

A Look Back at IRP in 2020

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The United States and Canada made headlines this year for changes both countries will be implementing regarding the way they price medicines, particularly those with higher costs. Although stalled twice, come the new year Canada's Patented Medicines Price Review Board's (PMPRB) rule will take effect. PMPRB will rely on an updated reference basket in which two countries where drug prices tend to often be higher – the United States and Switzerland – have been swapped out for markets where drug prices tend to be lower. Canada's basket will be composed of France, Germany, Italy, Sweden, and the UK, as well as newcomers Australia, Belgium, Japan, the Netherlands, Norway, and Spain. In the U.S., President Donald Trump signed his "Most-Favored Nations (MFN)" rule, which provides the U.S. with a basket of reference countries for the first time, a significant policy change for the States.

However, other updates were enacted around the world, this year.

IRP Updates That Took Effect This Year in Europe

Some changes in Europe were small, in response to Brexit. For example, Belgium is no longer referencing the United Kingdom since it formerly withdrew from the European Union.

In Latvia, medicine prices must be the average of the three lowest ex-factory prices among Latvia's reference basket countries. As of April 1, 2020, in order for medicines to be included in the reimbursement system, their price must not be higher than the second lowest manufacturer's sales price or wholesale price in the Czech Republic, Denmark, Romania, Slovakia, and Hungary, and must not exceed the manufacturer's selling price or wholesale price in Estonia and Lithuania.

Drugmakers will have to submit to the National Health Service (NSS) information on current prices in these countries by February 1 of each year. If the price does not meet the requirements, the applicant will have to reduce it.

As with Canada, the Netherlands experienced a delay in the implementation of its updated IRP schemes due to the impact of COVID-19 on the drug supply. The Netherlands held off on implementing its new international reference pricing IRP rule from April 1, 2020, to October 1, 2020. Via the Medicines Pricing Act (WGP), maximum prices are applied in the Netherlands based on the average price for comparable medicines in 4 reference countries: Germany, Belgium, France, UK. However, the Netherlands will be swapping out Germany with Norway because in Norway, medicine prices are 20% less than they are in Germany.

Ukraine also trudged forward with implementing reference pricing for the first time. Ukraine is relying on the average price among Poland, Slovakia, Hungary, Czech Republic and Latvia to conduct IRP both at launch and every year.

Russia

In 2019, Russian President Vladimir Putin signed a bill establishing a new methodology for regulating the prices of medicines in the Vital and Essential Drugs List (VED). Although this bill mandates reporting of price changes and re-registration, IRP has been in effect in Russia since 2010 and has been used for drugs in the VED that are produced outside Russia.

According to the rule, the marginal costs of original, patented drugs, as well as one of their respective generics on the Russian market were to be re-registered with the Ministry of Health.

Russia's reference basket for this is comprised of Hungary, Greece, Belgium, Spain, Netherlands, Poland, Romania, Slovakia, Turkey, France, Czech Republic and Country of origin. In this case, the price of a drug will be determined as the lowest price in one of the 11 reference countries (in particular Belgium, France, or Romania) or in the country of origin. After determining the minimum price for the drug, the Ministry of Health will decide on the cost of each of its generics, and the Federal Antimonopoly Service (FAS) will be allowed to demand a new price reduction from pharmaceutical companies if the cost of the drug falls in any of the reference countries.

The new pricing procedure will not affect drugs worth less than 100 rubles, vaccines, narcotic, and psychotropic drugs.

Middle East and Central Asia

Lebanon's new pricing policy was published January 2020. Price revision will now take place every four years as opposed to every three years, as was the case before the new rule was implemented. Price submissions must be made at the end of Q4 of the fourth year.

For foreign manufacturers' branded products, the minimum price is applied, whereas for local manufacturers of licensed branded products, generics and branded products, Lebanon will use a mix of reference pricing & IRP; however, in theory, it's free pricing. IRP is used as a benchmark (the price cannot exceed the IRP price), and for local generics, the price cannot exceed that of the branded original. As such, branded originals are privileged. In the case of orphan and innovative drugs, if the price changes by more than 10% in any of the reference countries the manufacturer must submit a new price declaration form and announce the new price.

Neighboring Jordan will conduct IRP at launch, using the median price found among its reference basket. For re-referencing, the minimum price will be used. Jordan's basket is expected to include France, Spain, Italy, Belgium, Greece, Australia, Cyprus, Hungary, Ireland, Portugal, Czech Republic, Croatia, Lebanon, Georgia, Tunisia, Azerbaijan, and Slovenia.

In July, Uzbekistan began phasing in a reference pricing system to combat unjustified overpricing of medicines, but according to Sardor Kariev, Director of the Agency for the Development of the Pharmaceutical Industry, "We are not aimed at forcing enterprises to lower the price of drugs or sell them at cost...we just want prices to be predictable, so we can be oriented."

Uzbekistan formulated a reference basket consisting of Hungary, Russia, Ukraine, Poland, Tajikistan, Slovenia, Kazakhstan, Bulgaria, Belarus, and Kyrgyzstan. Its IRP scheme applies to generic drugs of domestic and foreign production, not original medicines of domestic and foreign production, and the manufacturer must register the medicine's price for wholesale and retail, noting the trade name, dosage form, dosage, concentration, volume and packaging.



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In tandem with establishing a reference basket, the Agency for the Development of the Pharmaceutical Industry has been developing an online platform on which each manufacturer working in the market of Uzbekistan will have to indicate the selling prices of their medicines in 10 reference countries.

Countries to Watch in 2021

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Colombia will be soon taking the average price among the following reference countries to determine the price of new medicines: Argentina, Australia, Brazil, Canada, and Chile.

In addition, Morocco is expected to update its IRP rules, following an assessment of the scheme since its implementation in 2013. Of note, the World Health Organization (WHO) has offered ongoing support to Morocco as it fleshes out its update.

In 2019, Malaysia announced its plan to utilize IRP to benchmark medicines prices in Malaysia against cheaper drug prices in certain countries so that Malaysia's prices don't exceed the benchmark. The ceiling price will be based on the average of the three lowest prices, which will be imposed at the wholesale stage and retail level (in clinics, pharmacies, and hospitals).

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