GLOBAL BENCHMARKING SURVEY 2020

Benchmarking the competitiveness of the global animal health industry

RUSSIA
AUSTRALIA
BRAZIL
CANADA
CHINA
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Global Benchmarking Survey 2020
Report for Russia

1. Executive summary

The HealthforAnimals Global Benchmarking Survey is run every 5 years and has now grown to include 12 countries in the 2020 survey. The purpose is to examine the interactions between industry and regulatory systems for veterinary medicinal products, particularly the impact of regulations on the animal health industry's ability to access markets, be innovative, continue to commercialise existing products and be competitive.

This report is the first for Russia. It summarises the data from **4 international companies** surveyed, examines key trends and provides some basic analysis.

Data was collected through questionnaires in Q4 2019, which was aggregated and summarised to allow discussion in a subsequent workshop. The key points from the workshop discussions are an integral part of the report, which follows the questionnaire structure with 7 separate sections.

Key Conclusions

Section A - Economics of the animal health sector

The global animal healthcare industry continues to grow ($24 billion in 2015 and $41.5 billion in 2018), while the global veterinary pharmaceuticals market was estimated to be nearly $33,8 billion in 2018. The growth is driven by many factors. Acquisition is a common growth strategy to build competence and capacity in technologies, new science, new therapies and new geographies. The livestock and pet sector markets are themselves growing. At a global level the surveyed companies typically spend in the region of 7% of their revenue on research and development (R&D).

Section B - Impact of the RU regulatory environment on ability to innovate

Strict national regulations, insufficient harmonization with international standards and lack of adequate infrastructure, do not provide incentives for any R&D in Russia. Furthermore, current regulations restrict bringing innovative veterinary medicines to the Russian market. Changing the situation is unlikely without a change of approach to regulation and major modifications of regulations.

Section C - Commercialisation of existing product

Although the main regulation methods for medicines are the same in Russia and EU, their application in the country has much more impact on business and creates more barriers for the commercialisation of existing products and business development.

Section D - Regulatory predictability and quality

A feature of Russian regulations for veterinary medicines is the GMP regulation, which is developed by the Ministry of Industry and Trade but implemented by the Ministry of Agriculture. Compared to human pharma regulation, the application to the veterinarian sector is tougher, more unpredictable and based only on restrictive measures. As before, changing the situation will not be possible without a change of approach to regulation and major modifications of regulations.

Section E - Regulatory trends

Despite several positive regulatory changes, generally there is a strong trend towards increasing regulation. This is a general trend for the Russian economy and the human medicines market, but, for veterinary medicines market, the trend is especially notable.

Section F - Hopes and expectations for the next 5 years

Further regulatory control over the market is expected. It can be partly offset by the implementation of EAEU rules and increased communication of veterinary medicines producers with authorities and inclusion of veterinary issues in various government programs for livestock support.

Key trends

Despite some local beneficial changes in the Russian regulatory framework, globally the regulatory problems have become the major barrier for market development. This relates to both new regulation and applying existing rules. National GMP rules were implemented in 2017. The rules are very similar to those in the EU, but due to incomplete and sometimes inaccurate translation and different law enforcement practices, it has worsened business conditions.

Innovative product launches have almost completely ceased. Companies faced difficulties when applying for variations and renewal as well. New rules for GMO medicines make it virtually impossible to launch vector vaccines and even successfully complete variations and renewals of existing ones.

Several new regulatory initiatives have been announced that will worsen business conditions. The key challenge in the short to mid-term is the Market (state) release bill, which aims to make GMP certificates mandatory for importing medicines to Russia.

Joint reviews and parallel assessments are two new forms of official cooperation between authorities and businesses that were implemented. This allows more opportunity to engage in the regulatory process leading to final Government decisions on product authorisations. However, now these opportunities cannot be used with maximum efficiency.

A new EAEU Regulation (including EAEU GMP issues) is under development, and its impact on business is not yet clear.

Regulatory problems in Russia are more critical for business, than in the EU and consequently company priorities differ. Regulatory problems in Russia are more about sustaining the existing portfolio, than business development. GMP is currently the most critical problem, as the proportion of foreign manufacturing plants that are failed by Russian GMP inspectors is more than 70%. That, in turn, does not allow variations and renewals to be made (not mentioning new product launches), where a valid GMP certificate is required.

Summary and recommendations

Regulatory problems have become the major barrier for market development, indeed, even simply to market access, in the past 5 years. Increase of control over the economy is a global trend for the country, and it is particularly notable for the veterinary medicines market.

Further development of interactions between the industry and the regulatory system is required. The short-term goal is to simplify market access for existing products. Widespread innovative product launches and global increase of presence of MNC's on the Russian market requires serious legislation improvement and a change of approach to market regulation.

2. Introduction and background

The purpose of the HealthforAnimals Global Benchmarking Survey is to examine the interactions between industry and regulatory systems for veterinary medicinal products, particularly the impact of regulations on the animal health industry's ability to access markets, be innovative and be competitive. This includes the ability to bring new products to the market, as well as to retain and exploit existing products on the market and thus the impact on the availability of veterinary medicinal products.

