.

JEL Classification: I11, L65.

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1 Introduction

When launching a new drug on the international market, pharmaceutical firms decide on two important strategic dimensions: the pricing and the timing of launches for all countries. The timing of launches partly depends on aspects that are out of the firms’ control, such as the (supra-) national requirements of quality, safety and efficacy proofs and the length of time needed by the regulatory authorities to review the new product dossier. However, the timing of launches is also a best response of firms to some regulatory tools. In particular, international reference pricing (IRP) is generally held responsible for the sequential launching of new drugs. The many countries that use IRP impose a price cap that is based on the prices of the same product in other reference countries. In 2010, all EU countries except Germany, Sweden and the UK extensively use IRP. This policy leads to an interdependence of prices between countries. Many authors recognize that this interdependence gives pharmaceutical firms an incentive to launch new drugs in high-price countries first and to delay launch or even not to launch new drugs in low-price countries. These are [Danzon and Epstein, 2008], [Danzon et al., 2005], [Kyle, 2007], [Lanjouw, 2005], [Rankin, 2003], [Varol et al., 2012].

So far, no theoretical result exists on this issue. The paper by [Richter, 2008] provides a general game-theoretical framework to analyze the implications of international price interdependencies. This framework may prove useful for simulating the effects of IRP. However, it does not provide an optimal solution to the pricing and timing decision problem of firms because of its high complexity. Such theoretical results would be very important though both to guide empirical research on this issue and to inform health authorities about the possible consequences of regulatory tools such as international referencing. In particular, it is very important to distinguish between the two possible consequences of IRP, that is, either launches delays or absence of launch.
The modalities of application of IRP can also vary. For instance, international referencing can be retroactive or not. [Rankin, 2003] noted that retroactive IRP might place further restrictions on pricing strategy, limiting some of the rationale that is used to support a sequential entry strategy for a global launch. Furthermore, the basket of reference countries can vary between countries. In Europe, [Leopold et al., 2012] observe a great variation in the number of countries included in the reference country basket. Slovakia had the maximum number of countries in the reference basket (n=26) and Luxembourg had the minimum number of reference countries (n=1). Germany (n=13), Spain (n=13), France (n=11) and the UK (n=11) were the countries most frequently referenced. They also report that lower income countries refer to other lower wealth countries while more wealthy countries frequently define high-income states as reference countries. A tendency of changing the IRP modalities over time was noticed; in particular in terms of the composition of the reference basket as the number of reference countries in the basket has increased over time in many countries. [Leopold et al., 2012] even mention the possibility of ultimately having all countries referencing each other. It is therefore important to check whether different IRP modalities have different implications.

Several authors have empirically demonstrated and agreed on the link between IRP and the timing of launches. [Danzon and Epstein, 2008] find significant evidence that regulatory referencing by high-price countries to lower-price countries within the EU creates incentives for manufacturers to delay launch in low-price countries until higher prices have been established in other countries. The results of [Danzon et al., 2005] indicate that countries with lower expected prices or smaller expected market size have fewer launches and longer launch delays, controlling for per capita income and other country and firm characteristics. [Varol et al., 2012] conclude that product launch strategically takes place first in higher-priced EU markets as a result of threat of arbitrage and price dependency across the member states. [Kyle, 2007] found that companies delay launch into price-
controlled markets, and are less likely to introduce their products in additional markets after entering a country with low prices.

These empirical analyses do not distinguish between the various existing IRP modalities. In particular, the composition of the basket of reference countries and the possible retroactivity of IRP are left apart. Neither do existing empirical papers make a difference between the determinants of launch delays and those of absence of launch, except [Lanjouw, 2005] who concludes that the standard argument regarding price regulation - that it will dissuade market entry - appears to have more relevance among the high-income countries. For these countries, extensive price control is always found to lower the probability of market entry, and moderate regulation appears to do likewise, even in the long run. This is not so for the poorer countries. There she finds that while price regulation makes it less likely that new drugs will be available quickly, it does not appear to prevent new products from being launched eventually.

The present paper is the only one that analyzes the firms’ pricing and timing optimal responses to IRP in a general dynamic setting. We focus on IRP that takes the minimum price in the reference countries as the price cap. Our paper uniquely provides a benchmark solution to the firms’ behavior under IRP when all countries reference the prices in all other countries and in all previous periods of time. First, there is no withdrawal of drugs in any country in any period of time. Second, whenever the drug is sold in a country, it is also sold in all countries with larger willingness to pay (WTP). Third, there is no strict incentive to delay the launch of a drug in any country. In other words, when the basket of reference countries is complete (all countries reference each other) and the IRP is retroactive, a profit-maximizing firm has no incentive to strategically delay launches of new drugs. The firm is better-off foregoing sales in low-price markets forever to sustain high profits in high-price markets from the very beginning.

The rationale for this now or never optimal timing strategy is the following. When
deciding whether to launch a new drug in a country today rather than later, the firm trades off the profits from selling in that country today against the losses from propagating forever the price of that country to all the other countries that would have paid higher prices otherwise. The trade-off goes in favor of today if the country’s market is large enough or if its WTP for the new drug is high enough. Otherwise, it is better to delay the launch in that country. Until when is it better for the firm to delay? The answer is forever because the trade-off is actually repeated in every period. If it is better to delay the launch in a country once, then it is better to delay the launch all the time. This result is based on the ability of a price to propagate into other markets. Therefore, all the countries willing to pay a price above a given threshold are served while the others are not.

We generalize these benchmark results to cases where either countries do not refer to the prices of all other countries or the international referencing is not retroactive. In particular, we show that two benchmark results continue to hold when the sets of reference countries are incomplete yet transitive. By transitive we mean that whenever A is a reference for B and B is a reference for C, then A is a reference for C. In that case, there is neither withdrawal of drugs in any country and in any period of time nor strict incentive to delay the launch of a drug in any country. Transitivity of external referencing implies that, just as with complete reference countries sets, it takes exactly one period of time for a price to spread over the countries where it ever spreads. This fact explains the robustness of the first and third benchmark results. However, the second result is not granted anymore. Indeed, it is not necessarily the countries with the lowest WTP that are now excluded from sales for strategic reasons. When the reference baskets are not complete, the interdependence between the different markets is weaker than in the benchmark case so that the firm can break some possible interdependencies by simply foregoing sales in some markets that are central (central because referenced by many and referencing many). Even if the contexts are different, this rationale is similar to one studied by [Dziubinski and Goyal, 2013] where
the adversary of a network attacks the nodes that are critical for connectivity. Put in the context of IRP, the monopolist may find it optimal not to sell to countries that would allow low prices to propagate in the entire network.\footnote{The authors thank one referee for pointing out this similarity.} Such a sales break can concern a country with a WTP that is higher than in other countries where the drug is sold. Furthermore, we show that the firm’s profit is higher when the basket of reference countries includes fewer countries because there are fewer restrictions on prices.