The survey originally benchmarked the European and USA regulatory systems but has since evolved to include the main VICH markets and has now grown to include 12 countries in the 2020 survey (see box).

The evolution of the Global Benchmarking Survey

1. 1996: Europe, USA
2. 2001: Europe, USA
3. 2006: Europe, USA, Japan, Australia, Canada,
4. 2011: Europe, USA, Japan, Australia, Canada,
5. 2015: Europe, USA, Japan, Australia, Canada, China, Brazil
6. 2020: Europe, USA, Japan, Australia, Canada, China, Brazil, India, South Africa, Russia, Mexico

The survey is run every 5 years with the cooperation and involvement of the HealthforAnimals national member associations. The purpose reaches beyond simple benchmarking, to include monitoring of trends and to identify the emerging issues in the regulatory environment that may have an impact on competitiveness, ability to do business and medicines availability. The survey is also a useful tool to gain insight into expectations of the industry over the next 2-3 years in response to current regulatory dynamics and to provide information that allows development of clear action plans for meeting any identified challenges.

The outcome of this survey provides a wealth of information to support informed policy decisions in the continual search for best regulatory practice and opportunities for improvement.

This report is the **first** for Russia. It summarises the data from **4 international companies** surveyed.

3. Outline methodology

The previous Benchmarking Survey **questionnaire** from 2015 was updated to reflect the requirements for the 2020 survey, including: retention of core questions important for global benchmarking and long-term trend analysis; removal of less useful questions; addition of new questions reflecting known new developments within regulatory systems; and addition of selected 'local' questions of importance to an individual country for local versions of the questionnaires.

The survey was divided into two parts. Part 1 covered financial data and product development costs and was sent to the headquarters of each company (so regional offices were not involved). Part 2 covered the regulatory environment and its impact on innovation and competitiveness. The Part 2 questionnaire was adapted to the situation in each of the 11 surveyed markets and was completed by the country offices of companies active in those markets.

The national associations were responsible for requesting their membership to complete the questionnaires, to collect and collate the results using a standard template, and to organise a local 1-day **workshop** with those companies participating in the survey. At the workshop, an aggregated summary of the data for each question was presented and discussed in order to explore and record different views and the local context important for an understanding of the reasons behind a particular outcome.

The assimilated questionnaire data and the workshop 'narrative' explaining the findings formed the basis of each **country report**. The **report structure** follows the list of questions, which are used as sub-headings. The questions are reflected in the subheadings and are reproduced at the beginning of each section in a box below each sub-heading.

The GBS2020 survey covers 11 markets: Europe, United States of America, Japan, Canada, Australia, China, Brazil, India, Russia, South Africa and Mexico.

Final output: The country reports and a global overview report will be published on the HealthforAnimals website: https://healthforanimals.org/global-benchmarking.html

Details for Russia

In Russia, a local consultant was engaged to run the survey; a conference call was organised on 22 May 2020 during which the **4 participating companies** discussed the outcomes of the aggregated data from the filled questionnaires.

4. The findings for Russia

Section A – ECONOMICS OF THE ANIMAL HEALTH SECTOR

Global context

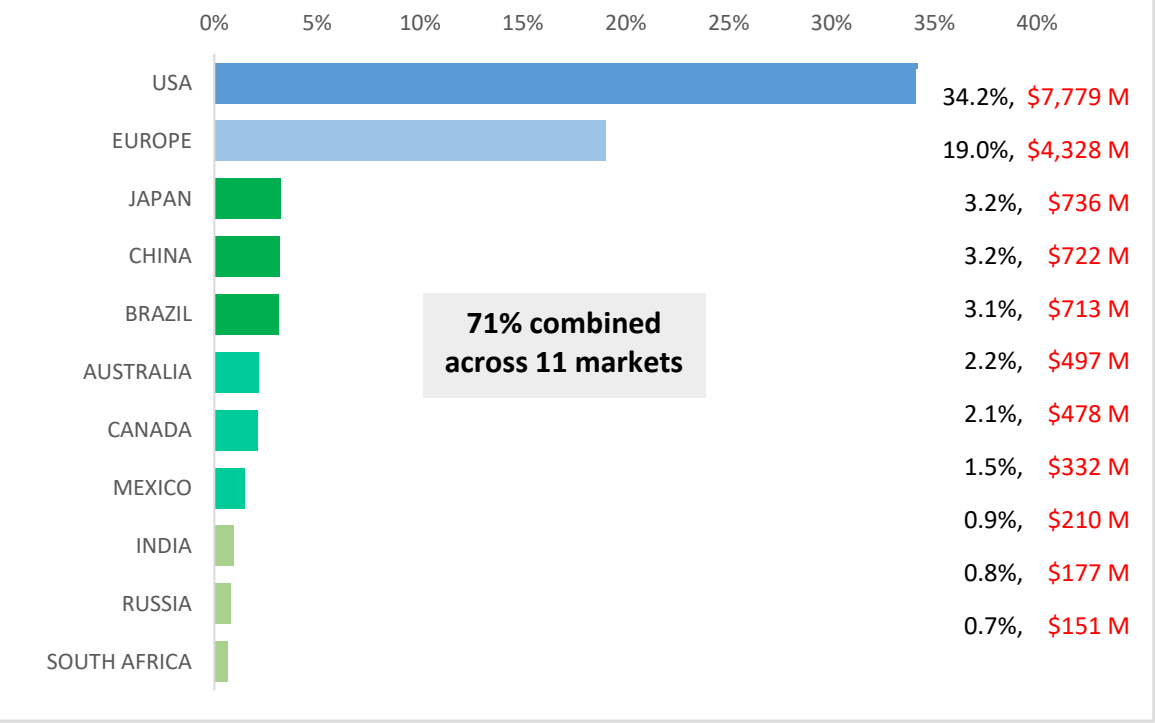
The financial data covers the 2018 full financial year. All data is presented in US dollars ($).

The GBS2020 Part 1 report on financial data is published separately. Key findings from that report are cross-referenced where relevant in this report for Russia, such as in the sections on product development trends and defensive R&D.

In 2018 the global animal health market was estimated to be worth $45.8 billion[1]. The 10 HealthforAnimals company members held over 50% of that market with a combined revenue of $22.7 billion, and an average of $2,274 million, of which 7% was invested in research and development.

The 11 benchmarked markets accounted for 71% of HealthforAnimals companies' global revenues (Figure 1), with Russia representing just under 1% of that revenue.

Figure 1: Revenue distribution of HealthforAnimals companies across 11 markets in 2018



Overall, top international companies directed their R&D spending mostly towards pharmaceutical (62%) and biological (24%) products. Investment in pesticide-based medicines remained a small segment of product portfolios (4%). The R&D share for the two principal animal segments was 51% for companion animals and 49% for major food animal species.

[1] Market Research Reports - https://www.marketremsearchreports.com/blog/2019/09/05/world%E2%80%99s-top-10-animal-health-companies

Section B – IMPACT OF REGULATIONS ON INNOVATION

1. Impact of the Russian regulatory environment on innovation

How does the regulatory environment in Russia impact your ability to innovate?

The response was unanimous that the regulatory environment impacts negatively on companies' ability to innovate.

Strict national regulations, lack of harmonization with EU regulations and lack of adequate infrastructure, do not provide incentives for any R&D in Russia. Furthermore, current regulation restricts entering the market with innovative veterinary medicines. Changing the situation is hardly possible without a change of approach to regulation and major modifications of regulations.

2. Factors relevant to innovation in the animal health industry

Below is a list of potential FACTORS RELEVANT TO INNOVATION in the animal health industry. Which of these, if any, are significant for innovation in the company you belong to?

For both questions, the lack of innovation is due to a volatile regulatory environment and frequently changing legislation, which prevents MNC (multinational companies) from building a long-term forecast of innovation) programmes in Russia. Moreover, launches of innovative products are often at risk or blocked due to the gaps in the regulation (for example, vector vaccines) and lack of predictability in GMP inspections affect all the MNC presence and business plans on the Russian Market.

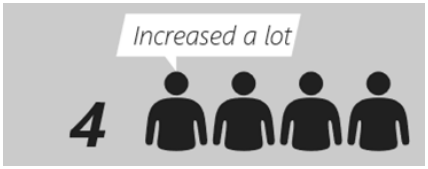
Table 1: Rankings of factors relevant to innovation

Factors relevant to innovation	Average ranking score
The Russia regulatory framework and legislative environment	1
Transparency policy of the regulatory authorities	2
Closure of Russia and/or other geographic markets for certain products	3
Inadequate intellectual property protection (for patents or commercial data)	4
Lack of access to specialist biotechnology companies	5
Lack of skilled staff	6
Small size of market segments	7
Poor technology transfer mechanisms between academia and business	8
Negative consumer attitudes	9
Internal company organisational or cultural barriers	10
Lack of availability of financial resources	11

3. Expenditure on mandatory defensive R&D

Which of the following statements best indicates how your expenditure on MANDATORY DEFENSIVE R&D in Russia has changed since 2015?

Again, the respondents were unanimous in their estimation that Mandatory Defensive R&D expenditures had increased a lot in the past 5 years.



Dossier requirements are not aligned with the EU and the USA. Russia requires country specific studies.

4. Factors causing the change in expenditure on mandatory defensive R&D

The factors reported as causing an increase in expenditure on mandatory defensive R&D (MD-R&D) are listed below in Table 2.