When reference pricing is not retroactive, it can be optimal for the firm to disrupt sales everywhere every second period so as to set the highest possible prices everywhere during the selling periods. Therefore, both withdrawing and postponing sales in markets can be optimal if reference pricing is not retroactive. Only one of the benchmark results holds now as long as the set of reference countries is complete, that is, whenever the drug is sold in a country, it is also sold in all countries with larger WTPs.

The remainder of this paper is structured as follows. The formal model and results are displayed in Section 2. Section 3 concludes. All proofs and technically useful lemmas are in the Appendix.

2 The model

We consider the optimal price vectors for a monopolistic firm offering a drug for the international market in different settings. With no lack of generality, we consider the case where the cost of producing the drug is null. Buyers are countries or the health authorities in each of the countries. We assume that the drug is sold in all countries with perfect segmentation. Said differently, there is no parallel imports. Let $N = (1, ..., N)$ be the set of countries.\footnote{With a slight lack of rigor, but with no risk of confusion, $N$ is both the set of countries and its cardinality.} Each country $i$ has a willingness to pay (WTP), $w_i$, that is the price above which it is not willing to buy the drug under any circumstances. Let $(w_1, ..., w_N) \in \mathbb{R}_{++}^N$. 

$$w_i = \text{the willingness to pay of country } i$$
be the WTPs for all countries. Each country $i$ is also characterized by a market size (MS), $\omega_i$. This is the quantity the seller can sell in country $i$ if country $i$ buys the drug. Let $(\omega_1, ..., \omega_N) \in \mathbb{R}^{+N}$ be the MSs for all countries. Finally, each country $i$ uses a subset of countries (possibly all others countries) in order to compute a reference price at which it is willing to pay for the drug at a given time. We call these countries the Reference Countries (RCs) for country $i$ (or $i$’s RCs set), denoted $R(i)$. Formally, $R$ is a function from $N$ onto $2^N$. We impose that countries are RCs for themselves: $\forall i \in N, i \in R(i)$.

The problem of the monopolistic seller is to maximize its profit over the price vectors $(p_t^i)_{i \in N, t \in N}$ where $\forall i \in N, \forall t \in N, p_t^i \in \mathbb{R}^+$. Then, we allow for prices that would change over time and countries. We consider discrete time and we denote $\beta$ the time discount factor of the seller.

### 2.1 Unlimited time referencing

In this section, we consider the following policy. In any country $i \in N$, the drug is reimbursed by health authorities if the price is not higher 1) than $w_i$, and 2) than a reference price that is, if it exists, the minimum of the prices set in all reference countries in the past. In any country $i \in N$, the seller is selling a volume $\omega_i$ if the drug is reimbursed by health authorities. Otherwise, no volume is sold.

Formally, we assume the following constraints to the intertemporal maximization problem of the seller: at each period of time $t$, the quantity sold in country $i$ is $\omega_i$ if $p_t^i$ is smaller or equal to the minimum of: 1) $w_i$ and, 2) $\min_{t' < t}(\min_{j \in R(i)} p_{t'}^j)$ if $t > 0$. Other-
wise, 0 volume is sold. Then, the intertemporal maximization problem faced by the seller is

$$\max_{(p'_t)_{i \in N}, t \in \mathbb{N}} \sum_{i \in \mathbb{N}} \beta^t \left( \sum_{i \in S^t_R((p'_j)_{j \in N, t' \in \mathbb{N}}) \in N} p'_i \omega_i \right). \tag{1}$$

where i) $S^0_R((p'_j)_{j \in N, t' \in \mathbb{N}}) = \{ i \in N, p'_i \leq w_i \}$, ii) if $t > 0$, $S^t_R((p'_j)_{j \in N, t' \in \mathbb{N}}) = \{ i \in N, p'_i \leq \min(w_i, \min_{j \in R(i), t' < t} (p'_j)) \}$.

Then, all the information required at each time to make a profit-maximization choice depends on the minimum of the prices in all countries in the periods before. Let $V : (\mathbb{R}^+)^N \to \mathbb{R}$ with $V(p)$ the intertemporal profit earned by the seller if the minimum of the prices in all countries set in the history before the current period is $p \in (\mathbb{R}^+)^N$. Obviously, $V$ must satisfy the following Bellman equation:

$$V(p) = \max_{p' \in (\mathbb{R}^+)^N} \sum_{i \in O(p', p)} p'_i \omega_i + \beta V((p, p')) \tag{2}$$

where:

- $\forall p = (p_1, ..., p_N), p' = (p'_1, ..., p'_N) \in (\mathbb{R}^+)^N$, $O(p', p) = \{ i \in N, p'_i \leq \min(w_i, \min_{j \in R(i)} p_j) \}$,
- $\forall p = (p_1, ..., p_N), p' = (p'_1, ..., p'_N) \in (\mathbb{R}^+)^N$, $(p, p') \in (\mathbb{R}^+)^N$ is defined by $\forall i \in N$, $(p, p')_i = \min(p_i, p'_i)$.

Then, maximizing Equation 1 is equivalent to maximize Equation 2 at each period with $p$ the minimum for each country of the prices ever set. Before the first period, we set $p = (p_1, ..., p_N)$ and $\forall i \in N, p_i > \max_{j \in N} w_j$, for the problem to be well-defined.

Let $V^a : (\mathbb{R}^+)^N \to (\mathbb{R}^+)^N$ be the price vector\(^7\) that maximizes Equation 2 depending on the price vector at the start of the period. Formally,

$$V^a(p) = \arg \max_{p' \in (\mathbb{R}^+)^N} \sum_{i \in O(p', p)} p'_i \omega_i + \beta V((p, p')).$$

\(^7\)Notice here that we have one price for each country but not for each period of time. With no risk of confusion, we call price vector a sequence of prices with time dimension or not, depending on the context.
2.1.1 Complete RCs sets

With a slight abuse in notation, and referring to the network formalism, we say that the RCs sets are complete when they equal \( N \). Then, the first case we consider is the case in which all RCs sets are complete. Formally, \( \forall i \in N, R(i) = N \).