Table 2: Factors causing an increase in expenditure on mandatory defensive R&D

Factors causing an increase in expenditure on mandatory defensive R&D	
Certification regulation (quality control, all FP specification parameters of 1-2 batches of each product once a year). Certification is already cancelled on the 29th of Nov. New regulation (local market release) is under development, timings of implementation – tbc **(2021)**.	State Release
GMP inspections for new products, renewals, variations (FP spec, FP control methods, additional manufacturing sites) require RU GMP certificate. Official statistics at RA web site shows up to 70 % rejection rate for GMP inspections of the foreign manufacturing sites and lack of CAPA process to address the observations leads to a re-inspection, increasing the cost and market access.	GMP inspections
Market (state) release new regulation (currently under development), GMP certificate is aimed to be a must for importing medicines to Russia.	State Release
GMO regulation: mandatory GMO organism registration prior to submitting the application for a medicine registration. Tests should be carried out in Russia	GMO regulation

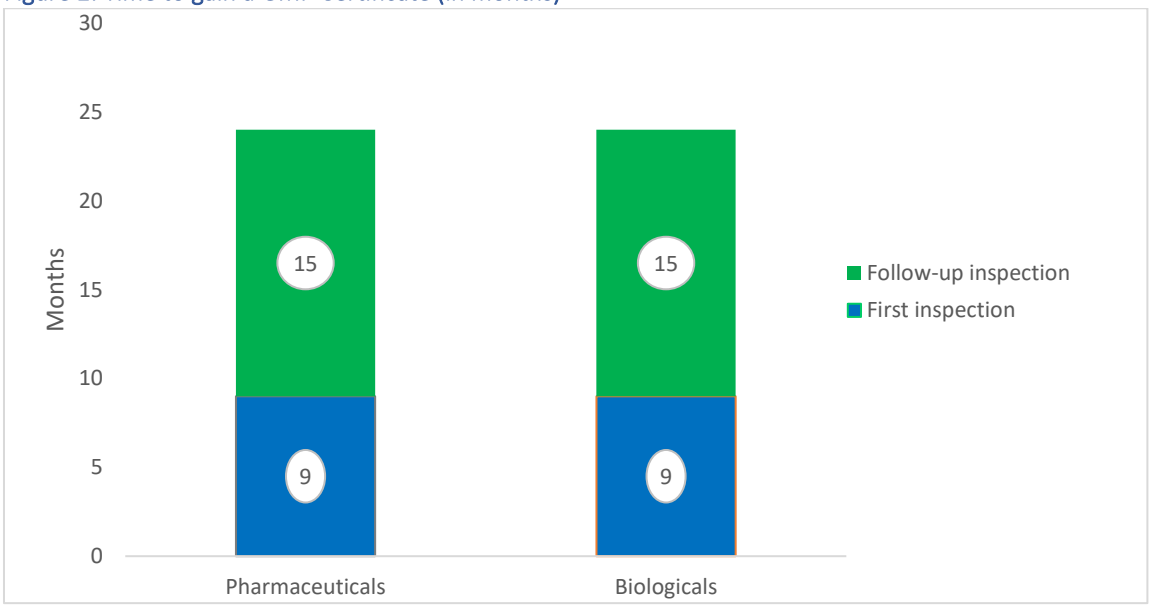
5. TIME to gain a GMP certificate

Please state the AVERAGE LENGTH OF TIME it takes you to gain GMP certificate within major new product registration in Russia, from submission of the application to obtaining the certificate.

By Law (Order 1314) the inspection should be conducted within 160 working days after the decision of the regulatory authority to conduct an inspection, i.e. within 9 months. In case the initial inspection does not yield certification and registration, considering specific Russian Regulatory Authorities requirements and high risks of rejection, a re-inspection is conducted, on average, within 24 months.

Most of Russian GMP inspections (up to 70%) require follow-up visit(s) after all the Corrective and Prevention Actions (CAPA) is points are closed. However, there is a risk of new observations and a new list of CAPAs during this follow-up visit. Moreover, there is no officially approved CAPA process in Russia; therefore, the site cannot align with the Authorities in the strategy of addressing the CAPA observations. So, the chosen strategy (by the site/company) might be rejected during the follow-up inspection. This makes the process non-transparent and unpredictable.

Figure 2: Time to gain a GMP Certificate (in months)



6. TIME to register a new product (excluding the GMP Certificate step)

Please state the AVERAGE LENGTH OF TIME it takes you to gain registration for a major new product in Russia (not including the GMP procedure step), from submission of the marketing authorisation dossier to first-market product approval.

This question focusses just on the length of the product registration step (not including the GMP procedure step), from submission of the marketing authorisation dossier to first-market product approval.

The average length of time it takes to gain registration for a major new product in Russia was 2 years for biological products and 1.5 years for pharmaceutical products. There is little variation by animal type both Pharmaceutical and Biological products as seen below in Table 3:

The stages and timelines for registration are summarised below.

Table 3: Time (years) to gain registration for a major new product in Russia (non-GMO products)

		Average 2018
Major Food Animals	Pharmaceuticals	1.5
	Biologicals	2.0
Companion Animals	Pharmaceuticals	1.5
	Biologicals	2.0
Minor species	Pharmaceuticals	1.5
	Biologicals	2.0

7. Stages and timelines for registration:

a) Non-GMO product requirements:

- ✓ GMP inspection(s) for all finished product manufacturing sites (2 years per site in case of rejection at the 1st inspection and the need for a follow-up inspection)
- ✓ Product registration (up to 18 months)

TOTAL: minimum 2 years and up to 3.5 years.

b) GMO product requirements:

- ✓ GMO(s) registration (timelines are unknown, GMO registration is not available now, approximate estimation is minimum 1 year)
- ✓ GMP inspection(s) for all finished product manufacturing sites (2 years per site in case of rejection at the 1st time and the need for a follow-up inspection)
- ✓ Product registration (up to 18 months)

TOTAL: minimum 3 years and up to 4.5 years.