We show that the optimal price vectors in the case we consider (unlimited time referencing and complete RCs sets) imply three important features about optimal drug sales: \textit{no withdrawal, monotonicity} and \textit{now or never}. We explain these three features using intuitive arguments and a three-country example with \( w_1 > w_2 > w_3 \), before stating them formally in Propositions 1 to 3.

The first proposition states that there is no withdrawal of drugs in any country. The withdrawal of a drug from a country would imply a loss of profits from sales in that country while it would not influence prices in other countries anymore.

In our three-country example with complete RCs sets, we consider that the monopolist starts selling the drug everywhere and then gives up the sales in country 3 from period 1 onwards, at the maximum possible prices at all periods. In that case, the price of the drug in country 3 is used as a reference price in the other two countries from period 1 onwards, no matter whether the drug is sold or not in country 3 anymore. In that case, total profits are \( V_1 \), with

\[
V_1 = \omega_1 w_1 + \omega_2 w_2 + \omega_3 w_3 + \frac{\beta}{1 - \beta} (\omega_1 + \omega_2) w_3.
\]

If instead, the monopolist maintains its sales in country 3 at maximum possible prices at all times, total profits increase to \( V_2 > V_1 \) since the profits from sales in country 3 are positive and prices are not different in the other countries, with

\[
V_2 = \omega_1 w_1 + \omega_2 w_2 + \omega_3 w_3 + \frac{\beta}{1 - \beta} (\omega_1 + \omega_2 + \omega_3) w_3.
\]

The next proposition generalizes this result.
**Proposition 1 (No withdrawal)**

With complete RC sets and unlimited time referencing, there is no withdrawal of drugs in any country.

Formally, assume $\forall i \in N, R(i) = N$. Let $p \in (\mathbb{R}^+)^N$ and let $p' \in V^a(p)$. Let $p'' \in V^a((p', p))$. $O(p', p) \subseteq O(p'', (p', p))$.

The second proposition states another important feature of the optimal price vectors in the case we consider (unlimited time referencing and complete RCs sets). It states that whenever the drug is sold in a country, it is also sold in all countries with larger WTPs. This is very intuitive since selling in countries with higher WTPs increase profits from sales without imposing further constraints on international prices.

In our three-country example, consider that the firm sells in countries 2 and 3 only and from the start, at maximum possible prices at all periods. In that case, total profits are $V_3$, with

$$V_3 = \omega_2 w_2 + \omega_3 w_3 + \frac{\beta}{1-\beta} (\omega_2 + \omega_3) w_3.$$  

If instead, the monopolist decides to sell in all countries from the start, at maximum possible prices, total profits increase to $V_2 > V_3$.

The next proposition generalizes this result to any set of $N$ countries.

**Proposition 2 (Monotonicity)**

With complete RC sets and unlimited time referencing, whenever a drug is sold in a country, it is also sold in all countries with larger WTPs.

Formally, assume $\forall i \in N, R(i) = N$. Let $p \in \mathbb{R}^{+\times N}$ and let $p' \in V^a(p)$. Let $i, j \in N$ be such that $w_i \geq w_j$. $j \in O(p', p) \Rightarrow i \in O(p', p)$.

Finally, the following proposition states a third important feature of the optimal price vectors in the case we consider (unlimited time referencing and complete RCs sets). It shows that there is no strict incentive to delay the launch of the drug in any country.
In the three-country example, consider that the monopolist sells in all countries from the start at the maximum possible prices at all periods. In this case, total profits are $V_2$. Alternatively, consider that the firm starts selling in country 3 one period after the start, at maximum possible prices at each period. The corresponding profits are $V_4$, with

$$V_4 = \omega_1 w_1 + \omega_2 w_2 + \beta(\omega_1 w_2 + \omega_2 w_2 + \omega_3 w_3) + \frac{\beta^2}{1-\beta}(\omega_1 + \omega_2 + \omega_3)w_3.$$ 

Last, consider that the firm sells the drug in countries 1 and 2 only and from the start, at the maximum possible prices at all periods. Accordingly, profits become $V_5$, with

$$V_5 = \omega_1 w_1 + \omega_2 w_2 + \frac{\beta}{1-\beta}(\omega_1 + \omega_2)w_2.$$ 

Comparing the alternative situations, we conclude that the monopolist is better off selling everywhere from the start if country 3 is attractive enough in terms of sales profits:

$$V_2 > V_4 > V_5 \iff \omega_3 w_3 > \beta(\omega_1 + \omega_2)(w_2 - w_3).$$

Otherwise, it is better for the monopolist to forego sales in country 3 forever, so as not to propagate its low price to the other two countries:

$$V_2 < V_4 < V_5 \iff \omega_3 w_3 < \beta(\omega_1 + \omega_2)(w_2 - w_3).$$

There is only one particular case in which the seller is indifferent between delaying sales in country 3 or not:

$$V_2 = V_4 = V_5 \iff \omega_3 w_3 = \beta(\omega_1 + \omega_2)(w_2 - w_3).$$

The intuition for this now or never optimal strategy is the following. When deciding whether to launch a new drug in a country today rather than later, the firm trades off the positive profits from selling in that country against the losses from propagating forever the price of that country to all the other countries that would have paid higher prices otherwise. The trade-off goes in favor of today if the country’s market is profitable enough. Otherwise,
it is better to delay the launch in that country. Until when? The answer is forever, because the same trade-off is repeated in every period of time.

The following proposition generalizes this result to any set of $N$ countries.

**Proposition 3 (Now or never)**

With complete RC sets and unlimited time referencing, there is no strict incentive to delay the launch of the drug in any country.

Formally, assume $\forall i \in N, R(i) = N$. Let $p \in \mathbb{R}^{+N}$ and let $p' \in V^a(p)$. Then, $\exists p'' \in V^a((p,p'))$ such that $O(p',p) = O(p'',(p',p))$.