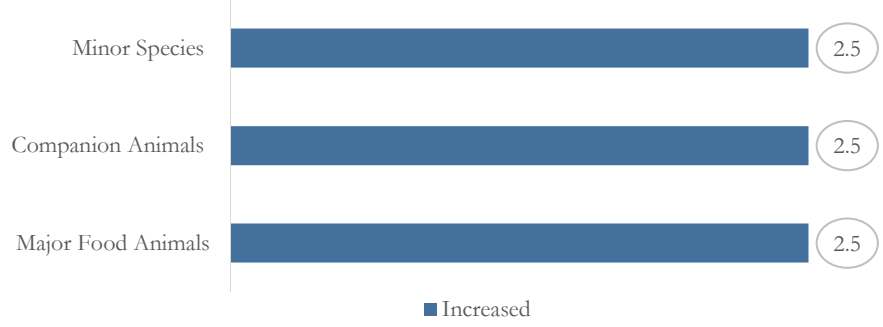
8. Regulations' impact on TIME to develop a new product

Have REGULATORY FACTORS caused a change in the AVERAGE LENGTH OF TIME it takes to develop a major new pharmaceutical product in Russia (from initial research to final market authorisation), compared to 2015?

This question looks at the impact of changing regulations on the average length of time it takes to develop a major new pharmaceutical product or a major new pharmaceutical product in Russia (from initial research to final market authorisation), compared to 2015.

Companies were asked to make separate estimates for major livestock species, companion animals and minor species. The estimation is that for all product types, pharmaceutical or biological, and for any species, the product development time had increased by 2.5 years.

Figure 3: Change in the average length of time to develop a major product since 2015 (in years)



Initial research is not done in Russia and has never been; however supplementary local studies may be necessary. The length of the final market authorisation step (which historically was in Russia) has significantly increased.

As stated above dossier requirements are not aligned with the EU and the US. Russia requires country specific studies.

9. Regulations' impact on COST of developing a major new product

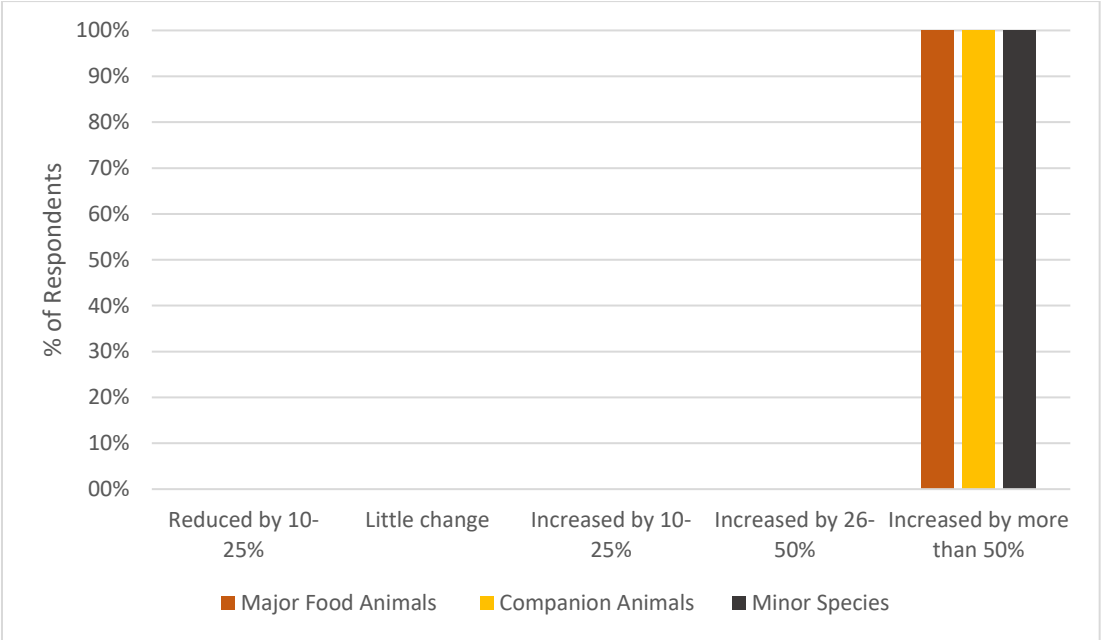
Have REGULATORY FACTORS caused change in the AVERAGE COST of developing a major new product in Russia (from initial research to final market authorisation) for all possible species and indications for that product, compared to 2015, in real terms?

As reported for the previous question, initial research is not done in Russia and dossier requirements are not aligned with the EU and the US. Russia requires country specific studies.

Pharmaceutical products (for production animals) require additional MRL studies and partially new pre-clinical and clinical studies (+ GMO safety data where applicable).

As a consequence, it is estimated that the cost to re-develop a major new pharmaceutical or biological product for the Russian market has increased by more than 50% since 2015.

Figure 4: Change in cost to develop new product in Russia



10. The impact of regulations on innovation

Thinking about government regulations in Russia, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO INNOVATE successfully?

The companies were asked to score the impact of 12 different regulations on a scale of 'very helpful' to 'very unhelpful'.

None of the options were considered to be helpful or very helpful. Two options were considered to have 'no impact' (Good Laboratory Practice and Environmental Safety regulations). The remaining options were considered to be either unhelpful or very unhelpful as shown in Table 4. In addition, the following comments were made:

- Lack of predictability of Russian GMP inspections affect business planning and launches as well as a company's ability to maintain its current portfolio of products.
- Lack of MRL regulation affects Pharmaceutical portfolio in the country.
- GMO registration requirements block all vector vaccines launches (and affect current portfolio as will be required during MA renewal process).
- Lack of IP regulation puts GMO registration at risk (as GMO registration requires significant disclosure of sensitive information).

Table 4: The least helpful areas of regulation in 2019

Very unhelpful areas of regulation	**Unhelpful** areas of regulation
Manufacturing-GMP Inspections	Registration Certificate
Maximum Residue Limits	In-market controls
Biotechnology regulations	Disease Resistance regulations
Manufacturing/Quality Inspection Requirements	Protection of Intellectual Property–commercial data
	Protection of Intellectual Property–patents

11. Data protection as an incentive

Thinking about the Russian legislation on protection of technical documentation, to what extent do you consider it to be an incentive?

The question asked about 3 areas of Russian legislation on protection of technical documentation. All three regulations were ranked as either unhelpful or very unhelpful, as shown in Table 5.

Table 5: The least helpful areas of regulation in 2019

Very unhelpful areas of regulation	**Unhelpful** areas of regulation
Order 916 "GMP Rules", GMO regulation	"Industrial" regulation (Federal Law #61 "On circulation of medicines")
	General civil regulation (Civil Code, etc)

Section C - COMMERCIALISATION OF EXISTING PRODUCT

1. Factors for exploiting EXISTING PRODUCTS

Below is a list of potential FACTORS RELEVANT TO THE EXPLOITATION OF EXISTING PRODUCTS in the animal health industry in Russia. Which of these, if any, are significant obstacles to the exploitation of your company's existing products?

The companies were asked to rank a list of 12 factors relevant to the exploitation of existing products in the animal health industry in Russia and to identify which present significant obstacles to the exploitation of existing products.

The outcome of the ranking of the 12 factors is shown in Table 6, with the most significant obstacle ranked as 1, and the least significant obstacle ranked as 12.

Regulatory background (including GMP issues) is the main obstacle for the exploiting of existing products as well. Formally, there are no significant preferences for local producers, but in fact regulatory practice is more favorable to domestic companies.

Intellectual property protection is inadequate too. Currently, this doesn't have a major impact, but may have in the medium- and long-term, linked to increasing pressure from competitors (including generics).

The factors that presented the least obstacle in Russia were negative consumer attitudes, counterfeited products, lack of skilled staff and lack of availability of financial resources.

Table 6: Factors relevant to exploiting EXISTING PRODUCTS

Factors relevant to exploiting EXISTING PRODUCTS	Ranking
Market regulation (reasonability of existing barriers)	1
GMP Requirements	2
Government support for local producers (subsidies, tariff and non-tariff barriers, etc.)	3
Politically based barriers ("countersanctions" etc)	4
Closure of the Russian market and/or other geographic markets for certain products	5
Inadequate intellectual property protection (commercial data & patents)	6
Pressure from competitors (including parallel imports and generics)	7
Small size of market segments	8
Demand volatility in certain segments	9
Legal restrictions on advertising, labels, trademarks and communication	10
Negative consumer attitudes	11
Counterfeited products	12
Lack of skilled staff	13
Lack of availability of financial resources	14

2. The effect of regulations on business

Do government regulations in Russia have any of the following effects on your business?

The companies were asked to rank a list of 11 potential effects of government regulations on business. The final ranking is shown in Table 7. The top 3 negative effects of government regulations were reported as uncertainty, delays to new product launches and the removal of profitable products from the market (Table 7). Government regulations are the main obstacle for business development.

Table 7: The effect of regulations on business

Factors relevant to business	Ranking
Create significant uncertainty	1
Delay the entry of products into the market	2
Remove profitable products from the market	3
Create disproportionate costs for maintaining/extending marketing authorisations	4
Increase the cost of production	5
Increase the cost of distribution and marketing	6
Limit the use of innovative marketing methods	7
Fail to protect intellectual property (patents & commercial data) adequately	8
Divert management time	9
Restrict the extension of existing technologies to additional species/indications	10
Divert financial resources away from the development of new, innovative products	11

3. The impact of regulations on commercialising EXISTING PRODUCTS successfully

Thinking about REGULATIONS in Russia, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO commercialize EXISTING PRODUCTS successfully?

The companies were asked to score 12 different regulations on a scale of 'very helpful' to 'very unhelpful', on their impact on a company's ability to commercialize existing products successfully.

None of the options were considered to be helpful or very helpful. Two options were considered to have 'no impact' (Environmental safety regulations and Packaging/Labelling Modification Rules). The remaining options were considered to be either unhelpful or very unhelpful as shown in Table 8.