Then, we have proved three important features of the optimal price vectors in the case with unlimited time referencing and complete RCs sets. First, there is no withdrawal of the drug in any country where the drug has already been sold (Proposition 1). Second, the countries where the drug is sold are the countries with the largest WTPs (Proposition 2). Third, there exists an optimal price vector for which all the countries where the drug is ever sold are the countries where the drug is sold from the first period (Proposition 3).

### 2.1.2 Incomplete RCs sets

In this section, we check the robustness of the propositions stated in the previous section for the case in which the RCs sets are not necessarily complete. Formally, we relax the following assumption: $\forall i \in N, R(i) = N$.

The results of Propositions 1 and 3 (no withdrawal and now or never) continue to hold when the sets of RCs are not complete but still transitive. We say that an IRP is transitive in a set of countries $N$ if, whenever country $i \in N$ references country $j \in N$ and country $j$ references country $k \in N$, then country $i$ also references country $k$. Formally, $\forall i,j,k \in N, [j \in R(i), k \in R(j)] \Rightarrow k \in R(i)$.

One implication of the transitivity for an IRP is that, just as in the case with complete RCs sets, it takes exactly one period of time for a price to spread over the countries where
it ever spreads. The following proposition shows that this feature is the one driving the no withdrawal and now or never results.\(^8\)

**Proposition 4**

Propositions 1 and 3 hold when the IRP is only transitive.

The following example shows that when the IRP is not transitive, the no withdrawal result does not necessarily hold.

**Example 1**

Let \( \beta = 0.9 \). Let us consider a set of 3 countries: \( N = \{1, 2, 3\} \) with WTPs \( (w_1, w_2, w_3) = (1, 5, 4) \), with MSs \( (\omega_1, \omega_2, \omega_3) = (10, 0.001, 10) \) and with the following RCs sets: \( R(1) = \{1\}, R(2) = N \) and \( R(3) = \{2, 3\} \).

A simple computation shows that in Example 1, the optimal price vectors are the following:

- in period 0, \( p^0 = (p_1^0, p_2^0, p_3^0) = (1, 5, 4) \),
- from period 1 on, \( p^1 = (p_1^1, p_2^1, p_3^1) = (1, p_2^1, 4) \), with \( p_2^1 \geq 4 \).

Then, in period 0, the drug is sold in all countries. From period 1 on, it is sold only in countries 1 and 3. In this example, considering its WTP and MS, country 3 is the most important in terms of potential profit. In order to keep this potential profit high, the monopolist needs to prevent a spreading of the low prices in country 1 to country 3. However, this spreading is done in two steps and before it happens, the monopolist can sell in countries 1 and 2. The transitivity of RCs would impose that any future price spreading occurs in one period and would not allow this reasoning.

The next example shows that there can be some cases in which all optimal price vectors are ones with sequential launches. Then, when the IRP is not transitive, the now or never result does not necessarily hold.

\(^8\)The proof is similar to the ones of Propositions 1 and 3. It is therefore not provided but is available from authors upon request.
Example 2

Let $\beta = 0.9$. Let us consider a set of 4 countries: $N = \{1, 2, 3, 4\}$ with WTPs $(w_1, w_2, w_3, w_4) = (1, 1, 2, 2)$, with MSs $(\omega_1, \omega_2, \omega_3, \omega_4) = (9, 5.2, 6.7, 9)$ and with the following RCs sets: $R(1) = \{1, 3\}$, $R(2) = \{2\}$, $R(3) = \{1, 3\}$ and $R(4) = \{2, 3, 4\}$.

A simple computation shows that in Example 2, the optimal price vectors are the following:

- in period 0, $p^0 = (p^0_1, p^0_2, p^0_3, p^0_4) = (1, p^0_2, 2, 2)$, with $p^0_2 \geq 2$,

- in period 1, $p^1 = (p^1_1, p^1_2, p^1_3, p^1_4) = (1, 1, 1, 2)$,

- from period 2 on, $p^2 = (p^2_1, p^2_2, p^2_3, p^2_4) = (1, 1, 1, 1)$.

Then, in Example 2, the drug is sold with strictly positive volumes in all countries, at the maximum possible price and at all periods but in period 0 where it is not sold in country 2. The intuition is the following. It is optimal to sell the drug in all countries in the long term. However, it is also optimal to have a "slow" decrease of the price in country 4 that represents a quite large MS. In order to achieve this slow decrease of prices, it is important not to launch the drug in country 2 in period 0. Since country 2 has a smaller MS than country 4 and since country 2 is taken as a RC by country 4, selling in period 0 in country 2 would mean an increase in the instantaneous profit but it would mean a decrease in the price in period 1 in country 4 and hence, a loss of profit that would overcome the instantaneous gain in profit. However, notice that it is not worth keeping a high price in country 4 at all costs. This objective would mean not selling in country 2 at all and also keep a high price in country 3, which in its turn would mean not selling in country 1, a loss of profit that would not be worth keeping a high price in country 4. This example relies on the fact that the non transitivity of the IRP allows for a "slow" decrease of prices in some countries.

Then, transitivity of the IRP, not allowing two steps propagation of prices is the main
feature that drives the *no withdrawal* and *now or never* results. The following example shows that it is not the case for the *monotonicity* result.

**Example 3**

Let $\beta = 0.9$. Let us consider a set of 3 countries: $N = \{1, 2, 3\}$ with WTPs $(w_1, w_2, w_3) = (10, 1, 100)$, with MSs $(\omega_1, \omega_2, \omega_3) = (1, 1, 1)$ and with the following RCs sets: $R(1) = \{1\}$, $R(2) = \{1, 2\}$ and $R(3) = \{1, 3\}$.

A simple computation shows that in Example 3, the optimal price vectors are the following:

- from period 0 on, $p^0 = (p_1^0, p_2^0, p_3^0) = (p_1^0, 1, 100)$, with $p_1^0 \geq 100$.

In this case, even though the IRP is transitive and $w_1 > w_2$, the drug is sold only in countries 2 and 3 at all times. The reason is that the monopolist wants to avoid a propagation of prices from 1 to 3 and so cannot sell in 1. However, there is no propagation from 2 to any other country and hence, it would be pure loss not to sell in country 2. This reasoning does not rely on the fact that price propagation takes place in one step but rather directly on the differences in WTPs between referencing countries. When the RCs sets are complete, propagation of prices is made through many different paths and hence not selling in a country would not avoid the propagation of prices by lower WTPs countries.