Although the main regulation methods are the same in Russia and EU, their application in the country has much more impact to business and creates more barriers. For example, GMP Inspections in Russia cause serious delays to product launches because it is typical that the first inspection will fail the manufacturing site, even if the site has been passed by regulatory agencies from other countries, triggering the need for a second inspection. The second inspection can take many months to occur.

Table 8: The least helpful areas of regulation in 2019

Very unhelpful areas of regulation	**Unhelpful** areas of regulation
In-market controls	Variations Regulation with respect to manufacturing changes (except GMP)
Maximum Residue Limits	Import regulations (intra & extra Russia)
Good Manufacturing Practice inspections	Disease Resistance regulations
GMO regulations	5-year renewal (except GMP)
Expected new regulations (e.g. "state permit for release", T&T system)	Pharmacovigilance regulations
	Anti-counterfeiting

Section D - REGULATORY PREDICTABILITY & QUALITY

1. Predictability & Quality of regulatory procedures in Russia

(a) Does the regulatory procedure in Russia as currently managed provide you with the regulatory predictability that you need and the regulatory quality you expect? (b) If not, please tell us what the top issues are and what might be done about them (your proposed solutions moving forward).

Respondents were unanimously negative towards the Ministry of Agriculture reporting that it ***never*** provides predictability or quality with its regulatory procedures. The Ministry of Industry and Trade was perceived as slightly better in that it brings predictability and quality ***sometimes***.

Figure 5: Regulatory predictability and quality under Ministry of Agriculture & Ministry of Industry and Trade

Figure 6: Regulatory quality and predictability issues

Ministry of Agriculture

- GMO requirement (separate registration of GMO products prior to a registration application) was included in the Law 61-FZ "On medicines circulation" of July 2019. GMO products registration was not part of legislation requirements (Law 61-FZ, Article 17) before July 2019 & there're currently no accredited laboratories to carry out the required trials. Nevertheless, Ministry of Agriculture and Rosselkhoznadzor reject the applications of GMP products submitted before July 2019
- State permit for release regulation is under development with no predictable timings. GMP for each production site is a requirement in the regulation, which if approved, will block import to Russia for a huge number of veterinary medicines.
- Very tough timings and specific PV requirements in Russia, international format is not accepted.
- Volatile regulatory environment (much uncertainty, no transition period, short notice is changes are implemented)

Ministry of Industry and Trade

- Lack of CAPA process, which results in immediate rejections in GMP inspections, amendments to Order 1314 to introduce CAPA were initiated earlier in 2019, no clear timing for implementation.
- Poor translation from English to Russian of Order 916 (EU GMP Rules), lack of amendments.
- Transfer to EAEU GMP in 2021 for veterinary is not clear

Section E - REGULATORY TRENDS

1. Recent beneficial changes to the regulatory frameworks in Russia

What beneficial changes have occurred in regulatory frameworks SINCE 2015?

The following beneficial changes in regulatory frameworks since 2015 were reported:

- July 2019, Law "On medicines circulation" amendments: Abolishment of Russian GMP requirement for APIs sites.
- July 2019, Law "On medicines circulation" amendments: Introduction of 180 days transition period for renewals, maintenance of MA number (unchanged after a variation is approved)
- Nov 2019, Law "On technical regulations" amendments: Certifications regulations cancellation for veterinary medicines.
- Bracketing approach acceptance for process validation during GMP inspections.

2. Expected changes that have NOT occurred in Russian regulatory frameworks

What expected changes have NOT occurred in regulatory frameworks SINCE 2015 in spite of expectations of change?

The following expected changes in regulatory frameworks have not occurred, despite expectations:

- Amendments to Order 1314 which introduce CAPA process after a GMP inspection
- Unified regulation within Eurasian Economic Union countries for VMPs

3. Problematic changes to the Russian regulatory frameworks

What regulatory changes SINCE 2015 have given you the most problems and why?

The following regulatory changes are reported to have given the most problems since 2015:

- January 2017, Law "On medicines circulation" amendments: Requirement of Russian GMP certificate for new products, renewals application.
- June 2018, Law "On medicines circulation" amendments: Requirement of Russian GMP certificate/RA decision that Russian GMP inspection is scheduled for variations of finished product specification/ finished product control methods, additional manufacturing sites (Law "On medicines circulation").
- July 2019, Law "On medicines circulation" amendments: GMO separate registration prior to submitting the medicine for registration. RA request GMO registrations for applications submitted prior to July 2019, there is no requirements how to perform biological safety testing, there are no accredited laboratories in Russia to perform the testing (Law "On medicines circulation").
- Certification regulation was a major blocking point for importing of VMP until it was abolished in November 2019.

4. Regulations' influence on business decisions

Have regulations played a major role in influencing you to take any of the following major decisions over the last five years?

The companies were asked to consider a list of 20 typical major business decisions, and whether regulations influenced those decisions. The decisions are presented as opposing decisions (Table 9).