Finally, notice that whatever the IRP, larger RC sets means more constraints for the monopolist seller and hence lower profits. The following proposition formally shows this intuition.

**Proposition 5 (Monotonic profits)**

*With unlimited time referencing, profits decrease as the size of the RCs sets increase.*

Formally, let $R, R' : N \to 2^N$ be such that $\forall i \in N, R(i) \subseteq R'(i)$. Let $V$ (resp. $V'$) be defined as in Equation 2 for $R$ (resp. $R'$). Then, $\forall p \in \mathbb{R}^+^N, V(p) \geq V'(p)$. 
2.2 Limited time referencing

We now consider that countries can use as reference prices only the prices in the previous period. Then, we assume the following constraints to the intertemporal maximization problem of the seller: at each period of time $t$, the quantity sold in country $i$ is $\omega_i$ if $p_t^i$ is inferior or equal to the minimum of: 1) $w_i$ and 2) $\min_{j \in R(i)} p_{t-1}^j$ if $t > 0$. Otherwise, 0 volume is sold. Then, all the information required at each time to make a profit-maximization choice depends on the prices in all countries in the period just before the current one. Let $W : (R^+)^N \rightarrow \mathbb{R}$ with $W(p)$ the intertemporal profit earned by the seller if the prices in all countries set in the previous period is $p \in (R^+)^N$. Obviously, $W$ must satisfy the following Bellman equation:

$$W(p) = \max_{p' \in (R^+)^N} \sum_{i \in O(p', p)} p'_i \omega_i + \beta W(p')$$

where

- $\forall p = (p_1, ..., p_N), p' = (p'_1, ..., p'_N) \in \mathbb{R}^N, O(p', p) = \{i \in N, p'_i \leq \min(w_i, \min_{j \in R(i)} (p_j))\}$.

Then maximizing the intertemporal seller’s profit is equivalent to maximize Equation 3 at each period with $p$ the prices for each country in the preceding period. Again, before the first period, we set $p = (p_1, ..., p_N)$ with $\forall i \in N, p_i > \max_{j \in N} w_j$ for the problem to be well-defined.

Let $W^a : (\mathbb{R}^+)^N \rightarrow (\mathbb{R}^+)^N$ be the price vector that maximizes Equation 3 depending on the price vector at the start of the period. Formally,

$$W^a(p) = \arg \max_{p' \in (R^+)^N} \sum_{i \in O(p', p)} p'_i \omega_i + \beta W(p')$$

The following example shows that neither Proposition 1 nor Proposition 3 are valid for function $W$. That is, there exist cases in which all the optimal price vectors imply that the drug is withdrawn from the market and even in a sense launched sequentially. Then,
there exist no optimal price vectors such that the set of countries in which the drug is sold is constant from period 1 on.

**Example 4**

Let $\beta = 0.9$. Let us consider a set of 5 countries: $N = \{1, 2, 3, 4, 5\}$ with WTPs $(w_1, w_2, w_3, w_4, w_5) = (1, 1, 3, 5, 5)$, with MSs $(\omega_1, \omega_2, \omega_3, \omega_4, \omega_5) = (8, 2, 2, 2, 1.5)$ and with complete RCs sets: $R(1) = R(2) = R(3) = R(4) = R(5) = N$.

A simple computation shows that in Example 4, the optimal price vectors are the following:

- in period 0 and even periods, $p^0 = (p_1^0, p_2^0, p_3^0, p_4^0, p_5^0) = (1, 1, 3, 5, 5)$,
- in odd periods, $p^1 = (p_1^1, p_2^1, p_3^1, p_4^1, p_5^1)$ with $\min(p_1^1, p_2^1, p_3^1, p_4^1, p_5^1) \geq 5$.

Then, the optimal price vector is to set maximum prices with constraint of selling in even periods, and withdraw the drug from all countries in odd periods. The intuition goes as follows. In this case, it is better to remove the drug from the market of all countries for one period every two other so that prices can be set at their maximum with the constraint of selling in even periods. The removal of the drug must be complete in order to have no binding reference price for no country in even periods. If the removal was not complete, the price in the remaining country would be 1, and the profit in the even periods would be too low. Then, in Example 4, quantities are abandoned in odd periods in order to have high prices in even periods.

**2.2.1 Complete RCs sets**

In this section, as we did in the case of unlimited time referencing, we consider that all RCs sets are complete. Formally, $\forall i \in N, R(i) = N$. Example 4 already proved that Propositions 1 and 3 are not robust when only limited time referencing is considered even in the case of complete RCs sets.
On the contrary, the following proposition shows that Proposition 2 is still valid when we consider only limited time referencing. Then, when the drug is sold in a country at a given period, it is sold in all countries with greater WTPs. The intuition is the same as in the case with unlimited time referencing.

**Proposition 6 (Monotonicity)**
With complete RC sets and limited time referencing, whenever a drug is sold in a country, it is also sold in all countries with larger WTPs.
Formally, let $p \in \mathbb{R}^{+N}$ and let $p' \in W^a(p)$. Let $i, j \in N$ be such that $w_i \geq w_j$, $j \in O(p', p) \Rightarrow i \in O(p', p)$.

**2.2.2 Incomplete RCs sets**
We have seen that only Proposition 2, adapted in Proposition 6 for limited time referencing, is robust when RCs sets are complete. The following example shows that again, this is not true anymore for incomplete RCs sets. Proposition 6 is not valid when RCs sets are incomplete and time referencing is limited, just as Proposition 2 is not valid when RCs sets are incomplete and time referencing is unlimited.

**Example 5**

$\beta = 0.9$. Let us consider a set of 4 countries: $N = \{1, 2, 3, 4\}$ with WTPs $(w_1, w_2, w_3, w_4) = (1, 2, 2, 3)$, with MSs $(\omega_1, \omega_2, \omega_3, \omega_4) = (6.5, 5.5, 9, 0.5)$ and with the following RCs sets: $R(1) = N$, $R(2) = N$, $R(3) = \{3, 4\}$ and $R(4) = \{1, 3, 4\}$.