Table 9: List of potential major business decisions

Locate R&D Facilities inside Russia / Locate R&D Facilities outside Russia
Switch R&D budgets to labs inside Russia / Switch R&D budgets to labs outside Russia
Invest in production inside Russia / Invest in production outside Russia
Increase product range in Russia / Reduce product range in Russia
Increase (geographic) market focus in Russia / Restrict (geographic) market focus in Russia
Increase coverage of species or indications in Russia / Reduce coverage of species or indications in Russia
Buy businesses in Russia / Sell or close businesses in Russia
Focus on new technologies in Russia / Focus on existing/older technologies in Russia
Introduce more 'breakthrough' products in Russia / Introduce fewer 'breakthrough' products in Russia
Develop certain product technologies in Russia / Avoid certain product technologies in Russia

For the large majority of these decisions the companies reported that the decision had not been done in Russia. For six of the business decisions, these had been done and regulations had either a significant influence or some influence (Table 10)

Despite several positive regulatory changes, generally there is a strong trend towards increasing regulation in Russia. This is a general trend for the Russian economy, including the human medicines market, but for the veterinary medicines market the trend is especially notable.

Table 10: List of major business decisions that were done and were influenced by regulations

Done & regulation has significant influence	**Done & regulation has some influence**
Reduce product range in Russia	Invest in production inside Russia
Increase (geographic) market focus in Russia	
Reduce coverage of species or indications in Russia	
Introduce fewer 'breakthrough' products in Russia	
Avoid certain product technologies in Russia	

Section F - HOPES AND EXPECTATIONS FOR THE NEXT 5 YEARS

1. Changes in regulatory approach and their impact on the future

The following trends or changes in regulatory approach have been taking place recently and may well have an impact in future. What impacts do you expect these changes to have on your business in the next 5 years?

The companies were asked to score 13 trends or changes on a scale of 'very helpful' to 'very unhelpful', on their potential impact in the future. The outcome is shown in Table 11.

Five of the trends were considered to have 'no impact', three were considered to be helpful or very helpful (Trend to wider participation in regulatory process, including public comment), and five were considered to be unhelpful (none were 'very unhelpful).

Trend to wider participation in regulatory activity is very important, but it cannot compensate general trend to increase control. EAUE regulation may be better than national one, but the transitional period (during which there is a lack of sub-acts, inconsistency between RU and EAEU regulations etc.) can result in barriers for business.

Table 11: Changes in regulatory approach and their impact on the future

Helpful Trends 2018:	Unhelpful Trends 2018:	Trends with no impact
1. Trend to wider participation in regulatory process, including public comment	1. Increasing transparency with respect to data disclosure	1. Acceptance of JECFA agreements for residues of non-contentious molecules
2. Increasing trend to move from a zero-risk approach to a benefit: risk assessment	2. Increasing requirements for post-marketing surveillance & pharmacovigilance	2. Moves towards electronic submission
3. Increasing globalisation of post-marketing surveillance outcomes	3. Increased employment of work-sharing and other simplification approaches in dealing with variations	3. Moves towards a common technical document
	4. The strategies on antimicrobials	4. The harmonisation of the summary of product characteristics (e.g. via referrals)
	5. EAEU regulation	5. International harmonization (PIC/S, VICH)

2. Impacts of NEW VETERINARY PRODUCT REGULATIONS on business

What impacts do you expect NEW VETERINARY PRODUCT REGULATIONS to have on your business and why?

In terms of new Eurasian Economic Union (EAEU) regulations:

Foreign manufacturers have become more consolidated. We form a common position, take part in different industry meetings, including those organised by RAs. We comment on legislative initiatives and try to form a more favourable regulatory environment.

EAEU regulations will unify the procedures and, in the long-term, will hopefully make regulatory procedures more transparent and simplified.

EAEU regulation is however expected to be very challenging due to several reasons:

- The regulations have been created by the Regulatory Authorities of different countries almost without industry involvement, mostly based on Russian national legislation requirements, not EU best practices like EAEU regulations for human health,
- The whole range of products registered on a national level will need to be renewed

According to EAEU requirements (timing – not clear), which could lead to delays due to Regulatory Authorities resources to assess all registered products in one go.

3. Desired changes

What changes do you still want to see and why?

Abolish the need for target animal testing of veterinary medicines in Russia, like in EU. According to Normative Document # 13-5-2/1062 "Veterinary medicines. Quality parameters. Requirements and norms" of 17.10.1997 the Target Animal Batch Safety Test (TABST) must still be conducted in Russia.

Russia is a participant in the VICH Outreach Forum. VICH has developed international guidelines on the criteria to allow a waiver of the TABST (and laboratory animal BST).

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Glossary of Abbreviations

CAPA – Corrective and Prevention Actions

EAEU- Eurasian Economic Union

GMP – Good Manufacturing Practice

GMO – Genetically modified organism

MNC – Multinational company

RA - Regulatory Authority

TABST - Target Animal Batch Safety Test

VICH - International Cooperation on Harmonisation of Technical Requirements for Registration of VMPs

VMP – Veterinary Medicinal Product

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This report and reports on the other markets included in the benchmarking survey are available at: HealthforAnimals.org/GBS2020

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global animal health association