A simple computation shows that in Example 5, the optimal price vectors are the following:

- in period 0, $p^0 = (p^0_1, p^0_2, p^0_3, p^0_4) = (1, 2, 2, 3),$
- in period 1 on, $p^1 = (p^1_1, p^1_2, p^1_3, p^1_4) = (1, 1, 2, p^1_4)$, with $p^1_4 \geq 2$.

Then, in this case, selling strictly positive volumes in all countries is important but it is also important not to decrease the price in country 3 which represent a large MS. In order
not to do that, it is crucial that country 4 does not propagate a low price since country 4 is an RC for country 3. Country 4 could propagate a low price coming from country 1. Then, selling the drug in country 4 for one period is acceptable since one period is not enough to propagate the low price implemented in country 1. Afterward, the country with the highest WTP (country 4) is abandoned by the seller because it represents a too small MS compared to the decrease in prices a sale there would imply.

Finally, we show that it is possible to generalize Proposition 5 to the case with only limited time referencing, the intuition being unchanged.

**Proposition 7 (Monotonic profits)**

With limited time referencing, profits decrease as the size of the RCs sets increase.

Formally, let $R, R' : \mathbb{N} \rightarrow 2^{\mathbb{N}}$ be such that $\forall i \in \mathbb{N}, R(i) \subseteq R'(i)$. Let $W$ (resp. $W'$) be defined as in Equation 3 for $R$ (resp. $R'$). Then, $\forall p \in \mathbb{R}_{+}^{N}, W(p) \geq W'(p)$.

## 3 Conclusion

To the best of our knowledge, the present paper is the first one to offer theoretical results linking IRP and timing of launches in a general dynamic setting. It identifies a useful benchmark case with three clear theoretical results when time referencing is unlimited and the set of reference countries is complete: First, there is no withdrawal of the drug in any country where the drug has already been sold (Proposition 1). Second, the countries where the drug is sold are the countries with the largest WTPs (Proposition 2). Third, there exists an optimal price vector for which all the countries where the drug is ever sold are the countries where the drug is sold from the first period (Proposition 3).

We extend these results outside the benchmark case. The first and third results continue to hold when RC sets are not complete as long as countries refer to the prices of other countries in a transitive way. The second result continues to hold when IRP is not retroactive, as long as RC sets are complete. Last, we show that the seller’s profits decrease
as RC sets increase, no matter whether IRP is retroactive or not.

These results can prove very useful for regulating authorities to anticipate the effects of different IRP modalities. They may also help empirical analyses to explain why some drugs never reach the consumers in some markets while they reach them at a late date in other markets. Concretely, to anticipate the effects of IRP, one has to observe the structure of the IRP network. For instance, if we have only limited clusters of similar countries referencing each other, then our results on complete RC sets apply. If countries are similar in WTP in every cluster, then all countries are likely to be served without any delay. This is the kind of IRP structure that the pharmaceutical industry actually encourages. Our results confirm that such a structure with a limited number of RCs leads to relatively low losses for the seller. Now, there is a trend in Europe towards increasing the RCs sets. If this trend ultimately results in a large group of countries referencing each other, then our results about complete RC sets suggest that some countries with low WTP (presumably, low-income countries) will not be served. The seller’s profits are lower in this situation because of increased constraints on international prices. Focusing on the countries situation, our conclusions are not far from [Ghiglino and Goyal, 2010] who analyze, in a completely different context, pricing and consumption decisions in a network with varying degrees of centrality. They claim that the poor lose and the rich gain when moving from a segregated community (separated networks for rich and poor) to an integrated community (a network in which rich and poor mix).

Currently, we observe a great disparity in the size of the RC baskets in Europe and the information on IRP in the EU reported by [Kanavos et al., 2011] confirms that the structure of the IRP network in Europe is currently not a complete one. If this structure proves to be transitive rather than complete (transitivity is far less exceptional than completeness in networks), then some countries in the network are in principle served from the very start and forever while others are excluded from drug sales forever. Our results
suggest that in a transitive network, the countries excluded from sales need not be the ones with the lowest WTPs, but rather the countries that are highly connected within the network. If the network is not even transitive, it can be optimal for a pharmaceutical firm to launch the drug sequentially. The same holds true if the IRP is not retroactive. In this case, we show that a firm first launches the drug in high-WTP countries before eventually launching it in lower-WTP countries.

Let us end our study with a few remarks. First, as is usually done in applied studies in the pharmaceutical industry, we did not introduce any dynamics inside each country such as market penetration that would be time-dependent. Introducing such a new dimension would possibly modify the incentives to not delay the launch of a drug by decreasing the WTPs in the beginning of the drug selling period. Second, we only considered minimum price references as cap prices. In reality, reference prices can be considered in more complex terms. Finally, we did not consider any cost for the pharmaceutical firm. Such a cost by itself would not change our results. However, it would change them if coupled with some liquidity constraints. Then, it would be possible that launching in only a part of the countries would have the effect of accumulating enough resources to pay for important fixed costs in countries in which the drug would be launched subsequently.
References


A Appendix

A.1 Unlimited time referencing

By assumption, the price in country $i$ is limited by its WTP, $w_i$, and the history of prices in countries $R(i)$, summarized by the minimum of the prices ever set in $R(i)$. Then, relaxing these minimums leads to an intertemporal profit that cannot decrease. This is formally expressed in the following lemma.

**Lemma 1**

Let $p, p' \in \mathbb{R}^N$ be such that $\forall i \in N, p_i \geq p'_i$. Then, $V(p) \geq V(p')$.

**Proof of Lemma 1:** Let $p'' \in V^a(p')$. Let $p''' = (p'', p')$. By definition, $\forall i \in O(p'', p')$, $p''_i \leq w_i$ and $p'''_i \leq \min_{j \in R(i)} p'_j$. Then, $\forall i \in O(p'', p')$, $p''_i \leq p'''_i \leq w_i$ and $p'''_i \leq \min_{j \in R(i)} p'_j \leq \min_{j \in R(i)} p_j$. Then, $O(p'', p') \subseteq O(p'''_i, p')$. Moreover, since $\forall i \in N, p_i \geq p'_i$, $(p'''_i, p') = (p''_i, p')$. Then, $V(p) \geq \sum_{i \in O(p'''_i, p')} p'''_i \omega_i + \beta V((p'''_i, p')) = \sum_{i \in O(p'''_i, p')} p'''_i \omega_i + \beta V((p'''_i, p'))$. Moreover, $\forall i \in O(p'''_i, p')$, $p'''_i \leq \min_{j \in R(i)} p'_j \leq p'_i$. Then, $\forall i \in O(p'''_i, p'), p'''_i = p'_i$. Hence, $\sum_{i \in O(p'''_i, p')} p'''_i \omega_i + \beta V((p'''_i, p')) = \sum_{i \in O(p'''_i, p')} p'_i \omega_i + \beta V((p'''_i, p')) = V(p')$. Then, $V(p) \geq V(p')$. □

The following lemma shows that unless some prices have already been set at 0 in the past, the monopolist is never interested in setting 0 price in any country. Remember that all WTPs and MSs are strictly positive and then, setting 0 prices is just a loss of revenue.

**Lemma 2**

Let $p \in \mathbb{R}^N$ be such that $\forall i \in N, p_i > 0$ and let $p' \in V^a(p)$. Then, $\forall i \in N, p'_i > 0$.

**Proof of Lemma 2:** Assume $p' \in V^a(p)$ with $p'_i = 0$ for some $i \in N$. Let us consider $p'' \in \mathbb{R}^N$ defined by:

$$
\forall k \in N, p''_k = \begin{cases} 
\min(w_i, \min_{j \in N} p_j), & \text{if } k = i \\
p'_k, & \text{otherwise}
\end{cases}
$$
Obviously, \( O(p'', p) = O(p', p) \) and \( p''_i > 0 \). Then, \( \sum_{j \in O(p'', p)} p''_j \omega_j + \beta V((p'', p)) > \sum_{j \in O(p', p)} p'_j \omega_j + \beta V((p', p)) \). By Lemma 1, \( V((p'', p)) \geq V((p', p)) \). Hence, \( \sum_{j \in O(p'', p)} p''_j \omega_j + \beta V((p'', p)) > \sum_{j \in O(p', p)} p'_j \omega_j + \beta V((p', p)) = V(p) \) contradicting the fact that \( p' \in V^a(p) \). □

A.1.1 Complete RCs sets

Obviously, by definition, what matters in the setting of prices at any period of time is the minimum of the prices in all countries in all the previous periods. We omit the proof of the following lemma. It is available upon request from the authors.

**Lemma 3**

Assume \( \forall i \in N, R(i) = N \). Let \( p, p' \in \mathbb{R}^N \) be such that \( \min_{j \in N} p_j = \min_{j \in N} p'_j \). \( V^a(p) = V^a(p') \).

The following lemma states that if the vector of prices at the start of the period is \( p \) and the seller does not sell in a country \( i \) in the same period, it is because, in the current and past periods, no price has ever been smaller than country \( i \)'s WTP. The reason is the following: assume there has already been or there currently is a price set below \( w_i \) in a country. Then, selling in country \( i \) at the minimum price ever seen, increases the profit earned by the seller in the current period and it does not necessarily harm its future payoff, since the price in country \( i \) is not lower than the minimum price ever set in any country.

**Lemma 4**

Assume \( \forall i \in N, R(i) = N \). Let \( p \in \mathbb{R}^{+N} \) and let \( p' \in V^a(p) \). \( \forall i \in N, i \notin O(p', p) \Rightarrow \min_{j \in N}((p', p)_j) > w_i. \)

**Proof of Lemma 4:** Assume it is not the case: let \( i \in N \) be such that \( i \notin O(p', p) \) and \( \min_{j \in N}((p', p)_j) \leq w_i. \) Let us consider \( p'' \in \mathbb{R}^N \) defined by:

\[
\forall k \in N, p''_k = \begin{cases} 
\min_{j \in N}((p, p')_j), & \text{if } k = i \\
p'_k, & \text{otherwise}
\end{cases}
\]
Obviously, \( \min_{j \in N} ((p,p^\prime)_j) = \min_{j \in N} ((p,p^{''})_j) \). Then, by Lemma 3, \( V(p) = \sum_{j \in O(p')p_i} p_j \omega_j + \beta V((p',p)) = \sum_{j \in O(p',p)} p_j \omega_j + \beta V((p',p)) \). Moreover, by assumption, \( p_i'' = \min_{j \in N} (p,p')_j \leq w_i \) and \( p_i'' = \min_{j \in N} (p,p')_j \leq \min_{j \in N} p_j \). Hence, \( O(p'',p) = O(p',p) \cup \{i\} \). By Lemma 2, \( p_i'' > 0 \). Hence, \( V(p) < \sum_{j \in O(p',p)} p_j' \omega_j + \beta V((p',p)) \). This contradicts the assumption that \( p' \in V^a(p) \). \( \square \)

**Lemma 5**

Assume \( \forall i \in N, R(i) = N \). Let \( p \in \mathbb{R}^{+N} \) and let \( p' \in V^a(p) \). Then, \( O(p',p) = O(p',(p,p')) \).

**Proof of Lemma 5:** Let \( i \notin O(p',p) \). By Lemma 4, \( \min_{j \in N} ((p',p')_j) > w_i \). Hence, \( p_i' > w_i \) which implies \( i \notin O(p',(p,p')) \).

Let \( i \notin O(p',(p,p')) \). Then, i) \( p_i' > w_i \) in which case \( i \notin O(p',p) \) or ii) \( p_i' > \min_{j \in N} (p,p')_j \). In case ii), \( p_i' > \min_{j \in N} p_j \) which implies \( i \notin O(p',p) \). \( \square \)

**Proof of Proposition 1:** By Lemma 2, \( p' \in \mathbb{R}^{+N} \) and then, \( (p',p) \in \mathbb{R}^{+N} \). Let us have \( i \notin O(p'',(p',p)) \). By Lemma 4, \( \min_{j \in N} ((p'',(p',p))_j) > w_i \). This implies \( p_i' > w_i \). Hence, by definition, \( i \notin O(p',p) \). \( \square \)

**Proof of Proposition 3:** Let \( p^{'''} \in V^a((p,p')) \). By Lemma 2, \( p' \in \mathbb{R}^{+N} \) and then, \( (p',p) \in \mathbb{R}^{+N} \). Let us assume the proposition is not true, \( \forall p' \in V^a((p,p')) \) \( O(p',p) \neq O(p'',(p',p)) \). By Lemma 5, \( O(p',p) = O(p',(p',p)) \). Then, by assumption, we must have \( p' \notin V^a((p,p')) \). Hence,

\[
\sum_{i \in O(p',(p,p'))} p_i' \omega_i + \beta V((p,p')) < \sum_{i \in O(p'',(p',p))} p_i'' \omega_i + \beta V((p'',(p',p))) = V((p,p')).
\]

Then, by Lemma 5,

\[
\sum_{i \in O(p',p)} p_i' \omega_i + \beta V((p,p')) < V((p,p')).
\]

Hence,

\[
V(p) < V((p,p')).
\]
Let us have \( i \in O(p'''(p,p')) \). By definition, this implies \( p'''_i \leq w_i \) and \( p'''_i \leq \min_{j \in N} (p,p')_j \leq \min_{j \in N} p_j \). Hence, \( i \in O(p'''(p')) \). Then,

\[
\sum_{i \in O(p'''(p,p'))} p'''_i \omega_i \leq \sum_{i \in O(p''(p'))} p'''_i \omega_i.
\]

Moreover, it is straightforward to check that \( \forall i \in N, (p'''_i, p) \geq (p'''_i, (p,p')) \). Then, by Lemma 1,

\[
V((p'''_i, (p,p'))) \leq V((p'''_i, p)).
\]

Hence,

\[
V(p) < \sum_{i \in O(p''(p'))} p'''_i \omega_i + \beta V((p'''_i, p))
\]

which contradicts the fact that \( p' \in V^a(p) \). □

**Proof of Proposition 2:** Assume it is not the case, let us have \( j \in O(p', p) \) and \( i \notin O(p', p) \). By Lemma 4, \( i \notin O(p', p) \) implies \( \min_{j \in N} (p', p)_j > w_i \). Then, \( p'_j \geq \min_{j \in N} (p', p)_j > w_i \geq w_j \). Then, by definition, \( j \notin O(p', p) \) which contradicts the assumption that \( j \in O(p') \). □

### A.1.2 Incomplete RCs sets

**Proof of Proposition 5:** Let

\[
V(p) = \max_{(p'_i)_{i \in N}, t \in N} \sum_{t \in N} \beta^t \left( \sum_{i \in S^t_R((p'_i)_{j \in N}, t \in N)} p'''_i \omega_i \right)
\]

and let

\[
V'(p) = \max_{(p'_i)_{i \in N}, t \in N} \sum_{t \in N} \beta^t \left( \sum_{i \in S^t_R((p'_i)_{j \in N}, t \in N)} p'_i \omega_i \right).
\]

with \( \forall i \in N, \forall t \in N, i \) if \( t = 0 \), \( i \in S^t_R((p''_j)_{j \in N}, t \in N) \Leftrightarrow p''_i \leq \min(w_i, \min_{j \in R(i)} (p_j)) \), ii) if \( t > 0 \), \( i \in S^t_R((p''_j)_{j \in N}, t' \in N) \Leftrightarrow p''_i \leq \min(w_i, \min_{j \in R(i), t' < t} (p''_j), \min_{j \in R(i)} (p_j)) \) (the same definition applies with \( R' \)).
Let \((p''_i)_{i \in N, t \in N}\) be an optimal price sequence maximizing in Equation 4. By assumption, \(\forall i \in N, R(i) \subseteq R'(i)\). Then, by definition, \(\forall t \in N, \forall i \in N, S_{R'}^t((p'_j)_{j \in N, t' \in N}) \subseteq S_{R}^t((p'_j)_{j \in N, t' \in N})\). Then, \(
abla_{t \in N} \beta^t \left( \sum_{i \in S_{R'}^t((p''_j)_{j \in N, t' \in N})} w_i \omega_i \right) \geq \nabla_{t \in N} \beta^t \left( \sum_{i \in S_{R}^t((p'_j)_{j \in N, t' \in N})} w_i \omega_i \right)\). Then, \(V > V'\). □

A.2 Limited time referencing

A.2.1 Complete RCs sets

Obviously, by definition, what matters in the setting of prices at any period of time is the minimum of the prices in all countries in the previous period. We omit the proof of the following lemma.

**Lemma 6**

Assume \(\forall i \in N, R(i) = N\). Let \(p, p' \in \mathbb{R}^N\) be such that \(\min_{j \in N} p_j = \min_{j \in N} p'_j\). \(W^a(p) = W^a(p')\).

**Lemma 7**

Let \(p \in \mathbb{R}^N\) be such that \(\forall i \in N, p_i > 0\) and let \(p' \in V^a(p)\). Then, \(\forall i \in N, p'_i > 0\).

**Proof of Lemma 7:** The proof is similar to the proof of Lemma 2 and therefore is omitted. □

**Proof of Proposition 6:** Let us assume it is not the case: \(j \in O(p', p)\) and \(i \notin O(p', p)\).

Let us consider \(p'' \in \mathbb{R}^N\) defined by:

\[
\forall k \in N, p''_k = \begin{cases} 
\min_{l \in N} (p'_l), & \text{if } k = i \\
p'_k, & \text{otherwise}
\end{cases}
\]

By definition, \(\min_{l \in N} (p'_l) = \min_{l \in N} (p''_l)\) and then, by Lemma 6, \(W(p') = W(p'')\). \(j \in O(p', p)\) implies \(p'_j \leq w_j\) and \(p'_j \leq \min_{l \in N} (p_l)\). Then, \(\min_{l \in N} (p'_l) \leq p'_j \leq w_j \leq w_i\) and \(\min_{l \in N} (p'_l) \leq p'_j \leq \min_{l \in N} (p_l)\). Then, \(O(p'', p) = O(p', p) \cup \{i\}\). Moreover, by Lemma 7, \(p''_i > 0\). Hence,

\[
\sum_{i \in O(p'', p)} p''_i \omega_i + \beta W(p'')
\]
\[
= \sum_{i \in O(p'')} p'_i \omega_i + \beta W(p')
\]

\[
> \sum_{i \in O(p',p)} p'_i \omega_i + \beta W(p') = W(p)
\]

This contradicts the assumption that \( p' \in W^a(p) \). \( \Box \)

### A.2.2 Incomplete RCs sets

**Proof of Proposition 7:** The proof is similar to the proof of Proposition 5 and is therefore omitted. \( \Box \)